

Challenges and prospects for TiO₂ in Europe

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Chair of TDMA Scientific Committee

Pigment & Colour Science Forum, 05 - 06 October 2022

A sector group of Cefic 



The Titanium Dioxide Manufacturers Association



TITANIUM DIOXIDE MANUFACTURERS ASSOCIATION

for a brighter future



📍 **Cinkarna** —————
Celje, Slovenia



📍 **Kronos** —————
Langerbrugge, Belgium
Leverkusen, Germany (2 plants)
Norderndam, Germany
Fredrikstad, Norway



📍 **LB Group** —————



📍 **Precheza** —————
Prerov, Czech Republic



📍 **Tayca** —————



📍 **The Chemours Company** —————



📍 **Tronox LLC** —————
Thann, France
Stallingborough, UK
Botlek, Holland



📍 **Venator** —————
Uerdingen, Germany
Duisburg, Germany
Scarlino, Italy
Huelva, Spain
Greatham, UK



Our agenda for today: three key trends for TiO₂ in Europe

1. Ongoing regulatory drivers
2. Chemicals Strategy for Sustainability
3. Sustainability in products and buildings



Regulatory drivers in Europe



EU classification of titanium dioxide

The EU classification of TiO_2 as a suspected carcinogen by inhalation in certain powder forms entered into force on 1 October 2021



EU restriction on TiO_2 in food as the additive E171

The European Food Safety Authority (EFSA) could not confirm the safety of E171 in May 2021 because genotoxicity concerns




Labelling obligations and changes in product regulations

The classification and EFSA assessment trigger renewed assessments in 'downstream' rules, such as cosmetics and toys

The complex EU classification

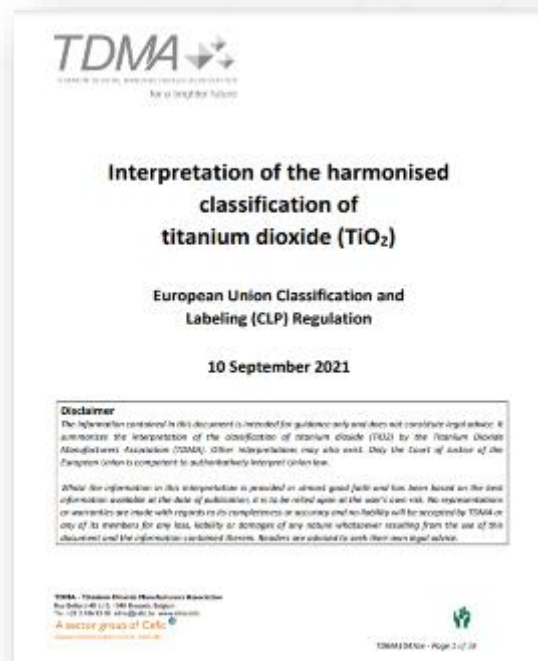
- EU classification introduced many new concepts and criteria without definition
- Tests show that many TiO₂ products do not meet the classification criteria
- Several legal actions brought before the General Court of the European Union requesting annulment

Index No	Chemical Name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Haz. State. Code(s)		
022-006-002	titanium dioxide; [in powder form containing 1% or more of particles with aerodynamic diameter ≤ 10 µm]	236-675-5	13463-67-7	Carc. 2	H351 (inhalation)	GHS08 Wng	H351 (inhalation)			V, W, 10

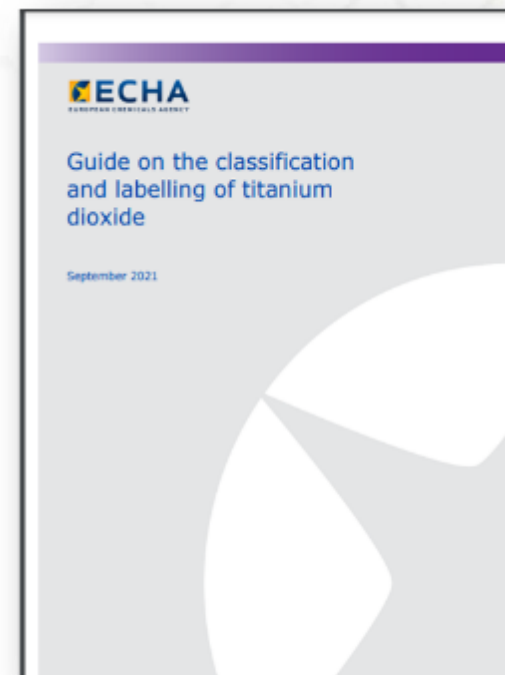
Labelling pictogram	GHS08	
Hazard statement	H351 (inhalation)	Suspected of causing cancer (inhalation)

