

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

1.2 Synonyms

Zinc oxide; Zinc oxyde, Zinc white, Zinc monoxide

2. DESCRIPTION**Appearance:** Soft, amorphous, fine powder, without agglomerates, free of sandy particles.**Colour:** White or slightly yellowish.**Origin:** Mineral inorganic substance.**Geographical origin:** Spain.**3. COMPOSITION/INFORMATION ON COMPONENTS**

Formula: ZnO

CAS: 1314-13-2

EINECS: 215-222-5

INCI: Zinc Oxide/CI 77947 (the name INCI CI 77947 should be used to identify the cosmetic colourant that meets EU labelling requirements).

Molecular weight: 81.39 g/mol

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

Method of production: The product is manufactured using the indirect method, by melting high-purity electrolytic zinc ingots. When the zinc evaporates and comes into contact with atmospheric oxygen, it forms zinc oxide. No more substances are used to manufacture this product. The product is manufactured in a dedicated plant for this purpose. Ethylene oxide is not used in the manufacturing process.**4. PHYSICO-CHEMICAL DATA**

For more information, see the analysis report.

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



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5. PROPERTIES/USES

Excipient for pharmaceutical use.

Food use.

Cosmetic use.

The product can be added to foodstuffs as an ingredient.

It is the user's responsibility to determine that their finished product is compliant with the maximum limits set by current legislation and that the product is safe and appropriate for its intended applications.

6. DOSAGE

No information available.

7. REMARKS

The product has been handled in a NON-sterile room; for batches suitable for sterile use, check availability.

STORAGE:

Store at room temperature, in a cool, dry place, away from sunlight, in a tightly closed container.

The documentation available related to the product's regulatory compliance is included below.

BSE/TSE:

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

GMOs:

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

CMR substances:

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

SVHC:

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



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NANOMATERIALS:

The product is not a nanomaterial as concerns the general definition included in Recommendation (2011/696/EU), which defines “nanomaterial” as a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm.

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

VOCs:

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

IRRADIATION:

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

PESTICIDES:

No pesticides have been used in the manufacturing process.

CONTAMINANTS:

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

RESIDUAL SOLVENTS:

No extraction solvents are used in 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 to Regulation (EC) No 1881/2006)



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TRACE METALS:

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

CALIFORNIA PROPOSITION 65:

The product is not included in the list of “chemicals that are known to the state to cause cancer or reproductive toxicity as of 19 March 2021” (Proposition 65, List of Chemicals). It is the user’s responsibility to determine whether the use of the product complies with current legislation for its intended application.

ALLERGENS:

- **Food allergens:** No allergenic substances listed in Annex II to Regulation (EU) 1169/2011 are used in the manufacturing process, which is carried out in an exclusive plant for the manufacture of this product. The product does not contain gluten, fructose, lactose.
- **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 to Regulation (EC) No 1223/2009, nor substances subject to restrictions, listed in Annex III, is not expected. Zinc oxide appears in the list of permitted colourants in Annex IV and in the list of permitted ultraviolet filters in cosmetic products in Annex VI. Preservatives are also not expected (Annex V).

HALAL:

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

KOSHER:

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

VEGAN/VEGETARIAN:

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

WADA:

No WADA-listed prohibited substances are handled in 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.



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RSPO:

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

REACH:

01-2119463881-32-0058