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# ZINC OXIDE SAFETY DATA SHEET

This SDS Compliant for use in **European Union member countries only**. This SDS is not valid outside EU /EEA.  
REACH Number: 01-2119463881-32-0065 (ZC ULC, >1000 tpy); 17-2120064320-70-0000 (ZC LLC US).

## Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier: ZINC OXIDE

Product Code: This SDS is valid for all zinc oxide product codes or grades

Synonyms: ZINKOXID, OXYDE DE ZINC, OSSIDO DI ZINCO, ZINKOXIDE,  
OXIDO DEL CINC, TLENED CYNKU

1.2 Relevant identified uses of the substance/mixture and uses advised against:

Common uses include:

- Rubber compound
- Coloring agents, pigments
- Food/feedstuff additives
- Fuels and fuel additives
- Intermediates
- Laboratory chemicals
- Lubricants and lubricant additives
- Plating agents and metal surface treating agents
- Process regulators, other than polymerization or vulcanization processes
- Component in batteries
- Corrosion inhibitors and anti-scaling agents
- Fertilizers
- Pharmaceutical substance
- Photosensitive agents and other photo-chemicals
- Process regulators, used in vulcanization or polymerization processes
- Processing aid, not otherwise listed
- Semiconductors

A complete list of uses for with Generic Exposure Scenarios (GES) were prepared is provided in the extended SDS GES table.

No uses advised against

### 1.3 Details of the supplier of the safety data sheet:

Supplier of the Safety Data Sheet:

REACH Only Representative (OR): ROR Ltd, U.K., +44(0) 1565 724241, email: [alerts@RORltd.com](mailto:alerts@RORltd.com).

REACH Number: 01-2119463881-32-0065 (Zochem ULC Canada, >1000 tpy);

REACH (Pre) Registration Number 17-2120064320-70-0000 (Zochem LLC USA, valid for tonnage band until 31May2018).

For additional information contact:

Zochem (Website: [Zochem.com](http://Zochem.com))

600 Printwood Drive, Dickson, TN 37055-3010 U.S.A., Phone: +1 615 446-8791

Attention: John Stourac, Director – Technical, ES&H, mobile +1 312-813-4620

1.4 Emergency telephone number: +44(0) 1565 724241, +1 312-813-4620

## Section 2: HAZARD IDENTIFICATION

### 2.1 Classification of the substance or mixture:

Classification according to Regulation (EC) No 1272/2008 (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 Labelling according to Regulation (EC) No 1272/2008 (CLP/GHS) in EEA member countries:

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

Signal word: Warning. Hazard pictogram: GHS09 environment



Precautionary: P273: Avoid release to the environment. P391: Collect spillage.

P501: Dispose of contents/container as hazardous or special waste in accordance with local law.

Note, "Preparations" containing 25% or greater zinc oxide, under EU law, will also need to be classified as "Dangerous for the Environment."

Preparations or mixtures containing less than 25% zinc oxide are not regulated.

2.3 Other hazards: None.

## Section 3: COMPOSITION/INFORMATION ON INGREDIENTS AND IMPURITIES

| <u>3.1 Constituent/Ingredient</u> | <u>Range</u> | <u>CAS no.</u> | <u>EC/EINECS</u> | <u>Other</u> |
|-----------------------------------|--------------|----------------|------------------|--------------|
| Zinc Oxide (ZnO)                  | 100%         | 1314-13-2      | 215-222-5        |              |

### 3.2 Additional information of impurities:

Other naturally occurring impurities below SDS threshold limits.

Product may contain processing aid coating/treatment additive/propionic acid at customer request.

After manufacturing during material handling & storage, product degrades with exposure to air acquiring some moisture and zinc carbonate (ZnCO<sub>3</sub>) & carbonate.

#### Section 4: FIRST AID MEASURES

##### 4.1 Description of first aid measures:

In case of skin contact: Wash with soap and water.

In case of eye contact: Rinse with plenty of water and seek medical advice.

In case of Ingestion: Drink plenty of water; do not induce vomiting; call a physician.

In case of Inhalation: Move to fresh air. Keep warm and at rest.

##### 4.2 Most important symptoms and effects, both acute and delayed:

Acute: Dry cough, headache. Chronic: None (overexposure has no lasting effects).

##### 4.3 Indication of any immediate medical attention and special treatment needed:

Bad cough or headache. Move person to fresh air. No special treatment known.