European Chemicals Agency and TDMA interpretations

TDMA attempted to provide an interpretation elaborating on how to apply key criteria – incl. method for measuring aerodynamic diameter



The TDMA attempted an interpretation of the classification
Available on [TDMA.info](https://www.tdmanet.org)



ECHA issued a guide on TiO₂ classification in September 2021
Available via [ECHA help net](https://echa.europa.eu/helpnet)

A sector group of Cefic 

EFSA's unconventional approach to E171

SCIENTIFIC OPINION

ADOPTED: 26 June 2016
doi: 10.2903/j.efsa.2016.4545

Re-evaluation of titanium dioxide (E 171) as a food additive

EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS)

Abstract

The present Opinion deals with the re-evaluation of the safety of titanium dioxide (TiO₂, E 171) when used as a food additive. From the available data on absorption, distribution and excretion, the EFSA Panel on Food Additives and Nutrient Sources added to Food concludes that the absorption of orally administered TiO₂ is extremely low and the low bioavailability of TiO₂ appears to be independent of particle size. The Panel concluded that the use of TiO₂ as a food additive does not raise a genotoxic concern. From a carcinogenicity study with TiO₂ in mice and in rats, the Panel chose the lowest observed adverse effects levels (NOAEL) which was 2,250 mg TiO₂/kg body weight (bw) per day for males from the rat study; the highest dose tested in this species and sex. The Panel noted that possible adverse effects in the reproductive system were identified in some studies conducted with material which was either non-food-grade or inadequately characterised nanomaterial (i.e. not E 171). There were no such indications in the available, albeit limited, data on reproductive endpoints for the food additive (E 171). The Panel was unable to reach a definitive conclusion on this endpoint due to the lack of an extended 90-day study or a multigeneration or extended one generation reproduction toxicity study with the food additive (E 171). Therefore, the Panel did not establish an acceptable daily intake (ADI). The Panel considered that, on the available currently available and the considerations on the absorption of TiO₂, the margins of safety (MOS) calculated from the NOAEL of 2,250 mg TiO₂/kg bw per day identified in the toxicological data available and exposure data obtained from the reported use of TiO₂ (E 171) would not be of concern. The Panel concluded that once definitive and reliable data on the reproductive toxicity of E 171 were available, the full dataset would enable the Panel to establish a health-based guidance value (ADI).

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Keywords: titanium dioxide, E 171, anatase, rutile, food colour

EFSA 2016 opinion

“The use of TiO₂ as a food additive does not raise a genotoxic concern.”

SCIENTIFIC OPINION

ADOPTED: 26 June 2018
doi: 10.2903/j.efsa.2018.5366

Evaluation of four new studies on the potential toxicity of titanium dioxide used as a food additive (E 171)

EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS)
Majed Younes, Peter Aggett, Fernando Aguilar, Riccardo Crebelli, Brigit Dusemund, Metka Filipic, Maria Jose Frutos, Pierre Galber, David Gott, Ursula Gundert-Remy, Gunter Georg Kuhne, Claude Lamore, Jean-Charles Leblanc, Inger Therese Liljebländ, Peter Moldeus, Alicja Mortensen, Agneta Oskarsson, Ivan Stanekovic, The Waalkens-Berenzen, Matthew Wright, Federica Lodi, Ana Maria Rincon, Camilla Smeraldi and Rudolf Antonius Woutersen

