

CERTIFICATE OF ANALYSIS

Batch Number **4395612**

Description **GOLD SEAL ZINC OXIDE**
 Best Before Date **May 2023**

CHEMICAL CHARACTERISTICS

Element	Specification %	Min	Max	Production Avg
As	0.0001 MAX	< 0.0001	< 0.0001	< 0.0001 ✓
Cd	<= 0.001 0	0.0002	0.0002	0.0002 ✓
Cl	0.0005 MAX	0.0004	0.0004	0.0004 ✓
Cu	<= 0.000 2	< 0.0001	< 0.0001	< 0.0001 ✓
Fe	0.0005 MAX	0.0002	0.0003	0.0002 ✓
Mn	<= 0.000 1	< 0.0001	< 0.0001	< 0.0001 ✓
Ni	0.0001 MAX	< 0.0001	< 0.0001	< 0.0001 ✓
ZnO	99.9 MIN	99.9000	99.9000	99.9000 ✓
Pb (including PbO)	0.0020 MAX	0.0010	0.0011	0.0012 ✓
S	0.0007 MAX	0.0001	0.0001	0.0001 ✓
Total Impurities	0.1 MAX	0.1000	0.1000	0.1000 ✓

OTHER CHARACTERISTICS

Item	Specification	Min	Max	Production Avg
Surface area BET method (m ² /g)	3.5 - 7	4.6000	4.6000	4.7000
Granulometry (through # 325 mesh) (%)	99.9 MIN	99.9810	99.9810	99.9750
Moisture (%) ²	0.2 MAX	0.0800	0.0800	0.0800
Volatile materials (%) ¹	0.2 MAX	0.1100	0.1100	0.1100
Ignition loss (%) ¹	0.2 MAX	0.1500	0.1500	0.1500
Specific weight (g/cm ³)	5.6	5.6000	5.6000	5.6000
pH ¹	7.3 - 7.5	7.4000	7.4000	7.4000
Water Soluble Salts (%) ¹	0.10 MAX	0.0800	0.0800	0.0800
Solubility in HCl (%) ¹	99.9 MIN	99.9800	99.9800	99.9820

¹ According Norm DIN 55908 ("Methods of analyzing zinc oxide pigments")

² According Norm ASTM D 280 Method "A"

Complies with USP and European Pharmacopoeia



ALLERGENS ZINC OXIDE

ALLERGENS	Product Free From YES/NO	Listed Item on Site at Manufacturer YES/NO	Where applicable, is there risk of cross-contamination? YES/NO or N/A
Free from Peanuts and Peanut Derivatives (including possible cross contamination)	Yes	Yes	Yes
Free from other Nut and Nut Derivatives <i>Almond (Amygdalus communis L.), Hazelnut (Corylus avellana), Walnut (Juglans regia), Cashew (Anacardium occidentale), Pecan nut (Carya illinoensis (Wangenh.) K. Koch), Brazil nut (Bertholletia excelsa), Pistachio nut (Pistacia vera), Macadamia nut and Queensland nut (Macadamia ternifolia)</i>	Yes	Yes	Yes
Free from Sesame Seeds and Sesame Seed Derivatives	Yes	Yes	Yes
Free from other Seeds and Seed Derivatives (Poppy Seeds, Cotton Seeds, Sunflower Seeds)	Yes	Yes	Yes
Free from Milk and Milk Derivatives (including lactose)	Yes	Yes	Yes
Free from Egg and Egg Derivatives	Yes	Yes	Yes
Free from Cereals and Derivatives containing OR POTENTIALLY CONTAMINATED WITH Gluten (<i>wheat, wheatgrass, furo, freekeh, spelt, kamut, rye, oats, barley, barley grass</i>)	Yes	Yes	Yes
Free from Soya and Soya Derivatives	Yes	Yes	Yes
Free from Lupin and Lupin Derivatives	Yes	Yes	Yes
Free from Mustard and Mustard Derivatives	Yes	Yes	Yes
Free from Celery or Celery Derivatives (including Celeriac)	Yes	Yes	Yes
Free from Fish and Fish Derivatives	Yes	Yes	Yes
Free from Molluscs and their Derivatives	Yes	Yes	Yes
Free from Crustaceans and their Derivatives	Yes	Yes	Yes
Free from Sulphur Dioxide and Sulphites (E220, E228) at levels > 10mg/kg or 10mg/litre	Yes	Yes	Yes