Excess dust must naturally purge or absorb.

#### Section 5: FIRE-FIGHTING MEASURES

##### 5.1 Extinguishing media: None. Zinc oxide will not burn.

Use extinguishing media appropriate for the surrounding fire.

##### 5.2 Special hazards: None. Hazardous decomposition product(s): None.

##### 5.3 Advise for firefighters: Avoid release of fire control water containing zinc oxide to the environment.

#### Section 6: ACCIDENTAL RELEASE MEASURES

##### 6.1 Personal precautions, protective equipment and emergency procedures:

Wear protective clothing, dust respirator, and goggles in bulk excess dust conditions.

Shovel up spills into appropriate labeled container.

Dry spills, not mixed with other chemicals, may be recyclable. Contact Zinc Oxide LLC.

##### 6.2 Environmental precautions:

Avoid release to the environment.

##### 6.3 Methods and material for containment and cleaning up:

Recover the product by vacuum. Use a damp cloth for small area.

Avoid sweeping to reduce creation of airborne dust.

#### Section 7: HANDLING AND STORAGE

##### 7.1 Precautions for safe handling:

Wear protective clothing, dust respirator, and goggles in bulk excess dust conditions.

##### 7.2 Conditions for safe storage, including any incompatibilities: Keep dry.

## Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control parameters

| Country/organisation | 8 hour-TWA  | 15 min-STEL mg/m <sup>3</sup>  |
|----------------------|---|--|
| Germany (MAK)        | 5 mg/m <sup>3</sup> (fumes)<br>6 mg/m <sup>3</sup> (dust)   | Einatembarer Staub (Dust) = 10 mg/m <sup>3</sup><br>Alveolengängiger Staub = 3 mg/m <sup>3</sup>             |
| France (INRS)        | 5 mg/m <sup>3</sup> (fume)<br>10 mg/m <sup>3</sup> (dust)   |  |
| UK (OEL)             | 5 mg/m <sup>3</sup> (fumes)<br>10 mg/m <sup>3</sup> (dust)  | TWA – 8 hour: 5 mg/m <sup>3</sup> (nuisance dust)<br>STEL – 15 minutes: 10 mg/m <sup>3</sup> (nuisance dust) |
| The Netherlands      | 5 mg/m <sup>3</sup> (fumes)   |  |
| Sweden               | 5 mg/m <sup>3</sup> (fumes)   |  |
| Denmark              | 4 mg/m <sup>3</sup> (fumes)<br>10 (dust)  |  |
| USA (Zinc Oxide)     | 5 mg/m <sup>3</sup> (fumes)<br>15 mg/m <sup>3</sup> (dust; total)<br>5 mg/m <sup>3</sup> (dust; respirable) |  |
| USA (Lead)           | 5 ug/m <sup>3</sup>   |  |
| USA (Cadmium)        | 5 ug/m <sup>3</sup>   |  |

#### DNELs: **Workers**

Inhalation, systemic effects, long term: 5mg Zn/m<sup>3</sup>

Inhalation, local effects, long term: 0.4 mg Zn/m<sup>3</sup> (respirable fraction) (Creutzenberg O., 2013).

Dermal, systemic effects, long term: 83 mg Zn/kg bw/day

#### **General population**

Inhalation, systemic effects, long term: 2.5mg Zn/m<sup>3</sup>

Dermal, systemic effects, long term: 83 mg Zn/kg bw/day

Oral, systemic effects, long term: 0.83 Zn/kg bw/day

#### PNECs derived for the zinc ion:

| Compartment (Environment) | PNEC value for Zn ion (*added value)   |
|---------------------------|--|
| Freshwater                | 20.6* µg/L   |
| Saltwater                 | 6.1* µg/L  |
| STP                       | 100 µg/L   |
| Freshwater sediment       | 117.8* mg/kg sediment d.w.<br>A generic bioavailability factor of 0.5 is applied by default: PNEC <sub>bioav</sub> : 235.6 mg/kg sediment d.w. |
| Saltwater sediment        | 56.5* mg/kg sediment d.w.<br>A generic bioavailability factor of 0.5 is applied by default: PNEC <sub>bioav</sub> : 113 mg/kg sediment d.w.    |
| Soil                      | 35.6* mg/kg soil d.w.<br>A generic bioavailability/ageing factor of 3 is applied by default: PNEC <sub>bioav</sub> : 106.8 mg/kg soil d.w.     |
| Oral                      | No potential for bioaccumulation   |

