

technical datasheet

1.05334 Eusolex® T-S UV Filter

TECHNICAL DATA

INCI Titanium Dioxide* [for EU: Titanium Dioxide (nano)], Alumina, Stearic Acid

***USAN** Titanium Dioxide
(United States
Adopted Name)

Chemical Description	CAS No.	Chem. Formula
Titanium dioxide	13463-67-7	TiO ₂
Aluminium oxide	1344-28-1	Al ₂ O ₃
Stearic acid	57-11-4	C ₁₈ H ₃₆ O ₂

TiO₂ modification Rutile

Appearance Off-white to yellowish powder

Odor Odorless

Storage Tightly closed. Dry.

Stability Minimum 3 years



REGULATORY STATUS EU

According to the European Cosmetics Regulation (EC) No 1223/2009, Titanium Dioxide (nano) is permitted in a maximum concentration up to 25 % as UV-filter (Annex VI, Reference No 27a).

Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation.

Only nanomaterials having the following characteristics are allowed:

- purity ≥ 99.0 %
- crystal form – rutile or rutile with up to 5 % anatase, with crystalline structure and physical appearance as clusters of spherical, needle, or lanceolate shapes
- median particle size based on number size distribution ≥ 30 nm
- aspect ratio 1.0 up to 4.5, volume specific surface area up to $460 \text{ m}^2/\text{cm}^3$
- coated with Silica, Hydrated Silica, Alumina, Aluminium Hydroxide, Aluminium Stearate, Stearic Acid, Trimethoxycaprylsilane, Glycerin, Dimethicone, Hydrogen Dimethicone, Simethicone
- photocatalytic activity ≤ 10 % compared to corresponding non-coated or non-doped reference
- nanoparticles are photostable in the final formulation

Eusolex® T-S is in full compliance with all above listed parameters (physicochemical /coatings).

REGULATORY STATUS USA

TiO₂ : 21 CFR (Code of Federal Regulations), Part 352 – Sunscreen Drug Products for Over-The-Counter Human Use.

1. § 352.10

Titanium Dioxide is listed as a sunscreen active ingredient in a concentration up to 25 %.

2. § 352.20 Permitted combinations

a) Titanium dioxide is permitted to be combined with other permitted sunscreen active ingredients except Avobenzone.

b) Combinations with Skin Protectant Active Ingredients (21 CFR Part 347.10).

Please observe restrictions.

REGULATORY STATUS JAPAN

UV scattering agents like TiO₂ are not regulated according to the New Cosmetic Standards, enforced on April 1st, 2001 by the Ministry of Health and Welfare (MHW).

TiO₂ coated with substances that meet the Cosmetic Standards are permitted for use in cosmetics, e.g. sunscreens.

Eusolex® T-S can be used for cosmetic applications under the responsibility of the cosmetic manufacturer.

REGULATORY STATUS CHINA

According to the Hygienic Standard Version 2007 (From December 1st, 2016: Safety and Technical Standards for Cosmetics, Version 2015), Titanium Dioxide is permitted as UV filter in a maximum authorized concentration of 25 %.



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NOTES

The coating materials for Titanium Dioxide are not specially regulated in most of the countries (exempt EU) - they are considered safe as cosmetic ingredients.

For further information see Specification and Safety Data Sheet.

Date: October 2019

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The Rona logo, featuring the word "Rona" in a bold, black, serif font. The logo is positioned on a light green, rounded rectangular background.