QM07/FOR09

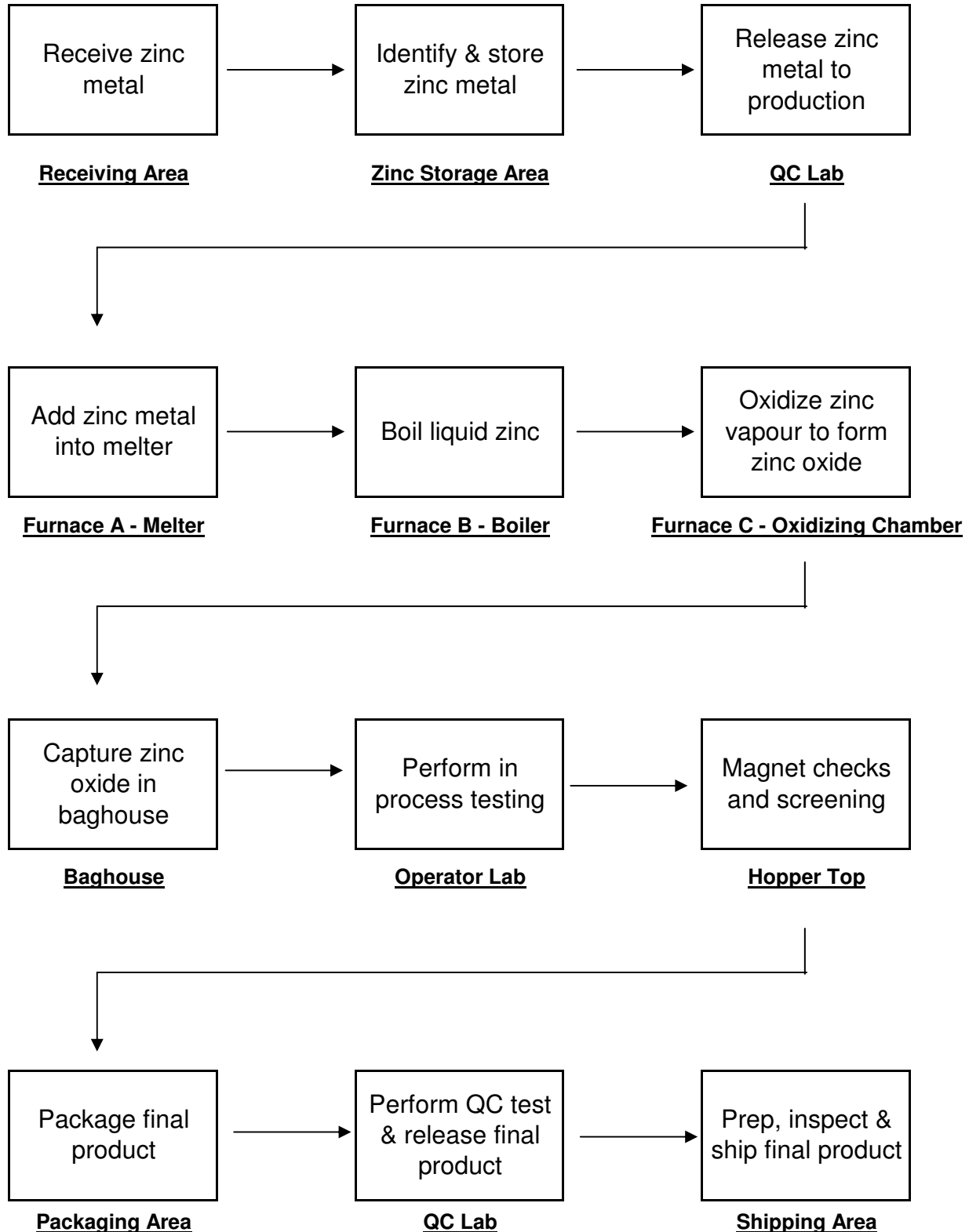
Version 11



ALLERGENS ZINC OXIDE

ADDITIVES / CONTAMINANTS / DIETARY REQUIREMENTS	Product Free From YES/NO	Listed Item on Site at Manufacturer YES/NO	Where applicable, is there risk of cross-contamination? YES/NO or N/A
Free from Additives	Yes	Yes	Yes
Free from Antioxidants	Yes	Yes	Yes
Free from Ethylene Oxide	Yes	Yes	Yes
Free from Gelatine	Yes	Yes	Yes
Free from Flavourings (Artificial / Nature Identical / Natural / Smoked)	Yes	Yes	Yes
Free from Maize / Corn and any Derivatives	Yes	Yes	Yes
Free from Legumes / Pulses	Yes	Yes	Yes
Free from Rice and Rice Derivatives	Yes	Yes	Yes
Free from Added Salt	Yes	Yes	Yes
Free from Added Sugar / artificial or natural sweeteners	Yes	Yes	Yes
Free from Aspartame	Yes	Yes	Yes
Free from BHA / BHT (E320 / E321)	Yes	Yes	Yes
Free from Caffeine	Yes	Yes	Yes
Free from Colours (Artificial / Nature Identical / Natural / Smoked)	Yes	Yes	Yes
Free from Dextrose	Yes	Yes	Yes
Free from Dioxins	Yes	Yes	Yes
Free from MSG (Added and Naturally Occurring E621) or Glutamates (E620 to E625)	Yes	Yes	Yes
Free from Nucleotides (E627, E630, E631, E635)	Yes	Yes	Yes
Free from Polyols (sugar alcohols)	Yes	Yes	Yes
Free from Benzoates (E210 / E219)	Yes	Yes	Yes
Free from Sorbic Acid (E200, E203)	Yes	Yes	Yes
Free from any other Preservatives	Yes	Yes	Yes
Free from Ethanol	Yes	Yes	Yes
Free from Honey	Yes	Yes	Yes
Free from Lactose	Yes	Yes	Yes
Free from Yeast and Yeast Derivatives	Yes	Yes	Yes
Free from All Animal Products (Beef, Pork, Poultry or other) and Derivatives (which may include growth/yield hormones, antibiotics etc.)	Yes	Yes	Yes
Free from Bovine Products or Derivatives (which may include growth/yield hormones, antibiotics etc.)	Yes	Yes	Yes