## 8.2 Exposure controls/Personal protection:

Route(s) Of Entry: 1. Inhalation. 2. Dermal. 3. Eyes. 4. Digestion.  
Eye protection: Recommend safety glasses in bulk excess dust conditions.  
Protection for skin: Recommend long sleeves in bulk excess dust conditions.  
Protection for hands: Recommend gloves to reduce drying of skin  
Respiratory protection: Recommend dust filter mask in bulk dust conditions.  
(Must wear respirator of proper type if exposure above 8 hour TWA)

### 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 with potential dust and fumes generation.  
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 to minimize dust emissions.  
Good general housekeeping and maintenance practices.

Organizational measures to prevent /limit releases, dispersion and exposure:

Management system (i.e. ISO9001 or OSHAS18000) for good work, training, cleaning, PPE and hygiene practices.

### 8.2.3. Environmental exposure control

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

Process enclosures and closed circuits where relevant and possible.  
Local exhaust ventilation with potential dust generation, dust capturing and removal techniques  
Containment of liquid volumes in sumps to collect/prevent accidental spillage.

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

On-site waste water treatment techniques.  
Containment of liquid volumes in sumps to collect/prevent accidental spillage  
Air emissions are controlled by use of bag-house filters or other air emission abatement devices.

Organizational measures to prevent/limit release from site:

Management system (i.e. ISO9001 or OSHAS18000) for good work, training, cleaning, PPE and hygiene practices.  
SEVESO 2 compliance, if applicable

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

|  |   |
|--|---|
| Appearance at 20°C and 1013 hPa:       | Solid, powder or pellet/granular  |
| Odor / smell:                          | Odorless.   |
| Odor threshold:                        | Not applicable.   |
| Color:                                 | White, off white, cream, grayish, or yellowish.   |
| pH:                                    | Neutral, 6.8 to 8 (7.37 nominal)  |
| Melting / Freezing point:              | Will not freeze. Will not melt.<br>Malleable above 300C/572F<br>No exothermic or endothermic peaks are observed.<br>No oxidation or decomposition was observed.<br>Sublimation temperature 1975C. |
| Boiling point:                         | Not applicable; the substance decomposes before boiling.  |
| Flash point:                           | Not applicable to inorganic substances.   |
| Evaporation rate:                      | Not applicable to solids  |
| Flammability:                          | Not flammable. Will not burn.   |
| Auto-ignition temperature:             | The substance is not auto-flammable.  |
| Upper / lower flammability limits:     | Not applicable.   |
| Upper / lower explosive limits:        | Not applicable.   |
| Vapour pressure:                       | Not applicable (melting point above 300°C).   |
| Vapour density:                        | Not applicable.   |
| Relative density/Specific Gravity:     | 5.68 g/cm <sup>3</sup> .  |
| Water solubility:                      | Negligible (solubility of Zn in ZnO is 2.9 mg/l).   |
| Soluble:                               | In bases and acids  |
| Partition coefficient n-octanol-water: | Not applicable to inorganic substance.  |
| Decomposition temperature:             | Not applicable.   |
| Viscosity:                             | Not applicable.   |
| Explosive properties:                  | Zinc oxide has no flammability, explosive or self-flammability properties   |
| Granulometry:                          | D50 1.05 µm, D80 <20 µm   |
| Molecular Weight:                      | 81.38 (ZnO)   |

## Section 10. STABILITY AND REACTIVITY

|  |   |
|--|---|
| 10.1 Reactivity:                         | Stable under normal dry air conditions.                   |
| 10.2 Chemical stability:                 | Product is stable.  |
| 10.3 Possibility of hazardous reactions: | None.   |
| 10.4 Conditions to avoid:                | Keep from getting wet (will damage substance usefulness). |
| 10.5 Incompatible materials:             | Heated magnesium. Chlorinated rubber above 215C.          |
| 10.6 Hazardous decomposition:            | None.   |
| 10.6.1 Decomposition:                    | Product decomposes in acids and bases.                    |
| 10.6.2 Degradation:                      | Slow degrade to zinc carbonate (not hazardous).*          |

\*ZnO + CO<sub>2</sub> in ambient air -> ZnCO<sub>3</sub> zinc carbonate. Rate accelerated with higher m<sup>2</sup>/g surface area or damp storage conditions. Shelf life: One year from date of manufacturing for rubber applications (due to potential hard particulate dispersion problems from ZnCO<sub>3</sub> hard particulate formation), one year for 8-10 surface area grades, and eighteen months for EP, USP, and non-rubber applications.

