



## CERTIFICATE OF ANALYSIS

**Product:** Zinc Oxide USP - Non  
**Batch No.** Nano 4431507  
**Best Before:** April 2024

<b>Cu</b>	0.0001
<b>Pb</b>	0.0005
<b>Cd</b>	0.0001
<b>Fe</b>	0.0001
<b>Sn</b>	<0.0001
<b>Mn</b>	<0.0001
<b>As</b>	<0.0001
<b>ZnO</b>	99.9
<b>M-325</b>	99.99
<b>Surface Area (m<sup>2</sup>/g)</b>	6



## ALLERGEN DECLARATION

**Product: Zinc Oxide USP - Non Nano**

<b>COSMETIC ALLERGENS</b>			
The following is from the 7 <sup>th</sup> amendment of the cosmetic directive of the European Union Annex iii.			
<b>Annex IIIa reference</b>		<b>CAS Number</b>	<b>Total Allergen Inclusion %</b>
67	Amyl cinnamal	122-40-7	0.00
68	Benzyl alcohol	100-51-6	0.00
69	Cinnamyl alcohol	104-54-1	0.00
70	Citral	5392-40-5	0.00
71	Eugenol	97-53-0	0.00
72	Hydroxy-citronellal	107-75-5	0.00
73	Isoeugenol	97-54-1	0.00
74	Amylcin-namyl alcohol	101-85-9	0.00
75	Benzyl salicylate	118-58-1	0.00
76	Cinnamal	104-55-2	0.00
77	Coumarin	91-64-5	0.00
78	Geraniol	106-24-1	0.00
79	Hydroxy-methylpentylcyclohexenecarboxaldehyd	31906-04-4	0.00
80	Anisyl alcohol	105-13-5	0.00
81	Benzyl cinnamate	103-41-3	0.00
82	Farnesol	4602-84-0	0.00
83	Butylphenyl Methylpropanol	80-54-6	0.00
84	Linalool	78-70-6	0.00
85	Benzyl benzoate	120-51-4	0.00
86	Citronellol	106-22-9	0.00
87	Hexyl cinnam-aldehyd	101-86-0	0.00
88	Limonene	5989-27-5	0.00
89	Methyl heptin carbonate	111-12-6	0.00
90	Alpha-Isomethyl Ionone	127-51-5	0.00
91	Oak Moss Extracts (Evernia Prunastri Extract)	90028-68-5	0.00
92	Tree Moss Extracts (Evernia Furfuracea extract)	90028-67-4	0.00



Zinc Oxide is produced using Zinc Special High Grade 99.995% and that organic elements are not used, no products produced from peanuts, milk, tree nuts, eggs, soy, fish, shellfish are produced in eth manufacturing facility, therefore our products do not contain allergens from these sources.

Issue 19.02.21



## CMR STATEMENT

**Product: Zinc Oxide USP - Non Nano**

Zinc Oxide USP which is supplied by MADAR Corporation Limited Is not classified as CMR Substance (carcinogenic, mutagenic or toxic for reproduction), in accordance with the current European Regulation (EC) No. 1223/2009 of the European Parliament and of the council of 30th November 2009 on cosmetic products.

Issue 19.02.21



## MANUFACTURING FLOW CHART

### 1.1 PRODUCT NAME:

Zinc Oxide USP - Non Nano

#### **Synonyms:**

Zinc White

Flowers of Zinc Philosopher's  
wool Chinese White

Ossido di Zinco

Zink Oxid.

#### **INCI name:**

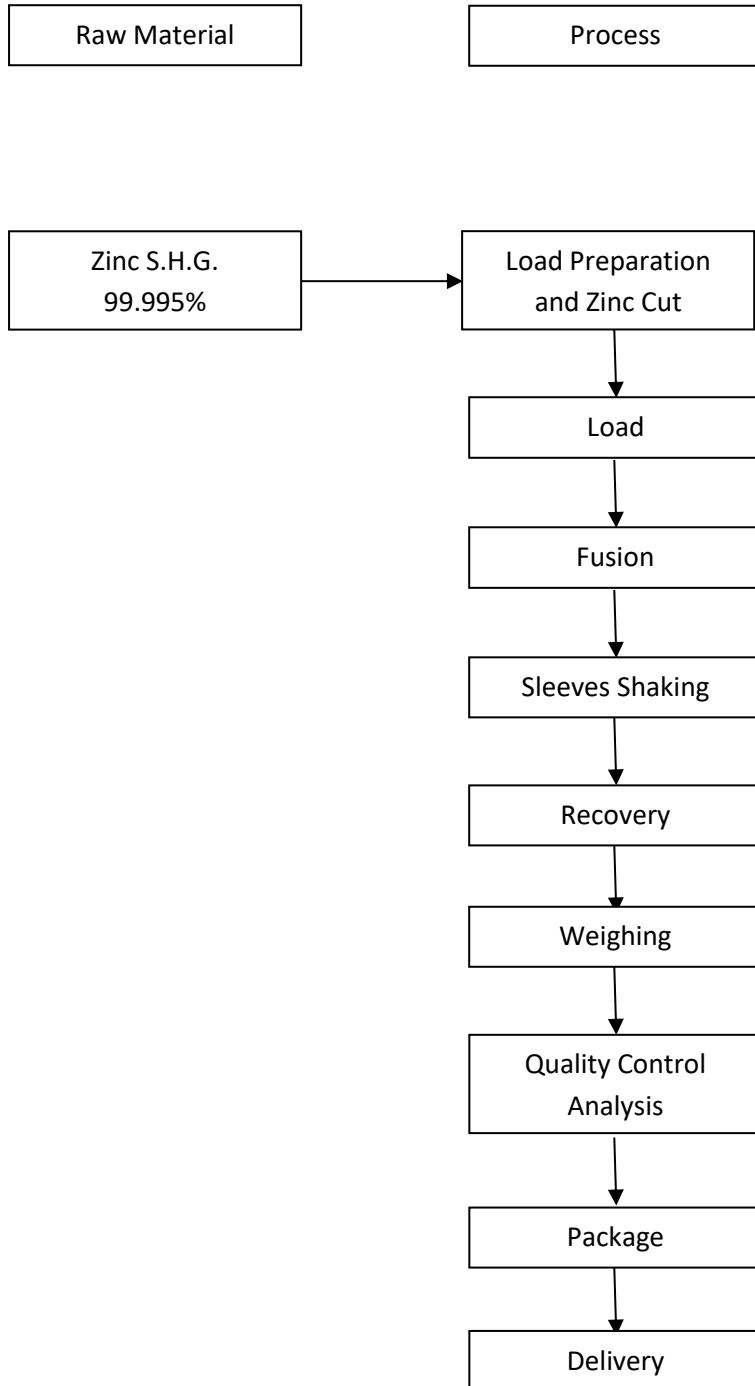
Zinc Oxide

#### **REACH Registered No.**

01-2119463881-32-0087 CAS

No. 1314-13-2

EC No. 215-222-5





## GMO STATEMENT

**Product: Zinc Oxide USP - Non Nano**

Zinc Oxide USP which is supplied by MADAR Corporation Limited is manufactured from petrochemical raw materials exclusively, using no materials of animal or vegetable origin. No gluten-containing raw materials or processing aids are used in the manufacture of Zinc Oxide USP. Zinc Oxide USP does not contain any GMO (Genetically Modified Organism) material and do not contain detectable levels of genetically modified materials, (known as PCR negative).