Abstract

The European Commission requested EFSA to carry out a scientific evaluation on four studies on the potential toxicity of titanium dioxide (TiO₂) used as a food additive (E 171) and to indicate whether they would merit re-opening the existing opinion of EFSA on the safety of TiO₂ (E 171) as a food additive. The results of the Bettini et al. (2017) study did not provide enough justification for a new carcinogenicity study, but should additional useful mechanistic information become available, this could be reconsidered in future. The new *in vitro* findings in the Proquin et al. (2017) study did not modify the conclusion on the genotoxicity of TiO₂ as stated in the previous EFSA opinion of 2016 on the safety of TiO₂ (E 171) as a food additive. The effects of engineered TiO₂ nanoparticles reported by the Guo et al. (2017) study were of uncertain biological significance and therefore of limited relevance for the risk assessment of the food additive TiO₂ (E 171). There was significant uncertainty in the risk assessment performed by Heringa et al. (2016), which did not include a weight of evidence analysis of the whole database. The Panel considered that the four studies evaluated, highlighted some concerns but with uncertainties, therefore their relevance for the risk assessment was considered limited and further research would be needed to decrease the level of uncertainties. Overall, three of the studies, reporting that TiO₂ induced various effects in *in vitro* and *in vivo* models, may be useful for hazard identification of TiO₂. In the fourth study by Heringa et al. (2016), numerous assumptions were made, which resulted in large uncertainty in their conclusion. Altogether, the Panel concluded that the outcome of the four studies did not merit re-opening the existing opinion of EFSA related to the safety of TiO₂ (E 171) as a food additive.

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EFSA 2018 opinion

“(…) did not modify the conclusion on the genotoxicity of TiO₂ as stated in the previous EFSA opinion of 2016”

STATEMENT

ADOPTED: 10 May 2019
doi: 10.2903/efsa.2019.5754

EFSA statement on the review of the risks related to the exposure to the food additive titanium dioxide (E 171) performed by the French Agency for Food, Environmental and Occupational Health and Safety (ANSES)

EFSA (European Food Safety Authority)

Abstract

On 15 April 2019, the French Agency for Food, Environmental and Occupational Health and Safety (ANSES) published an opinion on the risks related to the exposure to the food additive titanium dioxide (E 171) taking into account the most recent scientific studies available. Further to this publication, EFSA was requested by the European Commission to provide urgent scientific and technical assistance regarding the opinion issued by ANSES. In the ANSES opinion, 25 new relevant publications published between 2017 and 2019 were reviewed together with previous opinions by EFSA and ANSES and a systematic review on *in vitro* genotoxicity of nano titanium dioxide. In this statement, EFSA concludes that the ANSES opinion published in April 2019 does not identify any major new findings that would overturn the conclusions made in the previous two scientific opinions on the safety of titanium dioxide (E 171) as a food additive issued by the EFSA ANS Panel in 2016 and 2018. The ANSES opinion reiterates the previously identified uncertainties and data gaps, which are currently being addressed in the context of the follow-up activities originating from the previous EFSA evaluations and their recommendations. In addition to the aspects for which the follow-up work is currently ongoing, ANSES recommends further investigation of *in vivo* genotoxicity. EFSA considers this recommendation should be revisited once the ongoing work on the physico-chemical characterisation of the food additive titanium dioxide (E 171) is completed.

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Keywords: Titanium dioxide, E 171, food additive

Requester: European Commission

EFSA May 2019 opinion

“ANSES recommends further investigation of *in vivo* genotoxicity. (...) this recommendation should be revisited once the ongoing work on the physico-chemical characterisation of the food additive E 171 is completed”

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Keywords: Titanium dioxide, E 171, food additive

Requester: European Commission

EFSA June 2019 opinion

“In particular, the characterisation of titanium dioxide (E 171) **does not provide a reason to revise the conclusion on genotoxicity** (...) previously drawn by the ANS Panel. “

EFSA's unconventional approach to E171

EFSA's 2021 opinion did not conclude that E171 is unsafe



EFSA said it could not confirm E171's safety because of uncertainties about **genotoxicity**



The safety status of E171 did not change – the scientific approach did



TDMA identified several issues with the EFSA opinion, incl.:

