

	Dossier technique et réglementaire / <i>Technical and regulatory document</i> OXYDE DE TITANE CODEX	Octobre 2025 / <i>October 2025</i>
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INCI: **Titanium dioxyde CI 77891**

N°CAS: 13463-67-7

N°EINECS/ELINCS: 236-675-5

DESCRIPTION / *DESCRIPTION* :

Pigments en forme de poudre blanche impalpable, neutre, sans odeur.

Répond aux exigences de pureté du dioxyde de titane E171 dans l'UE, E171 est autorisé pour une utilisation dans les cosmétiques et les produits pharmaceutiques (Les applications alimentaires et des aliments pour animaux ne sont pas autorisées dans l'UE et Suisse).

Meets the purity requirements for titanium dioxide E171 in the EU, E171 is authorized for use in cosmetics and pharmaceuticals (food and feed applications are not authorized in the European Union and Switzerland).

Répond aux critères de pureté pour additive couleur conformément à la FDS au USA / *meets the purity requirements for color additives according to FDA in the US.*

CARACTERISTIQUES GARANTIES / *GUARANTEED SPECIFICATIONS* :

CARACTERISTIQUES	SPECIFICATIONS	METHOD
Apparence / <i>Appearance</i>	Conforme	EU No.23112012
Teneur en TiO ₂ / <i>Assay</i>	≥ 99.0%	DIN EN ISO 591-1
Substance soluble dans l'acide / <i>Acid soluble substances (HCL 0.5 mol/l)</i>	≤ 0.5 %	EU No.23112012
Substance soluble dans l'eau	≤ 0.5 %	EU No.231/2012
Perte à la dessiccation / <i>loss on drying (800°C)</i>	≤ 1 %	EU No.231/2012
Plomb / <i>lead (Pb)</i>	≤ 10 mg/kg	ELI No.231/2012
Antimoine / <i>antimony (Sb)</i>	≤ 2 mg/kg	ELI No.231/2012
Arsenic / <i>arsenic (As)</i>	≤ 1 mg/kg	ELI No.231/2012
Cadmium / <i>cadmium (Cd)</i>	≤ 1 mg/kg	ELI No.231/2012
Mercure / <i>mercury (Hg)</i>	≤ 1 mg/kg	ELI No.231/2012
Blancheur / <i>PLV Brightness</i>	98.4 – 99.4	DIN 53163

Ces éléments seront repris sur nos BA / *these elements will be on our CoA*

CARACTERISTIQUES A TITRE D'INFORMATION / *ADDITIONAL INFORMATION* :

Oil absorption (DIN EN ISO 787-5) : 19g/100g

Density (DIN EN ISO 787-10) : 3.8g/cm³

pH 10% = 7.0-8.5

APPLICATIONS:

Pharmaceutique, cosmétique / *Pharmaceuticals, cosmetics*

CONDITIONNEMENT STANDARD / *STANDARD PACKAGING* :

Sac papier de 20 kg / 20 kg paper bag

A stocker au frais et au sec dans un endroit bien ventilé / *Store in a cool and well-ventilated place*

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Additives	<i>No data available</i>
Allergen	Food Allergens (1169/2011) and cosmetics allergens (1223/2009 & 2023/1545) are not expected
Animal Testing	Manufacturer has not performed independent animal testing on this purified product. Industry groups in which Manufacturer is a member perform limited scientific testing on various grades of titanium dioxide using animals in compliance with applicable laws when necessary to maintain product registrations and regulatory authorizations (i.e. REACH in the EU).
BSE - Bovine Spongiform Encephalopathy	No risk of BSE
California Prop 65	California listed titanium dioxide as a carcinogen under proposition 65
Carcinogenic, Mutagenic and Reprotoxic (CMR)	<i>No data available</i>
Composition	> 98.5 % TiO ₂ INCI 100% Titanium dioxyde
Cosmetic	This product can be used in cosmetics, meets to the 1223/2009 regulation (E171)
Cosmos / Ecocert	Meets to the Cosmos V4 requirement
Danger	This product is not classified as dangerous in accordance with CLP nor ADR
Dioxane	Dioxins are not intentionally used in the manufacturing process and are not expected in the final product
Ecolabel	<i>No data available</i>
European Pharmacopeia	This product complies with the European Pharmacopoeia
Food	As of 7th February 2022, E171 titanium dioxide is no longer authorized for use in food or feed in the European Union.
Genetically Modified Organisms (GMO)	Are not intentionally used in the manufacturing process and are not expected in the final product
Inventories	Compliant with China IECSC, USA TSCA, New Zealand NZIoC, Taiwan TCSI, Korea ECL, Philippines PICCS, Australia AICS, Canada DSL, Japan ENCS
Geographic origin (for plant)	<i>No data available</i>
Glycol ether	Are not intentionally used in the manufacturing process and are not expected in the final product
Halal	do not contain any ingredient of animal origin do not contain ethanol (ethyl alcohol), nor is ethanol used in the manufacturing process Equipment used in the manufacturing process for food grade titanium dioxide is not used for the manufacture of products containing ingredients of animal origin
Heavy Metals	This product contains elemental impurities that are not added during the manufacturing process but are trace elements originating from the raw material used. Based on the recommendation given in § V. "Risk Assessment and Control of Elemental Impurities" of the Guideline for Elemental Impurities ICH Q3D, a table of the relevant elements to be considered was prepared. Testing has been performed on this product, which is available upon request, providing data to enable the manufacturer of the final product to assess the contribution of the excipient titanium dioxide to the PDE (Permitted Daily Exposure) of the final product.
HS code	28230000
Irradiation / ionization	There is no ionization / irradiation during the manufacturing process in this product
Kosher	do not contain any ingredient of animal origin do not contain ethanol (ethyl alcohol), nor is ethanol used in the manufacturing process Equipment used in the manufacturing process for food grade titanium dioxide is not used for the manufacture of products containing ingredients of animal origin

