

About Titanium Dioxide

What is titanium dioxide?

- Titanium dioxide (TiO_2) is a white solid inorganic substance that is thermally stable, non-flammable, poorly soluble, and not classified as hazardous according to the United Nations' (UN) Globally Harmonized System of Classification and Labeling of Chemicals (GHS).
- TiO_2 , the oxide of the metal titanium, occurs naturally in several kinds of rock and mineral sands. Titanium is the ninth most common element in the earth's crust. TiO_2 is typically thought of as being chemically inert.

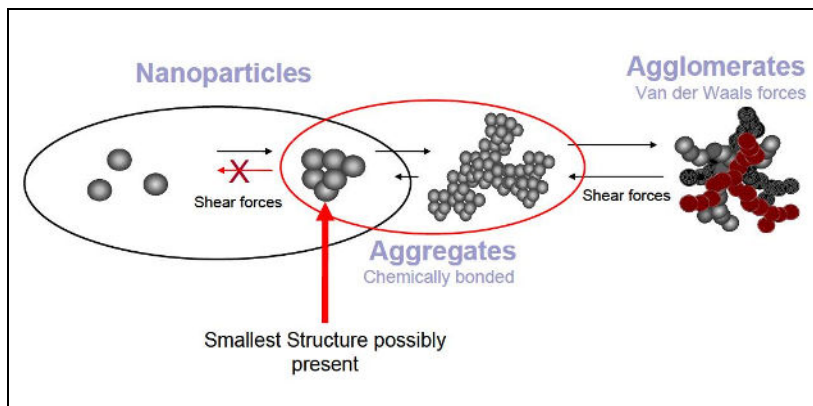
What products contain TiO_2 ?

- Titanium dioxide has been used for many years (ca. 90 years) in a vast range of industrial and consumer goods including paints, coatings, adhesives, paper and paperboard, plastics and rubber, printing inks, coated fabrics and textiles, catalyst systems, ceramics, floor coverings, roofing materials, cosmetics and pharmaceuticals, water treatment agents, food colorants and in automotive products, etc ...

What are the differences between TiO_2 as a pigment and as a nanomaterial (ultrafine)?

- Pigment grade TiO_2 is manufactured to optimise the scattering of visible light and consequently white opacity. This requires a primary particle size of approximately half the wavelength of the light to be scattered, that is half of 400 - 700nm for visible light.

- Pigment grade TiO₂ is manufactured in order to maximise the number of primary particles in this size range (approx. 200 – 350 nm). However as in all production processes of particulate materials, there will be a distribution of primary particle sizes around the average value and it is likely that a small fraction of the primary particles are < 100 nm, and therefore covered by the nanoparticle ISO definition (ISO/TC 229 Nomenclature system for nanoparticles). In practice, all these particles tend to agglomerate into the micron (µm) size range.
- TiO₂ nanomaterials (ultrafine) are transparent and more effective as UV absorbers or photocatalysts. The transparency and UV absorbance allow for effective use as a protective ingredient for sunscreens.
- Due to the smaller size of primary particles and higher surface area, TiO₂ as a nanomaterial allows the manufacture of various catalysts of enhanced activity.
- TiO₂ as a nanomaterial is engineered to have primary particles less than 100 nm in order to optimize such properties.
- TiO₂ as a nanomaterial is not used as a colorant as it is functionally different from pigment size particles and will not impart color or opacity to a product.
- Primary particles are strongly bound or fused together by chemical bonds to form aggregates. These aggregates further agglomerate via van der Waals attractive forces to form particles in the micron (µm) size range.



What are the benefits derived from TiO₂?

- As a pigment, TiO₂ has excellent **light-scattering** properties and is used in a variety of applications that require **white opacity and brightness**.
- It absorbs **UV light**. When TiO₂ pigment is incorporated in a polymer, it minimizes degradation of the system (embrittlement, fading and cracking). Surface treating of the TiO₂ can further improve this property.
- When used in paint or coating system, this effect ensures the longevity of the paint and the continued protection of the substrate.
- The use of light colored paints for interior applications provides an impression of openness and “space”. In addition, the high "luminosity" that comes from light colored paints reduces the energy needed to light the interior of buildings when compared to darker colors.
- In exterior applications the coolness conferred by TiO₂ colored surfaces leads to considerable energy savings in warm and tropical area by light reflectance thus reducing the need for air-conditioning.
- TiO₂ as a **nanomaterial** (ultrafine) appears **transparent** whilst still providing **UV light absorption**.
- Surface treatments allow dispersion in different media and efficient absorption of UV energy (e.g. in applications like sunscreens and light stabilization for wood coatings).
- When untreated, it can be used to decompose environmental pollutants by photocatalysis.
- TiO₂ as a nanomaterial (ultrafine) is used for example as a DeNO_x catalyst support in exhaust gas systems in cars, trucks and power plants, thus minimizing their environmental impact.

Are there any human health concerns with TiO₂?

- TiO₂ use is ubiquitous in our society. Most of the surfaces and items that are white in color contain TiO₂. Thus, we are surrounded by TiO₂ containing materials in our homes, workplaces and public areas. Since the introduction of TiO₂ as a commercial product in 1923, there have been no identified health concerns associated with its exposure among consumers or the general population.
- These facts are supported by the results from four large epidemiology studies involving more than 40,000 workers in the titanium dioxide manufacturing industry in North America and Europe which indicate no association with an increased risk of cancer or with any other adverse lung effects ^(1,2,3,4,6,10) These studies did not specifically differentiate between the ultrafine and pigmentary TiO₂.
- In 2006, the International Agency for Research on Cancer (IARC) evaluated TiO₂ as “possibly carcinogenic to humans” (Group 2B) based primarily on studies in rats. Inhalation exposures to TiO₂ in rats can result in lung effects and lung tumors.
- However, it is generally recognized that the rat is uniquely sensitive to the effects of “lung overload” which is not observed in other species including humans.
(⁸ + TDMA IARC statement July 2011)

Potential Exposure

- by inhalation

- Workers at titanium dioxide manufacturing plants can be exposed to TiO₂ dust. Protection measures including engineering controls and personal protective equipment are applied for exposure control and worker risk mitigation in accordance with existing regulations.
- Downstream users can also be exposed to TiO₂ dust. Appropriate safe handling and use information are included in product documentation such as Safety Data Sheets (SDS).