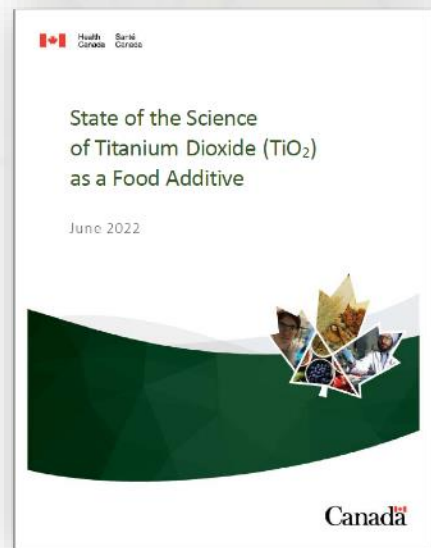
- Test materials and methodology not representative of TiO₂ in food
- Inconsistent application of new EFSA nano guidance

EU restriction on E171 in food

- Following EFSA opinion, the European Commission (EC) committed to removing E171 from EU list of approved food additive
- Proposal endorsed by Member States in October 2021
- Adopted by EC on 14 January 2022 and entered into force on 7 February 2022
- Growing body of evidence confirms the safety of TiO_2 and that the action is not justified



EFSA's position is not shared by global regulatory authorities



Health Canada

- No evidence of cancer or other adverse effects in mice and rats exposed to high concentrations of food-grade TiO₂
- No changes to DNA in various animal studies
- No adverse effects on reproduction, development, immune, gastrointestinal, nervous systems, or general health of rats

Health Canada's position is shared by the UK

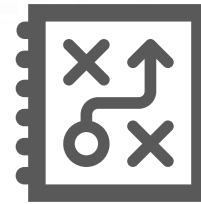


Food Standards Agency

TDMA's approach to EFSA opinion



**EFSA 2021 E171
Opinion took a radical
new approach to
safety science**



**No pre-existing
playbook to address
the completely novel
approach**



**TDMA sets up genotox
with independent
experts to carry out
scientific review and
advise on response**

Findings of TiO₂ Genotox Panel



April 2022 Genotox Panel conclusions

The genotox panel is continuing to review scientific studies on the potential effects of TiO₂

- 1** TiO₂ does not directly affect genetic information within cells
- 2** TiO₂ is practically not absorbed in the body when ingested
- 3** No consistent evidence that TiO₂ causes any indirect effects on genetic information

Labelling and downstream legislation challenges

Classification of TiO₂



Certain labelling obligations for TiO₂ substances and mixtures



Risk that TiO₂ containing waste could be considered hazardous



EU Ecolabelling of paints and varnishes containing TiO₂ to continue

EFSA opinion and E171 ban



European Medicines Agency (EMA) said it is not possible to replace TiO₂ but new review of situation in 2024



Renewed assessment of TiO₂ safety in cosmetics products and toys ongoing



Potential restrictions of TiO₂ in food contact materials (FCMs), incl. strict detection limit in plastic FCMs



International knock-on impacts

The European Green Deal

The Green Deal defines the plan to make the EU's economy sustainable and climate neutral by 2050



The EU is putting money behind the Green transition

At least 30% of the total expenditure of the **€1,824.3 billion** EU budget for 2021- 2027 must be climate-related

The Chemicals Strategy for Sustainability

- Chemicals Strategy for sustainability aims to transition the EU to a 'toxic free environment'
- The strategy is carrying out an overhaul of the EU's regulatory framework for chemicals
- TiO_2 could be impacted in several ways – e.g. certain applications e.g. food contacts, because of the classification



Ban of certain 'hazardous' chemicals in consumer and professional uses unless essential



Introduce 'safe and sustainable-by-design' criteria for chemicals

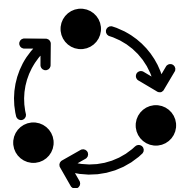


Move towards 'one substance, one assessment' approach for chemicals

Sustainability in buildings and products

Green Deal opens opportunities for TiO₂ in products and buildings

Sustainable Product Policy Framework



Sustainable products and business practices to become the norm

Transition to a sustainable built environment



Renovation wave in Europe with promotion of sustainable materials

TiO₂ is an essential building block

Brilliance & Hiding Power

TiO₂ pigment's color strength, opacity and brightness are unmatched.

