

93363- ZINC OXIDE**1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION.****1.1 Identification of the substance or preparation.**

Name: Zinc oxide

Bulk code: 93363

Internal code: 45940

Valid from batch : 130822

1.2 Synonyms.

Zinc oxide; Zinc oxide (Zinc white), White zinc, zinc monoxide

2. DESCRIPTION

Appearance: soft, amorphous, fine powder, without agglomerates, free of sandy particles.

Color: white or slightly yellowish.

Odor: Characteristic.

Origin: Inorganic mineral substance.

Geographical origin: Spain.

3. COMPOSITION/INFORMATION OF THE COMPONENTS.

Ingredients: Zinc oxide >99.9%

Formula: ZnO

CAS: 1314-13-2

EINECS: 215-222-5

INCI: Zinc Oxide/CI 77947 (To identify the cosmetic colorant that meets the requirements for labelling purposes in the EU, the INCI name CI 77947 should be used).

Molecular weight: 81.39 g/mol

Annex VI Index No.: 030-013-00-7

Method of production: The product is produced by indirect method, by melting high purity electrolytic zinc ingots. When zinc evaporates and comes into contact with atmospheric oxygen, it forms zinc oxide. No other substances are used in the production of this product. The product is manufactured in a dedicated plant. Throughout the manufacturing process, ethylene oxide is not used.

4. PHYSICAL-CHEMICAL DATA.

For more detailed information, please refer to the analysis bulletin.

Solubility: The product is practically insoluble in water, alcohol, chloroform and ether, soluble in dilute mineral acids and in alkaline hydroxide solutions.

93363- ZINC OXIDE**5. PROPERTIES/USES.**

Cosmetic use.

Food use.

Not suitable for direct consumption.

6. DOSAGE.

No data available.

7. OBSERVATIONS.

The product has been handled in a NON-sterile room; so the product is NOT sterile.

The documentation corresponding to the regulatory part of the product that is available for it is the one we reflect below.

NUTRITIONAL INFORMATION:

Not available.

FOOD ALLERGENS:

- **Food allergens:** No allergenic substances listed in Annex II of Regulation (EU) 1169/2011 are used during the manufacturing process, which is carried out in a plant dedicated exclusively to the manufacture of this product. The product does not contain gluten, fructose or lactose.

STORAGE:

Store at room temperature in tightly closed containers in a cool, dry place, protected from light and with the container tightly closed.

SHELF LIFE:

5 years. For more detailed information, see the analysis bulletin.

LEGAL REQUIREMENTS:

- Appropriate measures are taken to comply with the legal requirements established by Regulation (EC) No 178/2002 laying down the general principles and requirements of food law and Regulation (EC) No 852/2004 on the hygiene of foodstuffs.
- The product complies with Annex II of Regulation (EU) 1169/2011.

93363- ZINC OXIDE**BSE/TSE:**

The product is not a product of animal origin and therefore does not receive/have any treatment susceptible to contamination by agents that transmit spongiform encephalopathy (BSE/TSE) during the manufacturing process.

GMO:

The product has been manufactured without using genetically modified organisms (GMO).

CMR:

The product is not classified as carcinogenic, mutagenic or toxic to reproduction (CMR).

SVHC:

The product does not contain any substances on the Candidate List of Substances of Very High Concern (SVHC) whose concentration exceeds 0.1% (w/w). The provisions on SVHC substances set out in Regulation (EC) No 1907/2006 (REACH) are not applicable to this product.

NANOMATERIALS:

The product is not a nanomaterial , with respect to the general definition included in the Recommendation (2011/696/EU) which establishes as “ nanomaterial ” a natural, accidental or manufactured material that contains particles in a free state or forming aggregates or agglomerates, where 50% or more of the particles have a size distribution, in which one or more external dimensions have a size between 1 nm-100 nm .

A typical production sample shows a detection of particles in aqueous suspension with a range between 330 nm and 670 nm , with an average of 470 nm, and no particles smaller than 100 nm were observed . However, these values cannot be considered as a specification of the particle size distribution, however, the production of this product is consistent and no significant variations are expected.

VOC:

Due to the manufacturing process, these are not expected to be present.

IRRADIATION:

The product has not been subjected to ionization processes, nor has it been exposed to any type of radiation.

PESTICIDES:

No pesticides have been used during the manufacturing process.

CONTAMINANTS:

The product is not listed in the Annex of Regulation (EC) No 1881/2006.

93363- ZINC OXIDE**RESIDUAL SOLVENTS:**

No extraction solvents are used during the manufacturing process.

IMPURITIES:

Due to the origin of the raw material and the manufacturing process, the following substances are not expected to be present:

- Aflatoxins .
- Dioxins.
- Ethylene oxide.
- Melamine .
- Nitrosamines.
- Additives
- Latex
- PCBS (The product is not listed in the annex of Regulation (EC) No 1881/2006).

TRACE METALS:

No catalysts or inorganic reagents other than Zinc are used during the manufacturing process. Traces of metals listed in Annex II of Regulation (EC) 1223/2009, which are technically unavoidable during the manufacturing process and have not been intentionally added during the manufacturing process, can be expected.

CALIFORNIA PROPOSITION 65:

The product is not included in the "Chemicals known to the state to cause cancer or reproductive toxicity as of March 19, 2021" (Proposition 65, Chemical Listing).

It is the user's responsibility to determine whether the use of the product complies with current legislation for the application for which it is intended.

ALLERGENS:

- **Cosmetic allergens:** Due to the manufacturing process, these are not expected to be present. Due to the manufacturing process, the presence of prohibited substances listed in Annex II of Regulation (EC) 1223/2009 or restricted substances listed in Annex III is not expected. Zinc oxide appears on the list of permitted colourants in Annex IV and on the list of permitted UV filters in cosmetic products in Annex VI. Preservatives are also not expected to be present (Annex V).

HALAL:

The product has been manufactured without using animal fats, meats or related substances derived from any animal.

KOSHER:

The product has been manufactured without using animal fats, meats or related substances derived from any animal.

93363- ZINC OXIDE**VEGAN/VEGETARIAN:**

The product does not contain derivatives or by-products of animal origin. It is a substance of synthetic-inorganic origin.

WADA:

No prohibited substances included in the WADA list are manipulated during the manufacturing process and the product has not been contaminated or come into contact with them.

TESTED ON ANIMALS:

The product has not been tested on animals.

RSPO:

The product does not contain palm oil or derivatives, nor have these been used during the manufacturing process.

REACH:

01-2119463881-32-0058