Issue 19.02.21

DATE : 28/05/20  
Zinc Oxide USP - Non Nano

SHEET 1 of 16

## 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND COMPANY NAME

### 1.1 PRODUCT NAME:

Zinc Oxide

#### Synonyms:

Zinc White, Flowers of Zinc, Philosopher's wool, Chinese White, Ossido di Zinco, Zink Oxid.

#### Chemical name:

Zinc Oxide

#### REACH Registered No.

01-2119463881-32-0087

CAS No. 1314-13-2

EC No. 215-222-5

### 1.2 RELEVANT IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE AND USES ADVISED AGAINST:

#### Relevant identified uses of the substance or mixture:

Colouring agents, pigments., Food/feedstuff additives, Fuels and fuel additives, Corrosion inhibitors and anti-scaling agents, Fertilisers, Pharmaceutical substance, Photosensitive agents and other photo-chemicals, Process regulators, used in vulcanisation or polymerisation processes, Processing aid, not otherwise listed, Intermediates, Laboratory chemicals, Lubricants and lubricant additives, Plating agents and metal surface treating agents, Process regulators, other than polymerisation or vulcanisation processes, Component in batteries, Semiconductors, Ceramics, floor tiles, enamels., Rubber compounds, Ferrites, varistors

#### Uses advised against:

No data available.

### 1.3 DETAILS OF THE SUPPLIER:

MADAR Corporation Limited

19 - 20 Sandleheath Industrial Estate  
Fordingbridge  
SP6 1PA

01425 655555

e-mail: [technical@madarcorporation.co.uk](mailto:technical@madarcorporation.co.uk)

## 2. HAZARDS IDENTIFICATION

### 2.1 CLASSIFICATION OF THE SUBSTANCE OR MIXTURE:

According to Regulation (EC) No. 1272/2008 Regulation (CLP/GHS)

Aquatic Acute 1 H400: Very toxic to aquatic life, M factor 1.

Aquatic Chronic 1 H410: Very toxic to aquatic life with long lasting effects, M factor 1.

### 2.2. LABEL ELEMENTS:

This product has no label elements.

**GHS09: Environmental**





DATE : 28/05/20  
Zinc Oxide USP - Non Nano

SHEET 2 of 16

**Hazard statements:**

H410 : Very toxic to aquatic life with long lasting effects.

**Precautionary Statements:**

P273: Avoid release to the environment.

P391: Collect spillage.

P501: Dispose of contents/container in accordance with local/regional/ international regulations

**GHS Precautionary Statements – Pictograms**



Prevention: Keep only in original container or in similar tightly sealed container.

Response: Absorb spillage to prevent material damage.

Storage: Store in tightly sealed container.

Disposal: Dispose as per local, state or federal regulations.

**2.3 OTHER HAZARDS:**

Substance meets the criteria for PBT according to Regulation (EC) No. 1907/2006, Annex XIII:

No

Substance meets the criteria for vPvB according to Regulation (EC) No. 1907/2006, Annex XIII:

No

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

**3.1. CHEMICAL IDENTITY:**

Zinc Oxide.

**CAS REGISTRY NO.:**

1314-13-2

**CE NO.:**

215-222-5.

**IUPAC Name:**

Oxozinc.

**Index number:**

030-013-00-7

**% (w/w):**

97 - 100%

**4. FIRST AID MEASURES**

**4.1. DESCRIPTION OF FIRST AID MEASURES:**

**General Information:**

No specific effects and/or symptoms have been reported or known. Remove person from area of exposure.

**Eye contact:**

Immediately wash out with plenty of water. Remove any contact lenses and continue flushing for 15 minutes holding eyelids open. Consult a physician if symptoms persist

**Skin contact:**

Remove contaminated clothing. Wash off with plenty of water and soap. If necessary use a hydrating lotion. If irritation occurs, seek medical attention.



DATE : 28/05/20  
Zinc Oxide USP - Non Nano

SHEET 3 of 16

**Ingestion:**

Wash out mouth with water. Make affected person drink plenty of water. Do not induce vomiting. Consult a physician if symptoms persist.

**Inhalation:**

Move to fresh air. If not breathing, apply artificial respiration. If breathing is difficult, give oxygen. Consult a physician if symptoms persist.

**Protection of first aiders:**

Avoid exposure, wear additional protection as conditions warrant. (see section 8)

**4.2 MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED:**

Acute: Dry Cough, headache, throat irritation, flu-like condition. Delayed: No delayed symptoms expected.

**4.3 INDICATION OF ANY IMMEDIATE/SPECIAL TREATMENT NEEDED:**

Nausea, strong cough, migraine. Remove person to fresh air.

**5. FIRE FIGHTING MEASURES**

**5.1 EXTINGUISHING MEDIA:**

**Suitable extinguishing media:**

Product itself is non-combustible; adapt fire extinguishing measures to surrounding areas. Foam, water, dry chemical or carbon dioxide

**Unsuitable extinguishing media:**

No data available.

**NFPA Ratins:**

Health:1, Fire: 0 and Reactivity: 0

**Hazard Scale:**

0 = Minimum, 1 = Slight, 2 = Moderate, 3 = Serious and 4 = Severe

**5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE:**

Water contaminated with this material must be prevented from being discharged to the environment.

**Hazardous thermal decomposition products:**

Zinc Oxide fumes may be released in a fire involving zinc oxide.

**5.3 PROTECTION FOR FIRE-FIGHTERS:**

Fire fighters must be fully trained and wear full protective clothing including an approved, self-contained breathing apparatus which supplies a positive air pressure within a full face piece mask.