01



Safety

TiO₂ is approved for use in Europe, with studies repeatedly showing no harmful effects to the public or workers

04



Protection & Durability

TiO₂ pigment's resistance to heat, light and UV rays helps to extend product life.

02



Uniqueness

Difficult to replace as alternative pigments do not match TiO₂'s performance in technical terms

05



Versatility

TiO₂ pigment has a huge range of applications. New innovative uses are constantly being discovered

03



Availability

TiO₂ is by far the most versatile white pigment available. It is the best-selling white pigment, worldwide

06



TiO₂ contributes to a sustainable built environment



Energy efficiency

TiO₂ reflects the heat from the sun – meaning less energy is needed for cooling devices



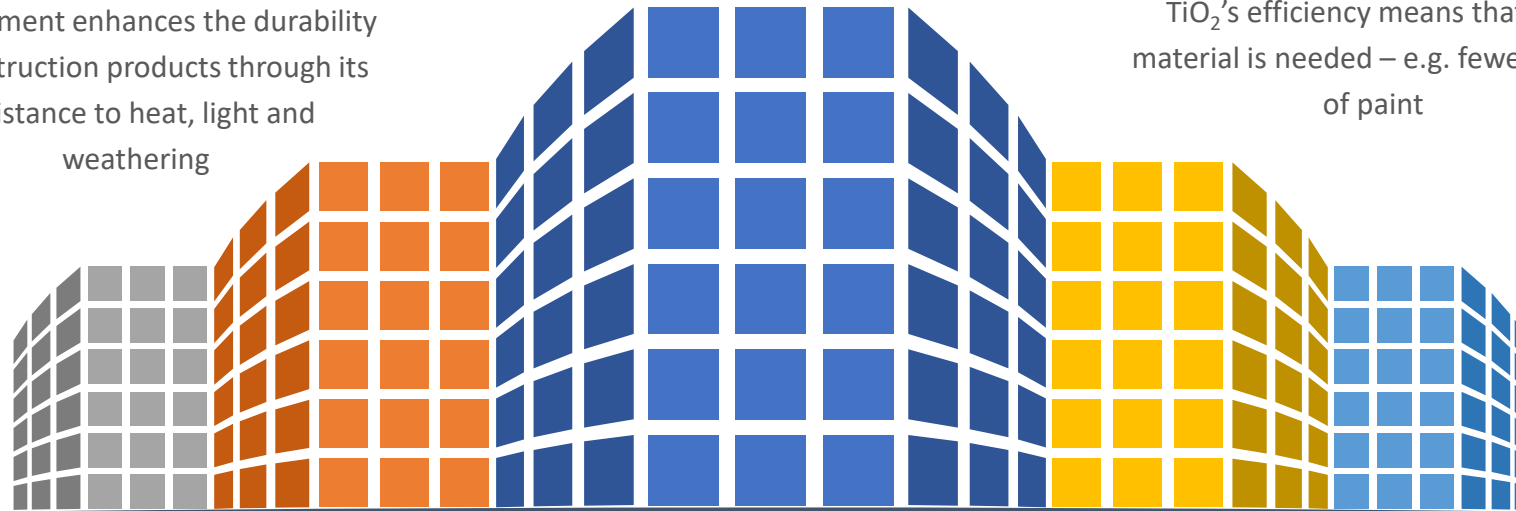
Material efficiency

TiO₂'s efficiency means that less material is needed – e.g. fewer layers of paint



Circular construction materials

TiO₂ pigment enhances the durability of construction products through its resistance to heat, light and weathering



TiO₂ is a building block for sustainable products

1. With TiO₂, fewer resources are needed to achieve high-performance products
2. TiO₂ helps to extend the life-cycle of products, resulting in less waste over time.
3. Less waste means less need for virgin raw materials in line with the circular model



Challenges and opportunities in the Green Deal

- TDMA is addressing regulatory challenges by engaging with key stakeholders and investing in science
- EU Chemicals Strategy raises the bar and the TDMA is prepared to engage
- TiO_2 is and will remain an important building block in the green transition



Thanks for your attention!



Contact: tdma@cefic.be

More information on tdma.info