TITANIUM DIOXIDE

Properties and Uses

Titanium dioxide (TiO_2) is added to to many products including paints, laundry detergents, foods, cosmetics and toothpastes. It gives whiteness and opacity. It is also added to sunblocks to help protect the skin from ultraviolet light.

TiO_2 is produced by milling natural ores. Its opacity and whiteness are highly dependent on the crystalline form (rutile, anatase or brookite) and the particle size. Smaller particles often correspond with more potent functionality.

It has ubiquitous global approvals as a pigment (*e.g.* titanium white, Pigment White 6). The rutile and anatase forms are approved as food colourings in the EU (E171) and USA (up to 1% by weight of food) and as cosmetics ingredients. Most approvals do not specify the particle size. The effect of particle size is a relatively new science, and small particles (*e.g.* nanoparticles) are difficult to define, specify and measure.

Toxicology

Titanium dioxide dust, when inhaled, has been classified by the International Agency for Research on Cancer (IARC) as a Group 2B carcinogen, meaning it is possibly carcinogenic to humans. The European Chemicals Agency (EChA) classified it as a suspected carcinogen in 2017.

The toxic mechanism from inhaling dust is dependent on the crystalline form. The risk also depends on the internalisation (particles getting to the cellular site where they will do most damage), which is worst for smaller particles. Although this is an emerging science, with many unknowns, there is an acknowledged risk to workers in TiO_2 production. The US National Institute for Occupational Health and Safety (NIOSH) consider "ultrafine" TiO_2 as an occupational-exposure carcinogen and have set airborne exposure limits, dependent upon particle size.

Many studies have concluded no evidence of carcinogenicity from TiO_2 ingested as a food additive. There has, however, been a consistent minority scientific view that nano-particulate TiO_2 does present a risk as a food additive. This view was supported by the May 2021 EFSA Opinion which concluded that "E171 can no longer be considered safe as a food additive". This change of opinion from EFSA was driven by taking specialist advice from experts on nanomaterials. There is no firm evidence of harm, but the concern is that aggregated nanoparticles could break up once ingested. The free nanoparticles could then internalise and damage the genetic DNA.

Environmental Fate

Historically, the production of TiO_2 has been highly polluting. It is persistent in the aquatic environment and there is concern that the small particles can enter the food chain. There are campaigns to ban TiO_2 on the basis that its production carries too high an environmental risk.

Regulation – Recent History, and Potential Changes

Regulatory review of TiO_2 in the EU has been hampered by there being no harmonised legal definition of nanomaterials. The cosmetics definitions are not applicable to food. This gap was recognised a decade ago (Commission Recommendation 2011/696/EC), technical proposals were last made in 2019, and European legislation is planned soon.

Food Additives

France imposed a unilateral ban on TiO_2 food additive use in January 2020. It is still widely used in most other EU countries and in the UK.
In 2019 EFSA recommended that the Commission should maintain E171's food additive approval but modify the legal specification to restrict smaller (< 100nm) particles. The European Parliament rebutted this in October 2020 and asked the Commission to ban E171 outright. Their basis for this request was:

- E171 is only added for cosmetic purposes and gives no functional benefit to the food. As there is toxicological uncertainty, the precautionary principle should apply.
- The French ban has caused no disruption. Substitutes for TiO_2 have been found without problem.
- Companies who have unilaterally withdrawn TiO_2 at their own expense should not be disadvantaged.

The May 2021 EFSA Opinion, that E171 can longer be considered safe, has made it much more likely that the Commission will accede to this request for a ban.

Cosmetics

Titanium dioxide (nano) and titanium dioxide are classed as different cosmetic ingredients with separate EU approvals. Both are approved, with the nano-form specifically as a sun filter. Their sum total must be less than 25% of the formulated product. Titanium dioxide (nano) has detailed legal specifications that limit the crystalline form, particle size, particle shape and purity. These approvals are based on opinions from the Scientific Committee on Consumer Safety (SCCS), last reviewed in 2018. There are no current plans to review the approvals.

Pigments

There are no current restrictions on TiO_2's use as a pigment. Its CLP hazard code is Carc.2 (*suspected* human carcinogens), by inhalation. Products which may be inhaled should be labelled H351 "Suspected of causing cancer".
The CLP hazard status of TiO_2 is under review (since 2018; ongoing), led by the French risk assessment agency, ANSES. ANSES had previously asked for TiO_2 to be reclassified as Carc.1b (*presumed* human carcinogens). Although only a subtle difference in labelling (H350 "May cause cancer), Carc.1b classification could be a first step in listing TiO_2 as a Substance of Very High Concern, SVHC.

TiO_2 is permitted to be present in plastics that are recycled for use as Food Contact Materials (EU FCM no. 610).