**5.4 PERSONAL PROTECTIVE EQUIPMENT:**

iate breathing apparatus may be required.

**5.5 ADDITIONAL INFORMATION:**

Collect contaminated firefighting water separately, must not be discharged into the drains.

**6. ACCIDENTAL RELEASE MEASURES**

**6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES:**

Refer to protective measures listed in sections 7 (handling and storage) and 8 (exposure controls/personal protection). Avoid dust formation and breathing dust.

**6.2 ENVIRONMENTAL PRECAUTIONS:**

Do not discharge into the drains/surface waters/groundwater. Inform authorities of spill where required.

**6.3 METHODS AND MATERIALS FOR CONTAINMENT AND CLEANING UP:**

Pick up mechanically. Avoid dry sweeping or other methods which raise dust. Send in suitable containers for recovery or disposal. Dispose of waste via licensed waste disposal contractor.

**6.4 REFERENCE TO OTHER SECTIONS:**

See section 8 to personal protective equipment and section 13 to waste treatment methods.

**7. HANDLING AND STORAGE**

**7.1 PRECAUTIONS FOR SAFE HANDLING:**

Provide good ventilation of working area (local exhaust ventilation, if necessary. Keep away from sources of ignition - refrain from smoking. Dust can form an explosive mixture with air. Take precautionary measures against static charges. Employees must not breath dust, wash thoroughly after handling.

**7.2 CONDITIONS FOR SAFE STORAGE:**

Keep in original packaging, tightly closed when not in use. Do not store together with foodstuffs. Do not store together with animal feedstocks. Do not store together with: Acids, Bases. Keep container tightly closed and dry in a cool, well-ventilated place. Protect bags from physical damage. Store in gry areas, avoid contact in storage with incompatible materials.

1) Material release or spill: Ventilate area, clean up-personnel require respiratory protection. Collect powder materials and deposit in sealed drums. Vacuum or sweep remaining material (don't dry sweep)

2) Waste disposal method: Dispose in a closed container or heavy bag: Material may be recycled or disposed of in accordance with federal, state and local environmental regulations. This material may be regulated under CERCLA, TSCA, SARA and/or RCRA regulations.

**7.3 SPECIFIC END USES:**

See section 1.2.

**8. EXPOSURE CONTROL/PERSONAL PROTECTION**

**8.1 CONTROLPARAMETERS:**

	<b>DNEL/DMEL (Workers)</b>	<b>DNEL/DMEL (General population)</b>	<b>PNEC (Water)</b>	<b>PNEC (Sediment)</b>	<b>PNEC (Soil)</b>
Oral		Systemic effects, long term: 0.83 Zn/kg bw/day			
Inhalation	Systemic effects, long term: 5m2/m3 Local effects, long term: 0.4 mg Zn/m3 (respirable fraction) (Creutzenberg O., 2013)	Systemic effects, long term: 2.5 mg Zn/m3			
Dermal	Systemic effects, long term: 83 mg Zn/kg bw/day	Systemic effects, long term: 83 mg Zn/kg bw/day			
PNEC aqua (freshwater)			20.6 µg/L		
PNEC aqua (marine water)			6.1 µg/L STP 100 µg/L		
PNEC sediment (freshwater)				235.6mg/kg dwt	
PNEC soil					106.8mg/kg dwt

OELs for ZnO - Group: "Slightly soluble / (e.g.: ZnO - Zn(OH)2 - Zn3(PO4)2 - ZnCO3 - Zn Metal - ZnS)	Country/organisation	8 hour-TWA mg/m3	15 min-STEL mg/m3	References
	USA	5 (fumes) 10 (dust)	10 (fumes) (ceiling)	ACGIH (1991) (guidance values)
	USA	5 (fumes) 10 (dust) 5 (dust; respirable)		OSHA (1989) (legal limit values)
	The Netherlands	5 (fumes)		SZW (1997)
	Germany	5 (fumes) 6 (dust)	140.9mg/l	DFG (1997)
	UK	5 (fumes) 10 (dust)	140.9mg/l	HSE (1998)
	Sweden	5 (fumes)		National Board of Occupational Safety and Health, Sweden (1993)
	Denmark	4 (fumes) 10 (dust)		Arbejdstilsynet (1992)

## 8.2. EXPOSURE CONTROLS:

### Hygienic controls:

Do not eat, drink or smoke during work time. After worktime and during work intervals the affected skin areas must be thoroughly cleaned. Store work clothing separately. Do not inhale dust.

### Personal protective equipment:

Safety glasses and gloves.

### Hand protection:

Protective gloves (EN 374). Natural rubber gloves.

### Eye Protection:

Safety glasses (EN 166):safety goggles are recommended.

### Skin and body protection:

Clothing as usual in the chemical industry.

### Respiratory protection:

Avoid creating dust. Use NIOSH approved particulate respirator if dust generation occurs.

### Additional protective measure:

Wash thoroughly after handling and before eating or drinking. Emergency showers and eye wash stations should be available. Educate and train employees in the safe use and handling of hazardous chemicals.

### 8.2.1 APPROPRIATE ENGINEERING CONTROLS

#### Technical conditions and measures at process level (source) to prevent release:

Process enclosures closed circuits or semi-enclosures where appropriate. Local exhaust ventilation on furnaces and other work areas with potential dust and fumes generation, dust capturing and removal techniques (high efficiency 90 - 95%). Containment of liquid volumes in sumps to collect/prevent accidental spillage.

#### Technical conditions and measures to control dispersion from source towards the worker:

Cyclones/filters (for minimizing dust emissions): efficiency: 70-90% (cyclones), 50-80% (dust filters), 85-95% (double stage, cassette filters). Dust control: ZnO dust needs to be measured in the workplace air (static or individual).

Special care for the general establishment and maintenance of a clean working environment by e.g.:  
Cleaning of process equipment and workshop. Storage of packaged Zn finished product in dedicated zones

**Organisational measures to prevent/limit releases, dispersion and exposure:**

In general, integrated management system would include general industrial hygiene practice e.g.:  
Information and training of personnel on prevention of exposure/accidents. Procedures for control of personal exposure (hygiene measures). Regular cleaning of equipment and floors, extended workers instruction-manuals. Procedures for process control and maintenance. Personal protection measures (see 8.2.2).

**8.2.2 PERSONAL PROTECTION**

The GES for ZnO production mentions the following in this respect:

Wearing of gloves and protective clothing is compulsory (efficiency  $\geq 90\%$ ). With normal handling, no respiratory personal protection (breathing apparatus is necessary).