Suitable for Ovo-Lacto Vegetarians	Yes	XXX	
Suitable for Vegans	Yes	XXX	
Kosher Certified	Yes	XXX	
Halal Certified	No	XXX	

FLOW CHART FOR ZINC OXIDE PRODUCTION





GMO Statement

PRODUCT NAME: Zinc Oxide

MADAR Corporation Limited can confirm that the above listed product is GMO Free.

06/03/2019



Date : 15/10/2014
Version : 2

SAFETY DATA SHEET

Zinc Oxide

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name : Zinc Oxide

REACH Registration number

Registration number	Legal entity
01-2119463881-32-0065	-

Product code : Not available.

Product description : Not available.

Product type : Solid.

Other means of identification : Zinc white and Chinese white

CAS number : 1314-13-2

EC number : 215-222-5

1.2 Relevant identified uses of the substance or mixture and uses advised against

Rubber products, chemical products, ceramics, paints & coatings, pharmaceuticals and many others.
See attached Material Uses and Codes in this PDF (Clips icon on left end side of this page).

1.3 Details of the supplier of the safety data sheet

Supplier's details : MADAR Corporation Limited
19-20 Sandleheath Industrial Estate, Fordingbridge, Hampshire, SP6 1PA

Approved sellers : Cosmetic Butters, Mystic Moments, New Directions, World of Moulds

1.4 Emergency telephone number

National advisory body/Poison Centre

SECTION 1: Identification of the substance/mixture and of the company/undertaking

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Product definition : Substance

Classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Aquatic Acute 1, H400

Aquatic Chronic 1, H410

Classification according to Directive 1999/45/EC [DPD]

The product is classified as dangerous according to Directive 1999/45/EC and its amendments.