## Section 11. TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects for zinc oxide:

#### Acute toxicity:\*

| Result                             | Species | Dose        | Exposure | Refs                          |
|------------------------------------|---------|-------------|----------|-------------------------------|
| LC50 Inhalation<br>Dusts and mists | Rat     | >5.7 mg/L   | 4 hours  | Klimisch and Freisberg (1982) |
| LD50 Oral                          | Rat     | 15000 mg/kg | NA       | Löser (1972)                  |
| LD50 Oral                          | Rat     | >5000 mg/kg | NA       | Löser (1977)                  |

\*With LD<sub>50</sub> values consistently exceeding 2,000 mg/kg bw, slightly soluble compounds such as, zinc oxide (LD<sub>50</sub> ranges between 5,000 and 15,000mg/kg bw) show low level of acute oral toxicity, not leading to classification for acute oral toxicity. Zinc oxide is shown to be of low acute inhalation toxicity (i.e., LC50 values of > 5.7 mg/L/4hrs), not leading to classification for acute inhalation toxicity.

Route(s) Of Entry: 1. Inhalation. 2. Dermal. 3. Eyes. 4. Digestion.

#### Irritation/Corrosion:

Skin: Not irritant (rabbit; Löser, 1977; Lansdown, 1991)  
Eye: Not irritant (rabbit; Van Huygevoort, 1999e; Thijssen, 1978; Löser, 1977)  
Respiratory tract: Not irritant (Klimi-sh et al, 1982)  
Ingestion: None (zinc oxide is used as a human vitamin supplement).

Sensitization: No sensitizing effects known (Van Huygevoort, 1999 g, h)

Germ cell mutagenicity: No biologically relevant genotoxic activity. (Based on cross-reading between Zn compounds; no classification for mutagenicity required) (Chemical Safety report (CSR) ZnO 2015).

Carcinogenicity: Not a NTP/IARC carcinogen.

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)

Reproductive toxicity: No evidence of reproduction toxicity.

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)

Specific target organ toxicity (single exposure):

No experimental or epidemiological sufficient evidence for specific target organ toxicity (single exposure) (no classification for target organ toxicity (single exposure: STOT-SE) required) (Heydon and Kagan, 1990; Gordon *et al.*, 1992; Mueller and Seger, 1985 [Cited in CSR zinc oxide. 2015]).

Specific target organ toxicity:

Specific target organ toxicity (repeated exposure): None. (Lam et al, 1985, 1988; Conner et al. 1988).

Specific target organ toxicity (single exposure): None. (Heydon and Kagan, 1990; Gordon et al., 1992; Mueller and Seger, 1985).

No experimental or epidemiological sufficient evidence for specific target organ toxicity (repeated exposure) (no classification for specific target organ toxicity (repeated exposure: STOT-RE) required) (Lam et al, 1985, 1988; Conner et al., 1988, Ma Hock, 2014, Creutzenberg, 2013 [CSR ZnO 2015])).

## Section 12: ECOLOGICAL INFORMATION

### 12.1 Toxicity

| Substance  | Result                           | Species | Dose        | Exposure | Reference(s)                     |
|------------|----------------------------------|---------|-------------|----------|----------------------------------|
| Zinc oxide | LC50 Inhalation<br>Dusts & mists | Rat     | >5.7 mg/L   | 4 hours  | Klimisch and<br>Freisberg (1982) |
| Zinc Oxide | LD50 Oral                        | Rat     | 15000 mg/kg | NA       | Löser (1972)                     |
| Zinc Oxide | LD50 Oral                        | Rat     | >5000 mg/kg | NA       | Löser (1972)                     |

Zinc oxide is not an acute oral or acute inhalation toxic.

#### 12.1.1. Acute aquatic toxicity

Acute EC50 0.413 mg/l Zn, 48 hour – Ceriodaphnia dubia  
Acute LC50 0.136 mg/l Zn, 72 hour – Selenastrum capricornutum

62% solubilization capacity at 1 mg/l at pH 8:

for pH <7: 0.67 mg Zn/l (48 hr Ceriodaphnia dubia test cfr. above).

for pH >7-8.5: 0.21 mg Zn/l (72 hr Selenastrum capricornutum test cf. above)

12.1.2. Chronic aquatic toxicity: freshwater – 20.6 PNEC value for Zn ion, algae reduced reproductive

12.1.3. Chronic aquatic toxicity: marine waters - 6.1\* µg/L PNEC value for Zn ion

12.1.4. Sediment toxicity: freshwater - 117.8\* mg/kg sediment d.w. PNEC value for Zn ion. A generic bioavailability factor of 0.5 is applied by default: PNEC<sub>bioav</sub>: 235.6 mg/kg sediment d.w.