If risk for exceedance of OEL/DNEL, use e.g.:

Dust filter-half mask P1 (efficiency 75%)

Dust filter-half mask P2 (efficiency 90%)

Dust filter-half mask P3 (efficiency 95%)

Dust filter-full mask P1 (efficiency 75%)

Dust filter-full mask P2 (efficiency 90%)

Dust filter-full mask P3 (efficiency 97.5%)

Eyes: Safety glasses are optional

Information-training of the workers and their staff and line managers focused on careful hygiene behaviour.

**8.2.3 ENVIRONMENTAL EXPOSURE CONTROL**

**Technical conditions and measures at process level (source) to prevent release:**

Process enclosures and closed circuits or semi-enclosures where relevant and possible.

Local exhaust ventilation on furnaces and other work areas with potential dust generation, dust capturing and removal techniques. Containment of liquid volumes in sumps to collect/prevent accidental spillage, acid solutions are treated with alkali. There is high temperature in the surroundings of the calcinations furnaces.

**Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil:**

On-site water treatment techniques can be applied to prevent releases to water (if applicable) e.g.: chemical precipitation, sedimentation and filtration (efficiency 99 - 99.98%). Containment of liquid volumes in sumps to collect/prevent accidental spillage. Air emissions are controlled by use of bag-house filters and/or other air emission abatement devices, e.g. fabric (or bag) filters (up to 99% efficiency), wet scrubbers (50-99% efficiency). This may create a general negative pressure in the building.

**Organisational measures to prevent/limit release from site**

In general, emissions are controlled and prevented by implementing an integrated management system (eg. ISO 9000, ISO 1400X series, or alike).

Such management system should include general industrial hygiene practice, e.g.:

Information and training of workers. Regular cleaning of equipment and floors. Procedures for process control and maintenance. Treatment and monitoring of releases to outside air, and exhaust gas streams (process & hygiene), according to national regulation. SEVESO 2 compliance, if applicable.

**8.3 OTHER**

Route(s) of entry: Inhalation and mechanical irritation of eyes and skin.

Carcinogen Status: Not a NTP/IARC carcinogen.

Signs and symptoms of exposure: Dry throat, cough and dry itchy skin.

Notes: Excess bulk exposure may cause acute respiratory irritation or dry skin.



DATE : 28/05/20  
Zinc Oxide USP - Non Nano

SHEET 7 of 16

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>APPEARANCE:</b>	Solid Powder
<b>COLOUR:</b>	White to yellowish white powder
<b>ODOUR:</b>	Odourless
<b>EVAPORATION RATE:</b>	Negligible.
<b>MOLECULAR WEIGHT:</b>	81.38
<b>SPECIFIC GRAVITY:</b>	5.4 to 5.8
<b>pH:</b>	6.8 to 7.4
<b>MELTING POINT (°C):</b>	ZnO is very stable. No melting occurs. No exothermic or endothermic peaks are observed . No oxidation or decomposition was observed.
<b>BOILING POINT (°C):</b>	Not relevant; the sample decomposes before boiling.
<b>FLASH POINT (°C):</b>	Not applicable to inorganic substances (Column 2 of Annex VII of REACH regulation)
<b>EVAPORATION RATE:</b>	Not applicable.
<b>FLAMMABILITY:</b>	All grades of zinc powder were not to be considered as flammable.
<b>VAPOUR PRESSURE:</b>	Not applicable if the melting point is above 300°C (Column 2 of Annex VII REACH regulation)
<b>VAPOUR DENISTY:</b>	Not applicable.
<b>RELATIVE DENSITY:</b>	5.68g/cm <sup>3</sup> .
<b>SOLUBLE:</b>	In bases and acids.
<b>SOLUBILITY IN WATER:</b>	2.9 mg/l.
<b>PARTITION COEFFICIENT: N-OCTANOL/WATER</b>	Not applicable if the substance is inorganic (column 2 of Annex VII of the REACH regulation)
<b>OXIDISING:</b>	Non-oxidising by EC criteria.
<b>VISCOSITY:</b>	Viscous.
<b>AUTOIGNITION TEMPERATURE:</b>	The substance is not auto-flammable.

## 10. STABILITY AND REACTIVITY

### 10.1 REACTIVITY:

Stable under normal, dry conditions.

### 10.2 CHEMICAL STABILITY:

Thermal stability

### 10.3 HAZARDOUS REACTIONS:

Zinc oxide can absorb carbon dioxide from air to form zinc carbonate.

### 10.4 CONDITIONS TO AVOID:

Zinc oxide is stable in closed containers at room temperature under routine conditions of storage and handling. It can absorb carbon dioxide from air to form zinc carbonate.

### 10.5 MATERIALS TO AVOID:

Acids, bases

### 10.6 HAZARDOUS DECOMPOSITION PRODUCTS:

ZnO-fume can be generated during thermal processing.



DATE : 28/05/20  
Zinc Oxide USP - Non Nano

SHEET 8 of 16

## 11. TOXICOLOGICAL INFORMATION

### 11.1 INFORMATION ON TOXICOLOGICAL EFFECTS:

#### Acute Toxicity:

Constituent	CAS N <sup>o</sup>	Method	Species	Via
Zinc oxide	1314-13-2	Klimisch and Freisberg (1982)	Rat	Inhalation

**Result:** Rat LD50 >5.7mg/l.

Constituent	CAS N <sup>o</sup>	Method	Species	Via
Zinc oxide	1314-13-2	Löser,1972	Rat	Oral

**Result:** LD50 = 15000 mg/kg

Constituent	CAS N <sup>o</sup>	Method	Species	Via
Zinc oxide	1314-13-2	Löser,1977	Rat	Oral

**Result:** LD50 >5000 mg/kg

#### Skin:

Constituent	CAS N <sup>o</sup>	Method	Species	Via
Zinc oxide	1314-13-2	Löser,1977 Lansdown, 1991	Not available	Not available

**Result:** Skin: Not irritant

#### Eye contact:

Constituent	CAS N <sup>o</sup>	Method	Species	Via
Zinc oxide	1314-13-2	Klimish et al, 1982 Thijssen,1978; Löser,1977	Not available	Not available

**Result:** Eye: Not irritant

#### Respiratory or skin sensitisation:

Constituent	CAS N <sup>o</sup>	Method	Species	Via
Zinc oxide	1314-13-2	Klimish et al, 1982	Not available	Not available