Classification : N; R50/53

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

See Section 16 for the full text of the R phrases or H statements declared above.

See Section 11 for more detailed information on health effects and symptoms.

2.2 Label elements

Hazard pictograms :



Signal word : Warning

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

Precautionary statements

General : Not applicable.

Prevention : P273 - Avoid release to the environment.

Response : P391 - Collect spillage.

Storage : Not applicable.

Disposal : P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations.

Hazard symbol or symbols :



Indication of danger : Dangerous for the environment

Risk phrases : R50/53- Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

SECTION 2: Hazards identification

- Safety phrases** : S61- Avoid release to the environment. Refer to special instructions/safety data sheet.
- Supplemental label elements** : Not applicable.
- Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles** : Not applicable.
- Special packaging requirements**
- Containers to be fitted with child-resistant fastenings** : Not applicable.
- Tactile warning of danger** : Not applicable.

2.3 Other hazards

- Other hazards which do not result in classification** : None known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures : Substance

Product/ingredient name	Identifiers	%	Classification		Type
			67/548/EEC	Regulation (EC) No. 1272/2008 [CLP]	
Zinc oxide	EC: 215-222-5 CAS: 1314-13-2 Index: 030-013-00-7	>=90	N; R50/53	Aquatic Acute 1, H400 Aquatic Chronic 1, H410	[1] [2]

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment, are PBTs or vPvBs or have been assigned a workplace exposure limit and hence require reporting in this section.

Type

- [1] Substance classified with a health or environmental hazard
[2] Substance with a workplace exposure limit
[3] Substance meets the criteria for PBT according to Regulation (EC) No. 1907/2006, Annex XIII
[4] Substance meets the criteria for vPvB according to Regulation (EC) No. 1907/2006, Annex XIII
[5] Substance of equivalent concern

Occupational exposure limits, if available, are listed in Section 8.

See Section 16 for the full text of the R-phrases declared above.

See Section 16 for the full text of the H statements declared above.

SECTION 4: First aid measures

4.1 Description of first aid measures

- Eye contact** : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 20 minutes. Get medical attention if irritation occurs.

SECTION 4: First aid measures

- Inhalation** : Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention if adverse health effects persist or are severe. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.
- Skin contact** : Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur. Wash clothing before reuse. Clean shoes thoroughly before reuse.
- Ingestion** : Wash out mouth with water. Remove dentures if any. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention if adverse health effects persist or are severe. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.
- Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.

4.2 Most important symptoms and effects, both acute and delayed

Potential acute health effects

- Eye contact** : Can cause irritation, tearing and mild temporary pain.
- Inhalation** : Zinc oxide dust is non-toxic if inhaled, except of a few reported cases of metal fume fever. Some workers develop a tolerance after repeated daily exposure to zinc oxide fume. This tolerance is lost after short periods away from work.
- Skin contact** : May cause skin irritation.
- Ingestion** : May cause vomiting, nausea, thirst, diarrhea and abdominal pain.

Over-exposure signs/symptoms

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : No known significant effects or critical hazards.

4.3 Indication of any immediate medical attention and special treatment needed

- Notes to physician** : Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
- Specific treatments** : No specific treatment.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

Hazards from the substance or mixture : No specific fire or explosion hazard.

Hazardous thermal decomposition products : Decomposition products may include the following materials:
metal oxide/oxides

5.3 Advice for firefighters

Special protective actions for fire-fighters : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training. This material is very toxic to aquatic organisms. Fire water contaminated with this material must be contained and prevented from being discharged to any waterway, sewer or drain.

Special protective equipment for fire-fighters : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode. Clothing for fire-fighters (including helmets, protective boots and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilt material. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.

For emergency responders : If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also Section 8 for additional information on hygiene measures.

6.2 Environmental precautions

: Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). Water polluting material. May be harmful to the environment if released in large quantities.

6.3 Methods and material for containment and cleaning up

Small spill : Move containers from spill area. Vacuum or sweep up material and place in a designated, labelled waste container. Dispose of via a licensed waste disposal contractor.