12.1.4.1 Sediment toxicity: saltwater - 6.1\* µg/L PNEC value for Zn ion. A generic bioavailability factor of 0.5 is applied by default: PNEC<sub>bioav</sub>: 113 mg/kg sediment d.w.

12.1.5. Soil toxicity - 35.6\* mg/kg soil d.w. PNEC value for Zn ion. A generic bioavailability/ageing factor of 3 is applied by default: PNEC<sub>bioav</sub>: 106.8 mg/kg soil d.w.

12.1.6. Toxicity to micro-organisms in STP - 100µg Zn/l PNEC value.

12.2. Persistence and biodegradability – Not Applicable (zinc is an element).

12.3. Bioaccumulative potential – Not Applicable (ZnO does not bioaccumulate or biomagnify).

Zinc is a natural essential element necessary for 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 soils – Not Applicable.

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 – Not Applicable (zinc oxide is not PBT or vPvB)

12.6 Other adverse effects – None.



### 13. DISPOSAL CONSIDERATIONS

#### 13.1 Waste treatment methods

This material may be a special or hazardous waste for regulated metals.

Empty packaging may also be regulated in EEA member countries.




To prevent water pollution, do not open release.

Recyclable: Waste material not co-mingled with other substances may be recyclable.

Contact Zochem for further information

### Section 14. TRANSPORT INFORMATION

Table for transportation information within the EEA: (European Economic Area).

|                                    | ADR/RID   | IMDG  | IATA  |
|------------------------------------|---|---|---|
| 14.1 UN number                     | UN3077  | UN3077  | UN3077  |
| 14.2 UN proper shipping name       | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Zinc Oxide)                         | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Zinc Oxide), Marine pollutant (Zinc oxide)  | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Zinc Oxide)                           |
| 14.3 Transport hazard Classes(es)  | 9<br> | 9<br>   | 9<br> |
|                                    | Hazard identification number: 90  | Sea (IMO): not regulated  | IATA Label: Miscellaneous   |
| 14.4 Packing group                 | III   | III   | III   |
| 14.5 Environmental hazards         | Yes   | Yes, Dangerous to the Environment   | Yes   |
| 14.6 Special precautions for users | No  | No  | Yes (see below)   |
| Additional information             | Tunnel code (E)   | none  |   |
| IATA special precautions for users |   | IATA-Passenger Aircraft: 400 kg (packing group 956),<br>IATA –Passenger Aircraft: 30 kg (packing group Y956)<br>IATA-Cargo Aircraft: 400 kg (packing group 956)<br>IATA-S.P.: A97, A158, A179 |   |

This material is not transportation regulated in the U.S.A.

### Section 15. REGULATORY INFORMATION

15.1 This SDS complies with REACH (EC 1907/2006) and USOSHA 29CFR1910.1200 SDS regulations, and GHS/CLP (Classification, Labelling and Packaging Regulation No. EC 1272/2008).

15.2 A Chemical Safety Assessment has been completed for this substance.

15.3 Nano: This product is not nano (over 50% of substance particles by number are over 100 nm size).

15.4 Labeling Signal Word: WARNING. See SDS Section 2 (labeling) for additional information.

15.4 SVHC: Zinc oxide is not an SVHC. Impurities are below SVHC or candidate SVHC thresholds. (SVHC list date 16January2016).

15.5 REACH: 17-2120064320-70-0000 REACH Pre-Registration valid for tonnage band till 1June2018.  
OR: ROR Ltd, U.K., +44(0) 1565 724241, email: [alerts@RORLtd.com](mailto:alerts@RORLtd.com).

#### 15.6 Inventory/Lists.

TSCA (U.S.): Yes, listed, notification not required.

DSL (Canada): Yes, listed. NDSL: (Canada): No, not listed, notification not required.

EINECS (Europe): Yes, on Inventory. ELINCS (Europe): No, notification/reporting not required.