**Result:** Respiratory tract: not irritant

#### Germ cell mutagenicity:

Constituent	CAS N <sup>o</sup>	Method	Species	Via
Zinc oxide	1314-13-2	Read across	Not available	Not available

**Result:** No biologically relevant genotoxic activity (based on cross-reading between Zn compounds; no classification for mutagenicity required) (Chemical Safety Report (CSR) Zinc Oxide, 2015)

#### Reproduction toxicity:

Constituent	CAS N <sup>o</sup>	Method	Species	Via
Zinc oxide	1314-13-2	Read across	Not available	Not available

**Result:** No experimental or epidemiological evidence exists to justify classification of zinc compounds for reproductive or developmental toxicity (based on cross-reading between Zn compounds; no classification for reproductive toxicity required) (Chemical Safety Report (CSR) Zinc Oxide, 2015)

#### Carcinogenicity:

Constituent	CAS N <sup>o</sup>	Method	Species	Via
Zinc oxide	1314-13-2	Read across	Not available	Not available

**Result:** No experimental or epidemiological evidence exists to justify classification of zinc compounds for carcinogenic activity (based on cross-reading between Zn compounds; no classification for carcinogenicity required) (Chemical Safety Report (CSR) Zinc Oxide, 2015)

**STOT-single exposure:**

Constituent	CAS N <sup>o</sup>	Method	Species	Via
Zinc oxide	1314-13-2	Heydon and Kagan, 1990; Gordon et al., 1992; Mueller and Seger, 1985	Not available	Not available

**Result:** No experimental or epidemiological sufficient evidence for specific target organ toxicity (single exposure) (no classification for target organ toxicity (single exposure: STOT-SE) required) (Cited in Chemical Safety Report (CSR) Zinc Oxide, 2015)

**STOT-repeated exposure:**

Constituent	CAS N <sup>o</sup>	Method	Species	Via
Zinc oxide	1314-13-2	Lam et al, 1985, 1988; Conner et al.,1988	Not available	Not available

**Result:** No experimental or epidemiological sufficient evidence for specific target organ toxicity (repeated exposure) (no classification for target organ toxicity (repeated exposure: STOTRE) required) (Cited in Chemical Safety Report (CSR) Zinc Oxide, 2015)

**Aspiration hazard:**

Constituent	CAS N <sup>o</sup>	Method	Species	Via
Zinc oxide	1314-13-2	Not available	Not available	Not available

**Result:** Not available. Data lacking

**12. ECOLOGICAL INFORMATION**

**12.1 TOXICITY:**

**12.1.1 Acute Aquatic Toxicity:**

The acute aquatic toxicity database on zinc contains data on 11 standard species obtained under estándar testing conditions at different pH and hardness. Since the transformation/dissolution of zinc metal is dependent on pH, the available acute aquatic toxicity dataset has also been considered for 2 different pH ranges separately. The full analysis of these datwais given in the CSR. The reference values for acute aquatic toxicity, based on the lowest observed EC50 values of the corresponding databases at different pH and expressed as Zn<sup>++</sup> ion concentration are:

- for pH <7: 0.413 mg Zn<sup>++</sup>/l (48 hr. Ceriodaphnia dubia test according to US EPA 821-R-02-012 standard test protocol; reference: Hyne et al 2005)
- for pH >7-8.5: 0.136 mg Zn <sup>++</sup>/l (72 hr. Selenastrum capricornutum (=Pseudokirchchorniella subcapitata) test according to OECD 201 standard protocol; reference:284:284 Van Ginneken, 1994).
- As demonstrated by transformation/dissolution (T/D) testing according to OECD guidelines, zinc oxide is less soluble, as compared to soluble zinc compounds.

Applying the molecular weight correction and the results of the T/D testing (CSR), the specific reference values for acute aquatic toxicity of zinc oxide are:

For Zinc Oxide: (Based on 62% solubilisation capacity on finest powders at most conservative loading of 1mg/l at pH 8 (RA zinc oxide, ECB 2008):

- for pH <7: 0.67 mg Zn/l (based on 48 hr Ceriodaphnia dubia test cfr. above)
- for pH >7-8.5: 0.21 mg Zn/l (based on 72 hr. Selenastrum capricornutum test cf. above)

M-factor: 1



### 12.1.2 Chronic Aquatic Toxicity (Freshwater):

The chronic aquatic toxicity database on zinc contains high quality chronic NOEC/EC10 values on 23 species (8 taxonomic groups) obtained under a variety of conditions. These data, outlined in the CSR, were compiled in a species sensitivity distribution, from which the PNEC was derived (expressed as Zn<sup>++</sup>ion concentration).

This PNEC is an added value, i.e. it is to be added to the zinc background in water, see table under section 8.

The general reference value for chronic aquatic toxicity due to the Zn<sup>++</sup>ion (relevant for pH >7-8.5) is based on the lowest species NOEC/EC10 value of the chronic aquatic effects database.

The value is a species geomean of 34 NOEC/EC10 values obtained on the standard species *Pseudokirchneriella subcapitata* (unicellular algae) and is expressed as Zn<sup>++</sup>ion concentration: 19 µg Zn/l (Chemical Safety Report Zinc Oxide, 2015).

The reference value for chronic aquatic toxicity at pH 6 was calculated from the same chronic ecotoxicity database for the standard species at each taxonomic level (algae, invertebrates and fish) for which bioavailability models are available.

And by selecting the lowest value of the 3 taxonomic group as follows:

- for algae, the NOEC of the BLM-species *Pseudokirchneriella subcapitata* is the lowest of the SSD at pH 8 (19 µg/l - see above). This value corresponds to a water of pH 8.0, hardness 24 mg CaCO<sub>3</sub> and DOC 2.0 mg/l.

With the BLM a corresponding species NOEC of 142 µg/l was calculated for this species at pH 6 (other water conditions kept the same).

- for invertebrates, the BLM-species *Daphnia magna* gives a species mean at pH 8 of 98 µg/l, corresponding to a water of pH 8, hardness 24 mg CaCO<sub>3</sub>/l and DOC 1.2 mg/l.

The *Daphnia magna* - BLM predicts at pH 6 (other water conditions same) a species NOEC of 82 µg/l

- for *Oncorhynchus Mykiss*, the species mean at pH 8 is 146 µg/l (hardness 45 mg/l, DOC 2mg/l). Using the corresponding fish BLM gives a species NOEC of 146 µg/l at pH 6 (other conditions same).

From this analysis, the reference value for chronic aquatic effect for zinc at pH 6.0 was set at 82 µg Zn/l (*Daphnia magna*) (Chemical Safety Report Zinc Oxide, 2015).