Large spill : Move containers from spill area. Approach the release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Vacuum or sweep up material and place in a designated, labelled waste container. Dispose of via a licensed waste disposal contractor.

SECTION 6: Accidental release measures

- 6.4 Reference to other sections** : See Section 1 for emergency contact information.
See Section 8 for information on appropriate personal protective equipment.
See Section 13 for additional waste treatment information.

SECTION 7: Handling and storage

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

7.1 Precautions for safe handling

- Protective measures** : Put on appropriate personal protective equipment (see Section 8). Do not ingest. Avoid contact with eyes, skin and clothing. Avoid release to the environment. Refer to special instructions/safety data sheet. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.

- Advice on general occupational hygiene** : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

7.2 Conditions for safe storage, including any incompatibilities

Zinc oxide gradually absorbs carbon dioxide upon exposure to air. Keep container tightly closed when not in use. Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination.

Seveso II Directive - Reporting thresholds (in tonnes)

Danger criteria

Category	Notification and MAPP threshold	Safety report threshold
E1: Hazardous to the aquatic environment - Acute 1 or Chronic 1	100	200
C9i: Very toxic for the environment	100	200

7.3 Specific end use(s)

- Recommendations** : Not available.
- Industrial sector specific solutions** : Not available.

SECTION 8: Exposure controls/personal protection

The information in this section contains generic advice and guidance. Information is provided based on typical anticipated uses of the product. Additional measures might be required for bulk handling or other uses that could significantly increase worker or exposure or environmental releases.

8.1 Control parameters

Occupational exposure limits

Product/ingredient name	Exposure limit values
Zinc oxide	EH40/2005 WELs (United Kingdom (UK)). TWA: 5 mg/m ³ Form: Dust and fumes STEL: 10 mg/m ³ Form: Dust and fumes

Recommended monitoring procedures : If this product contains ingredients with exposure limits, personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment. Reference should be made to monitoring standards, such as the following: European Standard EN 689 (Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy) European Standard EN 14042 (Workplace atmospheres - Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents) European Standard EN 482 (Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents) Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

DNELs/DMELs

No DNELs/DMELs available.

PNECs

No PNECs available

8.2 Exposure controls

Appropriate engineering controls : Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

Individual protection measures

Hygiene measures : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields. Recommended: Safety glasses.

Skin protection

Hand protection : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

SECTION 8: Exposure controls/personal protection

- < 1 hour (breakthrough time): Natural rubber (latex).
- Body protection** : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product. Recommended: Lab coat.
- Other skin protection** : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Respiratory protection** : Use a properly fitted, particulate filter respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.
- Environmental exposure controls** : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance

- Physical state** : Solid. [Fine powder.]
- Colour** : White.
- Odour** : Odourless.
- Odour threshold** : Not available.
- pH** : Not available.
- Melting point/freezing point** : Sublimation temperature: 1975°C
- Initial boiling point and boiling range** : Not available.
- Flash point** : Not available.
- Evaporation rate** : Not available.
- Flammability (solid, gas)** : Not flammable.
- Upper/lower flammability or explosive limits** : Not available.
- Vapour pressure** : Not available.
- Vapour density** : Not available.
- Relative density** : 5.61
- Solubility(ies)** : Very slightly soluble in the following materials: cold water and hot water.
- Partition coefficient: n-octanol/water** : Not available.
- Auto-ignition temperature** : Not available.
- Decomposition temperature** : Not available.
- Viscosity** : Not available.
- Explosive properties** : Not available.
- Oxidising properties** : Not available.

9.2 Other information

No additional information.

SECTION 10: Stability and reactivity

- 10.1 Reactivity** : No specific test data related to reactivity available for this product or its ingredients.
- 10.2 Chemical stability** : The product is stable.
- 10.3 Possibility of hazardous reactions** : Under normal conditions of storage and use, hazardous reactions will not occur.
- 10.4 Conditions to avoid** : Avoid release into the environment.
- 10.5 Incompatible materials** : Reactive or incompatible with the following materials: oxidising materials. Zinc oxide and chlorinated rubber reacts violently at 215 deg C. Contact with magnesium and linseed oil can cause violent reaction. Contact with strong acids may cause vigorous reaction. Contact with strong bases will form water and soluble zincates. Contact between zinc oxide and hydrogen fluoride, aluminum, hexachloroethane, zinc chloride or phosphoric acid, and water should be avoided.
- 10.6 Hazardous decomposition products** : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

There is no data available.