- Consumer exposure to TiO₂ dust is presumed to be very low because TiO₂ is typically incorporated into a product matrix where it is tightly bound such as in paints or plastics. Thus, inhalation exposure is not considered as relevant for the general public.

- by oral intake

- Pigmentary TiO₂ which meets appropriate purity standards is approved as a colorant for use in foods (E171 - e.g. candies, cookies, sweets, coffee whitener, toothpaste, etc ...) and pharmaceuticals (several Pharmacopoeias).

- by skin contact

- TiO₂ in pigmentary and ultrafine forms is used in cosmetics applications (e.g. lipsticks, make-up products and sunscreens). It has been conclusively demonstrated that TiO₂ is safe for use in sunscreen products to protect skin from harmful effects of solar UV radiation. Comprehensive in vivo and in vitro dermal penetration studies have been performed.
- Studies show TiO₂ particles (pigmentary or ultrafine) do not penetrate either intact or damaged skin (^{5, 9}). Even if the skin is sunburned the penetration of TiO₂ nanoparticles from representative sunscreen formulations is not enhanced (⁷).
- The former European Scientific Committee on Cosmetic Products and Non-Food Products (SCCNFP) reviewed in 2000 data on TiO₂. Based on the results, SCCNFP concluded that TiO₂ is *“safe for use in cosmetic products at a maximum concentration of 25% in order to protect the skin from certain harmful effects of UV radiation. This opinion concerns crystalline (anatase and/or rutile) titanium dioxide, whether or not subjected to various treatments (coating, doping, etc.) irrespective of particle size, provided only that such treatments do not compromise the safety of the product”* (¹¹).

Are there specific health concerns associated with ultrafine TiO₂ exposure?

- Based on existing safety information, it can be concluded that the use of titanium dioxide nanomaterial (ultrafine) as an ingredient in cosmetic sunscreen products at a concentration up to 25 % poses no risks to human health (^{12, 13}).
- New information obtained from research models should be put into a proper perspective by taking into account the relevance of the model used and the dose-levels or concentration tested that might not be representative of typical consumer exposure situation.

Life Cycle Thinking

- The value TiO₂ provides in product applications can often be equated with tangible environmental benefits. For example, TiO₂ is a potent opacifier, enabling thinner films and thus improved resource efficiency and avoided waste. In cradle-to-grave footprint analyses of products that contain TiO₂, both the upstream footprint of TiO₂ manufacture and the downstream environmental performance benefits facilitated by TiO₂ should be considered.
- To support the development of accurate and consistent product carbon footprints, TDMA is developing a standard methodology to calculate the cradle-to-gate carbon footprint of TiO₂ and plans to publish industry average TiO₂ carbon footprint data and the underlying method later this year.

Regulatory framework

- Depending on the use of the titanium dioxide products, different legislative definitions for the purity of the raw material must be fulfilled.
- A list of some key applications with relevant laws and provisions (depending on the country of use) can be found below:

Use as a colorant

- **Automotive:** Council directive 2000/53/EC (end-of life vehicles)
- **Contact lenses:** FDA 21 CFR § 73.3126
- **Cosmetics:** Council Directive 76/768/EEC • FDA 21 CFR § 73.2575

- **Electronic equipment:** Council directives 2002/95/EC and 2002/96/EC (Restriction of the use of Certain Hazardous substances in electrical and electronic equipment (RoHS))
- **Food:** E171 in the European directive 2008/128/EC, replacing 95/45/EC • FDA 21 CFR § 73.575 • Food Chemical Codex (FCC) • CODEX Alimentarius • FAO JECFA Monographs
- **Food contact applications:** EU Regulation (EU) 10/2011 • Council Directive 2004/19/EEC • FDA 21 CFR § 178.3297 (Colorants for polymers) • FDA 21 CFR § 175.300 (Resinous and polymeric coatings) • FDA 21 CFR § 176.170 & 176.180 (Paper & Paperboard) • Bundesinstitut für Risikobewertung (BfR) Section IX, LII, XXXVI, XXXVI-1, XXXVI-2
- **Packaging:** Council Directive 94/62/EC • CONEG legislation (USA)
- **Paints:** Volatile Organic Compounds (VOC) according to the definition of the EU directive 2004/42/EC “decopaint directive”
- **Pharmaceuticals:** United States Pharmacopoeia (USP) • European Pharmacopoeia (EP) • Japanese Pharmacopoeia (JP) • Food and Drugs Administration (FDA) 21 CFR § 73.1575
- **Toys:** DIN EN 71-3 (Security of toys) • ASTM F963 – 11 Standard Consumer Safety specification for Toy Safety

Use without coloring effect

- **Cosmetics:** Council Directive 76/768/EEC • FDA 21 CFR § 352.10 (Sunscreen active ingredients)
- Additional conformity with Good Manufacturing Practice (GMP), different ISO or other standards can be provided. Even the manufacture of Kosher or Halal titanium dioxide products can be achieved.

Conclusion

Titanium dioxide is a global product with many important applications that has been proven as safe in its intended uses over many decades.

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