The specific reference values for chronic aquatic toxicity of zinc oxide are calculated by applying the correction for the ZnO/Zn molecular weight ratio ( $81.4/65.4 = 1.25$ ).

Only this molecular weight correction is applied, since no transformation/dissolution data over 28 days testing are available on ZnO (also considering the solubility of Zn in ZnO after 8d, see 12.1.1):

- for pH 6 - <7:  $0.082 \text{ mg Zn/l} \times 1.25 = 102.1 \text{ µg/l}$  (*Pseudokirchneriella subcapitata*)

- for pH >7-8.5:  $0.019 \text{ mg Zn/l} \times 1.25 = 23.8 \text{ µg/l}$  (*Daphnia magna*).

In addition, for determination of the chronic aquatic effects classification according to the 2nd ATP CLP Criteria, it has to be considered further if the substance is rapidly degradable or not.

The concept of "Degradability" was developed for organic substances and is not applicable as such to inorganic substances like zinc.

As a surrogate approach for assessing "degradability", the concept of "removal from the water column" was developed to assess whether or not a given metal ion would remain present in the water column upon addition (and thus be able to exert a chronic effect) or would be rapidly removed from the water column. In this concept, "rapid removal from the water column" (defined as >70% removal within 28 days) is considered as equivalent to "rapidly degradable". The rapid removal of zinc from the water column is documented (Chemical safety report ZnO 2015). Consequently, zinc and zinc compounds are considered as equivalent to being 'rapidly degradable' in the context of classification for chronic aquatic effects.

M-factor: 1

#### **12.1.3 Chronic Aquatic Toxicity Marine Waters:**

The chronic aquatic toxicity database on zinc contains high quality chronic NOEC/EC10 values on 39 species (9 taxonomic groups) obtained under a variety of conditions.

These data, outlined in the CSR, were compiled in a species sensitivity distribution, from which the PNEC was derived (expressed as Zn<sup>++</sup>ion concentration). This PNEC is an added value, to be added on the zinc background in water, see section 8.1.4 of SDS.

#### **12.1.4 Sediment Toxicity:**

The chronic toxicity of zinc to sediment organisms in the freshwater was assessed based on a database containing high quality chronic NOEC/EC10 values on 7 benthic species obtained under a variety of conditions. These data, outlined in the CSR, were compiled in a species sensitivity distribution, from which the PNEC was derived (expressed as total Zn contained in the sediment). This PNEC is an added value, to be added on the zinc background in the sediment, see table below. For the marine sediments, a PNEC was derived using the equilibrium partitioning approach, see section 8.1.4 of SDS.

#### **12.1.5 Soil Toxicity:**

The chronic toxicity of zinc to soil organisms was assessed based on a database containing high quality chronic NOEC/EC10 values on 18 plant species, 8 invertebrate species and 17 microbial processes, obtained under a variety of conditions. These data, outlined in the CSR, were compiled in a species sensitivity distribution, from which the PNEC was derived (expressed as total Zn contained in the soil). This PNEC is an added value, to be added on the zinc background in the soil, see section 8.1.4 of SDS.

#### **12.1.6 Toxicity To Micro-Organisms In STP:**

Extrapolation method: assessment factor Considering that the nitrification inhibition test is most relevant of the data available, the PNEC is derived from the NOEC (100 µg Zn/l ; Juliastuti et al. 2003) divided by AF 1 to give the PNEC-STP of 100µg Zn/l.

#### **12.2 PERSISTENCE AND DEGRADABILITY:**

##### **Biodegradability:**

Zinc is an element, and as such the criterion "persistence" is not relevant for the metal and its inorganic compounds in a way as it is applied to organic substances. An analysis on the removal of zinc from the water column has been presented as a surrogate for persistence. The rapid removal of zinc from the water column is documented in the CSR. So, zinc and zinc compounds do not meet this criterion, neither.

#### **12.3 BIOACCUMULATIVE POTENTIAL:**

Zinc is a natural, essential element, which is needed for the optimal growth and development of all living organisms, including man. All living organisms have homeostasis mechanisms that actively regulate zinc uptake and absorption/excretion from the body; due to this regulation, zinc and zinc compounds do not bioaccumulate or biomagnify.

#### **12.4 MOBILITY IN SOIL:**

For zinc (like for other metals) the transport and distribution over the different environmental compartments e.g. the water (dissolved fraction, fraction bound to suspended matter), soil (fraction bound or complexed to the soil particles, fraction in the soil pore water,...) is described and quantified by the metal partition coefficients between these different fractions. In the CSR, a solids-water partitioning coefficient of 158.5 l/kg (log value 2.2) was applied for zinc in soils (CSR Zinc 2010).

#### **12.5 RESULTS OF PBT and vPvB ASSESSMENT:**

Considering the items 12.2. and 12.3. above, zinc and zinc compounds are not PBT or vPvB.

## 13. DISPOSAL CONSIDERATIONS

### 13.1 WASTE TREATMENT METHODS:

#### Product:

Dispose of in accordance with all applicable local and national regulations. Use recovery/recycling where feasible. Dispose of surplus and non-recyclable products via licensed waste disposal contractor. Waste should not be released into sewer system unless regulations permit such release.

#### Packaging:

Empty containers may contain hazardous residues. Do not cut, puncture or weld on or near to the container. Labels should not be removed from containers until they have been cleaned. Contaminated containers must not be treated as household waste. Containers should be cleaned by appropriate methods. Make sure to follow all local, state, federal and international regulations when disposing of packaging materials.

## 14. TRANSPORT INFORMATION

### 14.1 TRANSPORT ADR/RID/ADN:

UN number (ADR/RID/GGVSE): 3077

UN number (IMDG): 3077

UN number (IATA/ICAO): 3077

### 14.2 TRANSPORT IMDG:

UN number (ADR/RID/GGVSE): ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Zinc Oxide)

UN number (IMDG): ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Zinc Oxide)

UN number (IATA/ICAO): ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Zinc Oxide)

### 14.3 TRANSPORT ICAO-TI/IATA:

UN number (ADR/RID/GGVSE):



Hazard Identification Number: 90

UN number (IMDG):



Sea (IMO): DG, MP

UN number (IATA/ICAO):



IATA Label: Miscellaneous

### 14.4 OTHER INFORMATION:

Packing Group (ADR/RID/GGVSE): III

Packing Group (IMDG): III

Packing Group (IATA/ICAO): III

### 14.5 ENVIRONMENTAL HAZARDS:

ADR/RID/GGVSE: Yes

IMDG: Yes, Dangerous to the environment, marine pollutant.