Yes, listed on the following lists: ASIA-PAC, SWISS, PICCS (Philippines), ENCS (Japan),  
AICS (Australia), KECI (Korea), ICESC (China), New Zealand, Taiwan.

#### 15.7 U.S. Regulations:

Transportation: Not transport regulated in the U.S. (USDOT 49CFR172), Canada, or Mexico.  
HS Tarriff Class #: 2817.00.0000, preference B

SARA 302: Name listed (zinc). RQ=None, TPQ=None.

SARA 312: Yes, acute hazard, EPCRA Tier 2 must be filed with state and local agencies.

SARA 313: Yes, TRI on Form R must be filed for Zn & Pb Compounds if usage above threshold.

CA Prop. 65: No, ZnO is not a Prop 65 listed substance. Impurities Pb & Cd listed.

CAA 112, 61 HAP: No, not regulated, no Hazardous Air Pollutants (HAP's)

FIFRA 152 et seq.: No, product is not subject to FIFRA registration.

CERCLA 102/103: Zinc is on Name List, RQ=None.

CONEG: Compliant.

ODS/ODC 82: No ozone depleting substances.

USFDA: Approved by FDA. Substance is listed as GRAS at 21CFR182.8991 (GRAS=Generally Recognized as Safe) and may be used in any FDA regulation where use of a GRAS substances is authorized including an ingredient in food and in food contact in rubber articles at 21CFR177.2600(c)(1); Food can linings and coatings at 21CFR175.300(b)(2), and Plastics at 21CFR170.30(d).

### Section 16. OTHER INFORMATION

#### 16.1 HMIS Hazard Rating (Paint and Coating Industry)

Health 1 (slight)

Flammability 0

Reactivity 0

Personal Protection E (mask, gloves, and goggles are recommended in bulk dust conditions)

16.2 This SDS provides information to work safety with ZnO substance. It is not a performance or property guarantee. The information is believed accurate utilizing reasonably available published data. We are not responsible for any inadvertent error or omission.

## **Extended SDS Zinc Oxide**

*Effective 20December2017*

### **Extended SDS Contents:**

- A. Identified uses for ZnO and corresponding Generic Exposure Scenario (GES) table
- B. Additional SDS Section 12 Ecological references.
- C. Additional citation references.
- D. Signal word, H and P phrases in multiple languages.

### **A. Table: Identified uses for ZnO and corresponding Generic Exposure Scenario (GES)**

| IU number | Identified Use (IU) name  | GES code                      |
|-----------|---|-------------------------------|
| 2         | Zinc oxide production-Indirect  | GESZnO 0                      |
| 9         | Component for production of inorganic zinc compounds                    | GESZnO 2                      |
| 10        | Electrogalvanizing  | 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                      |
| 16        | Component for production of organic zinc compounds                      | GESZnO 2                      |
| 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 & coatings                                 | GESZnO 7                      |
| 20        | Artists supply: Use of ZnO-containing paints & coatings                 | Generic consumer/environment* |
| 21        | Component for Paper coating   | 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 & 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 tires (tyres)                                     | GESZnO 7   |
| 42 | Use of ZnO-containing rubber and other resins for medical devices and applications | 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 & isolating coatings           | GESZnO 7   |
| 46 | Use of ZnO-containing polymers for tube & 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 adsorbents   | 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                     |
| 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 |

\* corresponds to "GES 8" in IUCLID

## **B. Additional Ecological Reference Information for SDS Section 12 – Ecological.**

Note: there is extensive data available on the eco-toxicity of zinc and zinc compounds. The hazard of zinc and zinc compounds is determined by the Zn<sup>++</sup> ion and the capacity of the zinc ion to be released from the substances. Therefore the ecotoxicity databases on different zinc substances can be cross-read, while taking into account solubility of the specific substances. The extensive database on aquatic toxicity of zinc has been presented and discussed in the CSR. In the e-SDS, only the outcome of the analyses is reported, and only the data that define the classification for aquatic toxicity are given.