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Latex	Are not intentionally used in the manufacturing process and are not expected in the final product
Manufacturing location	Canada, Korea
Microbiological data	<p>This product is calcined in a rotary furnace for several hours at a temperature above 900°C and are subject to automated milling and packaging directly thereafter. Process related microbiological contamination can be excluded, as confirmed by microbiological testing by a certified external lab. Test criteria:</p> <p>Total plate count < 10 in 1 g Yeast and Moulds < 10 in 1 g Escherichia coli negative in 1 g Enterobacteria negative in 1 g Pseudomonas aeruginosa negative in 1 g Staphylococcus aureus negative in 1 g Salmonella sp. negative in 1 g</p>
Microplastics	<i>No data available</i>
Nanomaterials	<p>This product consists of typical pigmentary titanium dioxide finely milled to meet requirements and demands as requested. This product does not meet the definition of nanomaterial according to the definition of nanomaterials in Chapter 1, Article 2, 1 (k) of Regulation (EC) 1223/2009.</p> <p>Small particles contained in the product result from various milling processes with the particle size distribution of the primary particles lying within a very close range. This statement is in accordance with the “Guidance Paper on Nanomaterials in Cosmetics” of the EFFCI (European Federation for Cosmetic Ingredients).</p>
Nitrosamines	<p>manufacturer has reviewed potential sources of nitrosamines per EMA/369136/2020 and has not identified risks of nitrosamine formation during production (including cross contamination) or degradation of the product. Raw materials used in the manufacturing process of this product are subject to an incoming goods inspection to exclude cross contamination. This product has been tested for the presence of nitrosamines by an independent, accredited analytical laboratory using appropriately validated and sensitive methods (DIN EN ISO/IEC 17025). The testing confirmed no nitrosamine impurities are present at concentrations above corresponding laboratory method detection limits.</p>
Nutritional data	Doesn't contain any organic material such as proteins, fats, carbohydrates, dietary fibers or vitamins and as no nutritional value
Origin	100% mineral
PAH/PFAS	Are not intentionally used in the manufacturing process and are not expected in the final product
Pesticide	Are not intentionally used in the manufacturing process and are not expected in the final product
Phthalate	Are not intentionally used in the manufacturing process and are not expected in the final product
Preservative	Are not intentionally used in the manufacturing process and are not expected in the final product
Process	ilmenite → digestion by sulfuric acid → crystallization, centrifuge, precipitation, filtration, calcination, milling, surface treatment, filtration, drying, milling
REACH	This product is registered 01-2119489379-17
Residual Solvents	<p>No solvents are used during production and therefore no residual solvents are to be expected in the final product. The grades comply with “ICH Guideline Q3C (R9) on Impurities: Guideline for Residual Solvents.” The product is not exposed to the Class 1, 2 or 3 residual solvents (organic volatile impurities) addressed in the current US Pharmacopeia (USP), Chapter 467, during manufacturing, handling, or storage. For this reason testing is not performed as prescribed in the current USP Chapter 467 and residual solvents are not expected in the product.</p>

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RSPO	This product doesn't contain palm or palm oil derivatives – not concerned
Shelf Life before re-check	5 years
Substances of Very High Concern (SVHC)	<i>No data available</i>
Volatiles organic compounds (VOC)	Are not intentionally used in the manufacturing process and are not expected in the final product

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Ce document annule et remplace tous documents techniques et réglementaires précédents / *This document cancels and replaces all technical and regulatory previous documents.*