IATA/ICAO: Yes

### 14.6 SPECIAL PRECAUTIONS FOR USER:

	Classification Code	Hazard Identification Nr.
ADR/RID/GGVSE:	274/335/601	90
IMDG:	274/909/944 M7	
IATA/ICAO:	A97	

### 14.7 TRANSPORT IN BULK ACCORDING TO ANNEXII OF MARPOL AND THE IBC CODE:

Not available

## 15. REGULATORY INFORMATION

### 15.1 SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE:

#### Safety, health and environmental regulations/legislation specific for the substance or mixture:

This MSDS complies with rules of GHS-CLP

### 15.2 CHEMICAL SAFETY ASSESSMENT:

Chemical Safety Report has been carried out.

#### TSCA Equivalent "inventory" regulations:

AICS	Yes
SWISS	Yes
PICCS	Yes
DSL	Yes
NDSL	No
ASIAPAC	Yes
EINECS	Yes

#### U.S. Regulatory Information:

SARA 302	Yes, name listed (Zinc). RQ = None, TPQ = None.
SARA 311/312	Yes, acute hazard, 29CFR1200
SARA 313	Yes, Zn & Pb compounds
TSCA	Yes, on inventory. Compliant with TSCA.

### 15.3 EUROPEAN UNION

EC No. 215-222-5 Environmentally hazardous substance, solid, N.O.S. (Zinc Oxide) UN 3077, Class 9, PG III  
Ingredients listed on the EINECS: Yes, on inventory

### 15.4 REACH GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS (GHS):

#### Environmental Hazards:

Hazardous to the aquatic environment - Acute Hazard - Category 1 (CLP: Aquatic Acute 1)

Hazardous to the aquatic environment - Chronic Hazard - Category 1 (CLP: Aquatic Acute 1)

### 15.5 LABELLING



### 15.6 SIGNAL WORDS

WARNING

### 15.7 HAZARD STATEMENTS

H410: Very toxic to aquatic life with long lasting effects.

### 15.8 PRECAUTIONARY STATEMENTS

- Prevention: P273 Avoid release to the environment.
- Response: P391 Collect spillage
- Disposal: P598 Dispose of contents/container in accordance with local/regional/international regulations

### 15.9 RISK PHRASES R50/53

Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.



DATE : 28/05/20  
Zinc Oxide USP - Non Nano

SHEET 14 of 16

### 15.10 SAFETY PHRASES

S60 - This material and its container must be disposed of as hazardous waste.

S61 - Avoid release to the environment. Refer to special instructions / Safety Data Sheets.

### 16. OTHER INFORMATION

This safety data sheet is prepared in accordance with Commission Regulation (EU) No. 1907/2006 (REACH), 1272/2008 (CLP) as amended, EC Directives 2000/39/EC, 2006/15/EC, 2009/161/EU.

IU Number	Identified Use (IU) name	GES Code
1	Zinc oxide production-Direct	GESZnO 0
2	Zinc oxide production-Indirect	GESZnO 0
3	Zinc oxide production-Wet	GESZnO 0
9	Component for production of inorganic zinc compounds.	GESZnO 2
10	Electro galvanizing	GESZnO 2
11	Electroplating	GESZnO 2
12	Zinc production by electrowinning	GESZnO 2
13	Laboratory reagent	GESZnO 3
14	Zinc production by pyrometallurgy	GESZnO 2
15	Zinc oxide production & refining	GESZnO 0
16	Component for production of organic zinc compounds	
17	Component for production of inorganic pigments	GESZNO 1, GESZnO 4
18	Component for production of Coatings / paints, inks, enamels, varnishes.	GESZNO 1, GESZnO 4
19	Use of ZnO-containing paints of coatings,	GES ZnO 7
20	Artists supply: Use of ZnO-containing paints & coatings.	Generic consumer/environment
21	Component for Paper coatings.	GESZnO 1, GESZnO 5
22	Use of ZnO-containing paper coatings.	GESZnO 6
23	Component for Textile & leather coating / treatment	GESZnO 1, GESZnO 5
24	Use of ZnO- containing textile and leather coatings.	GESZnO 6
25	Additive / component for production of ceramics.	GESZnO 1, GESZnO 4
26	Additive / component for production of frits	GESZnO 1, GESZnO 4
27	Use of ZnO-containing glazes and glassy thin film coatings.	GESZnO 6
28	Additive for the production of friction agents.	GESZnO 1, GESZnO 4
29	Use of ZnO-containing friction agents: Brake pads.	GESZnO 6
30	Additive / component for production of glass	GESZnO 1, GESZnO 4
31	Surface treatment of flat glass	GESZnO 1, GESZnO 4
32	Use of ZnO-containing glass & ceramics in dinnerware	GESZnO 6
33	Use of ZnO-containing glass in displays.	GESZnO 6
34	Use of ZnO-containing glassy thin film coatings.	GESZnO 6
35	Additive in the manufacturing of electronic components	GESZnO 1, GESZnO 4
36	Additive in the manufacturing of ferrites	GESZnO 1, GESZnO 4