### 12.1 Acute toxicity

| <u>Product/Ingredient Name</u> | <u>Result</u>                    | <u>Species</u> | <u>Dose</u> | <u>Exposure</u> | <u>Reference(s)</u>           |
|--------------------------------|----------------------------------|----------------|-------------|-----------------|-------------------------------|
| Zinc oxide                     | LC50 Inhalation<br>Dusts & mists | Rat            | >5.7 mg/L   | 4 hours         | Klimisch and Freisberg (1982) |
| Zinc Oxide                     | LD50 Oral                        | Rat            | 15000 mg/kg | NA              | Löser (1972)                  |
| Zinc Oxide                     | LD50 Oral                        | Rat            | >5000 mg/kg | NA              | Löser (1972)                  |

With LD<sub>50</sub> values consistently exceeding 2,000 mg/kg bw, slightly soluble compounds such as, zinc oxide (LD<sub>50</sub> ranges between 5,000 and 15,000mg/kg bw) show low level of acute oral toxicity, not leading to classification for acute oral toxicity

Zinc oxide is shown to be of low acute inhalation toxicity (i.e., LC50 values of > 5.7 mg/L/4hrs), not leading to classification for acute inhalation toxicity

#### 12.1.1. Acute aquatic toxicity

The Acute aquatic toxicity database on zinc contains data on 11 standard species obtained under standard 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 data is 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* (=Pseudokirchneriella subcapitata) test according to OECD 201 standard protocol; reference: 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 1 mg/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: 19µg 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 groups 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 2 mg/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 82µg 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 28days 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 2<sup>nd</sup> 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.

Acute EC50 0.413 mg/l Zn, 48 hour – Ceriodaphnia dubia

Acute LC50 0.136 mg/l Zn, 72 hour – Selenastrum capricornutum

62% solubilisation capacity at 1 mg/l at pH 8:

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)

### 12.2. Persistence and biodegradability – Not Applicable (zinc is an element)

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 – Not Applicable (zinc oxide does not bioaccumulate or biomagnify)

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 soils – Not Applicable

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 – Not Applicable (zinc oxide is not PBT or vPvB)

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

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#### **D. Signal Word, H and P Phrases in additional languages.**

DE Deutsch (German).

Substance name: ZINKOXID.

Signalwort: Achtung.

H410: Sehr giftig für Wasserorganismen mit langfristiger Wirkung.

P273: Freisetzung in die Umwelt vermeiden.

P391: Verschüttete Mengen aufnehmen.

P501: Diesen Stoff und seine(n) Behälter entsprechend geltendem Recht der Problemabfallentsorgung zuführen.

FR Français.

Substance name: OXYDE DE ZINC.

Signalword (Mention d'avertissement): Attention.

H410: Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme.

P273: Éviter le rejet dans l'environnement.

P391: Recueillir le produit répandu.

P501: Éliminer le contenu/récipient dans des déchets dangereux ou spéciaux conformément à la loi qui s'applique.

IT Italiano.

Substance name: OSSIDO DI ZINCO.

Signalword (Avvertenza): Attenzione.

H410: Molto tossico per gli organismi acquatici con effetti di lunga durata.

P273: Non disperdere nell'ambiente. P391: Raccogliere il materiale fuoriuscito.

P501: Smaltire il prodotto/recipiente in conformità alla normativa vigente sui rifiuti speciali e pericolosi.

NL Dutch, Flemish (Nederland's).

Substance name: ZINKOXIDE.

Signaalwoord: Waarschuwing.

H410: Zeer giftig voor in het water levende organismen, met langdurige gevolgen.

P273: Voorkom lozing in het milieu. P391: Gelekte/gemorste stof opruimen.

P501: Verwijder inhoud/container als gevaarlijk of bijzonder afval in overeenstemming met de geldende wetgeving.

ES Español.

Substance name: OXIDO DEL CINC.

Signalword (Palabra de advertencia): Atención.

H410: Muy tóxico para los organismos acuáticos, con efectos nocivos duraderos.

P273: Evitar su liberación al medio ambiente.

P391: Recoger el vertido.

P501: Disponga del contenido/envase como basura peligrosa o especial de acuerdo con la ley aplicable.

DA Danish, Dansk (Denmark).

Substance name: ZINK OXID.

Signalord: Advarsel.

H410: Meget giftig med langvarige virkninger for vandlevende organismer.

P273: Undgå udledning til miljøet.

P391: Udslip opsamles.

P501: Indholdet/holderen bortskaffes som farligt affald i overensstemmelse med gældende regler.

PL Polish, Polska.

Substance name: TLENED CYNKU.

Signalword (Hasło ostrzegawcze): Uwaga.

H410: Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.

P273: Unikać uwolnienia do środowiska.

P391: Zebrać wyciek. P501: Wyzuwać pojemniki zawierające toksyczne i niebezpieczne substancje zgodnie z instrukcją