37	Additive in the manufacturing of varistors	GESZnO 1, GESZnO 4
38	ZnO in electrotechnical contact material.	GESZnO 1, GESZnO 4
39	Batteries/ fuel cells.	GESZnO 1, GESZnO 4, GESZnO 5
40	Component for production of rubber, resins and related preparations.	GESZnO 1, GESZnO 5
41	Use of ZnO-containing rubber for tyres	GESZnO 7
42	Use of ZnO-containing rubber and other resins for medical devices and	GESZnO 7
43	Component for polymer-matrices, plastics and related preparations	GESZnO 1, GESZnO 5
44	Use of ZnO-containing polymers for floor, wall coverings and similar preparations.	GESZnO 7
45	Use of ZnO-containing polymers for cable protecting and isolating coatings.	GESZnO 7
46	Use of ZnO-containing polymers for tube and sheet articles	GESZnO 7
47	Use of ZnO-containing polymers for molded articles	GESZnO 7
48	Use of ZnO-containing plastic thin films coatings.	Generic consumer/environment
49	Additive for the production of Sealants/ Adhesives / Mastics	GESZnO 1, GESZnO 5
50	Use of ZnO-containing Sealants / Adhesives / Mastics	Generic consumer/environment
51	Additive for the production of Lubricants / Grease / Metal working fluids	GESZnO 1, GESZnO 5
52	Use of ZnO-containing Lubricants / Grease / Metal working fluids	Generic consumer/environment
53	Additive for the production of Polishes / wax blends.	GESZnO 1, GESZnO 5
54	Use of ZnO-containing Polishes / wax blends.	Generic consumer/environment
55	Use of ZnO-containing catalysts.	GESZnO 1, GESZnO 5
56	Use of ZnO-containing absorbents	GESZnO 1, GESZnO 5
57	Additive for production of de-icing products	GESZnO 1, GESZnO 5
58	Use of ZnO-containing de-icing products	Generic consumer/environment
59	Additive for the production of pyrotechnic products.	GESZnO 1, GESZnO 4
60	Use of ZnO-containing pyrotechnic products	Generic consumer/environment
61	Additive for the formulation of nutrition additives	GESZnO 1, GESZnO 4, GESZnO 5
62	Additive for the formulation of animal feedstuffs	GESZnO 1, GESZnO 4, GESZnO 5
63	Additive for the formulation of biocidal products.	GESZnO 1, GESZnO 4, GESZnO 5
64	Use of ZnO-containing biocidal products	GESZnO 6, GESZnO 7, Generic Consumer/environment
65	Additive for the formulation of cleaning products.	GESZnO 1, GESZnO 4, GESZnO 5
66	Use of ZnO-containing cleaning products	GESZnO 6, GESZnO 7, Generic Consumer/environment
67	Additive for the formulation of fertilizers.	GESZnO 1, GESZnO 4, GESZnO 5
68	Use of ZnO-containing fertilizer's formulations.	Generic consumer/environment



DATE : 28/05/20  
Zinc Oxide USP - Non Nano

SHEET 16 of 16

69	Additive in the formulation of cosmetics	GESZnO 1, GESZnO 4, GESZnO 5
70	Use of cosmetics.	GESZnO 6, GESZnO 7, Generic Consumer/environment
71	Additive in dentistry products.	GESZnO 1, GESZnO 4, GESZnO 5
72	Additive in the formulation of pharma / veterinary products.	GESZnO 1, GESZnO 4, GESZnO 5
73	Use of pharma / veterinary products.	GESZnO 6, GESZnO 7, Generic Consumer/environment

**Legal disclaimer:**

The information provided in this safety data sheet is correct to the best of our knowledge at the time of publication. It is given in good faith but no warranty is implied with respect to the quality and specification of the product. The information given only describes the products with regard to safety arrangements and is not to be considered as a warranty or quality specification and does not constitute a legal relationship. The information contained in this Safety Data Sheet relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

The customer must satisfy themselves that the product is entirely suitable for their own purposes.

Although certain hazards may be described we cannot predict that these are the only hazards, or combination of hazards, that may exist in a workplace. This MSDS, therefore, forms a component only of a risk assessment carried out by, or on behalf of, the user.



## Zinc Oxide USP - Non Nano

### Technical Data

Description: White fine powder  
Method: French method starting with Zinc SHG.  
Formula: ZnO  
CAS No.: 1314-13-2  
EINECS: 215-222-5

### Chemical Properties (Typical)

ELEMENTS	TYPICAL (%)	REFERENCE METHOD
ZnO	99,9 Min	USP 40
Total impurities	0,1 Max	ASTM D4075
Pb (including PbO)	0,002 Max	ASTM D4075
Cd	0.001 Max	ASTM D4075
Fe	0.0005 Max	ASTM D4075
Cu	0.0002 Max	ASTM D4075
Cl	0.0005 Max	ASTM D4075
S	0.001 Max	ASTM D4075
Mn	0,0001 Max	ASTM D4075
As	0,0001 Max	USP 40
Ni	0,0001 Max	ASTM D4075

### Physical Properties (Typical)

DESCRIPTION	RESULTS	REFERENCE METHOD
325 Mesh (45 µm)	99.9%	ASTM D4315
Loss of Ignition (500°C)	0.2% Max	USP 40
Water Insolubles	0.1% Max	ASTM D3280
Insolubility in HCl	0.001% Max	ASTM D3280
Specific Gravity	53.5 – 5.7 g/cm <sup>3</sup>	ASTM D854
Humidity at 110°C	0.2% Max	ASTM D280
Specific Surface Area	4 – 9 m <sup>2</sup> /g	ASTM D4315
Average Particle Size	0.8 µm Max.	Laser Diffraction
pH	6.8 – 7.5	Potentiometer





**The content of this data sheet is given in good faith and without warranty.**

**MADAR Corporation Limited makes the limited warranty that at the date of delivery this product will be free from defects in materials and workmanship.**

**No warranty of merchantability, fitness for any use, or any other warranty is expressed or to be implied, regarding the accuracy of this data. The results to be obtained from the use thereof, or the hazards connected with the use of this product.**

**MADAR Corporation Limited assumes no liability for any alleged ineffectiveness of the product or any injury or damage, direct or consequential, resulting from the use of this product unless such injury or damage is solely attributable to negligence on the part of MADAR Corporation Limited.**

Issue 12.02.21



## DECLARATION AND CONFORMITY VEGAN INGREDIENT STATEMENT

**Product: Zinc Oxide USP - Non Nano**

MADAR Corporation Limited declare that the raw materials listed below may be considered vegan according to the following definitions:

- 1) It does not contain any ingredient of animal origin, including: any meat such as beef, pork, lamb, fish, marine animals, poultry and all other animal species; substances from parts of animals or their sequestrations; milk, cheese or other dairy products; substances derived from dairy products; eggs; honey; substances derived from honey or bees or any other insect; carmine dye (from cochineal); casein of animal origin; glycerin of animal origin; lactose; animal skins or animal skins or parts thereof; animal collagen; silk; bones; cartilage; clarifiers of animal origin; or any colorant, stabilizer, preservative, emulsifier, sweetener or other ingredient having animal, vertebrate or invertebrate origin;
- 2) During the development of which no animal, vertebrate or invertebrate, has been used in toxicity tests or any other test or experimentation;
- 3) During the manufacturing process, no ingredient, product or by-product of animal origin has been used, even if it is absent from the finished product;
- 4) It may be ensured that during the development of the ingredients, inputs and substances present in the composition and / or used in the manufacture of the product, no vertebrate or invertebrate animal has been used in toxicity testing or any other test or experimentation.
- 5) Due to the fact that the material is an inorganic substance, it is confirmed that it does not contain any nutritional value (energetic value, carbohydrates, sugars, proteins, fats, saturated fatty acids, sodium).

Issue 19.02.21