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
Zinc oxide	Eyes - Mild irritant	Rabbit	-	24 hours 500 mg	-
	Skin - Mild irritant	Rabbit	-	24 hours 500 mg	-

Sensitisation

There is no data available.

Carcinogenicity

There is no data available.

Specific target organ toxicity (single exposure)

There is no data available.

Specific target organ toxicity (repeated exposure)

There is no data available.

Aspiration hazard

There is no data available.

Information on the likely routes of exposure : Routes of entry anticipated: Oral, Dermal, Inhalation.

Potential acute health effects

Eye contact : Can cause irritation, tearing and mild temporary pain.

SECTION 11: Toxicological information

- Inhalation** : Zinc oxide dust is non-toxic if inhaled, except of a few reported cases of metal fume fever. Some workers develop a tolerance after repeated daily exposure to zinc oxide fume. This tolerance is lost after short periods away from work.
- Skin contact** : May cause skin irritation.
- Ingestion** : May cause vomiting, nausea, thirst, diarrhea and abdominal pain.

Symptoms related to the physical, chemical and toxicological characteristics

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : No known significant effects or critical hazards.

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

- Potential immediate effects** : No known significant effects or critical hazards.
- Potential delayed effects** : No known significant effects or critical hazards.

Long term exposure

- Potential immediate effects** : No known significant effects or critical hazards.
- Potential delayed effects** : No known significant effects or critical hazards.

Potential chronic health effects

- General** : No known significant effects or critical hazards.
- Carcinogenicity** : No known significant effects or critical hazards.
- Mutagenicity** : No known significant effects or critical hazards.
- Teratogenicity** : No known significant effects or critical hazards.
- Developmental effects** : No known significant effects or critical hazards.
- Fertility effects** : No known significant effects or critical hazards.

Other information : Not available.

SECTION 12: Ecological information

12.1 Toxicity

Product/ingredient name	Result	Species	Exposure
Zinc oxide	Acute EC50 0.042 mg/L Fresh water	Algae - Pseudokirchneriella subcapitata - Exponential growth phase	72 hours
	Acute LC50 98 µg/L Fresh water	Daphnia - Daphnia magna - Neonate	48 hours
	Acute LC50 1.1 ppm Fresh water	Fish - Oncorhynchus mykiss	96 hours
	Chronic NOEC 0.017 mg/L Fresh water	Algae - Pseudokirchneriella subcapitata - Exponential growth phase	72 hours

12.2 Persistence and degradability

There is no data available.

SECTION 12: Ecological information

12.3 Bioaccumulative potential

Product/ingredient name	LogP _{ow}	BCF	Potential
Zinc oxide	-	60960	high

12.4 Mobility in soil

Soil/water partition coefficient (K_{oc}) : There is no data available.

Mobility : There is no data available.

12.5 Results of PBT and vPvB assessment

PBT : Persistent.

vPvB : Not applicable.

12.6 Other adverse effects : No known significant effects or critical hazards.

SECTION 13: Disposal considerations

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

13.1 Waste treatment methods

Product

Methods of disposal : The generation of waste should be avoided or minimised wherever possible. Disposal of this product, solutions and any by-products should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction.

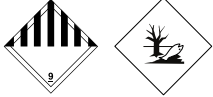
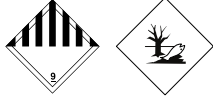
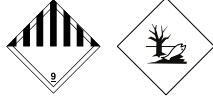
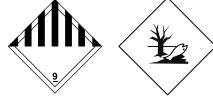
Hazardous waste : The classification of the product may meet the criteria for a hazardous waste.

Packaging

Methods of disposal : The generation of waste should be avoided or minimised wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.

Special precautions : This material and its container must be disposed of in a safe way. Care should be taken when handling empty containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.

SECTION 14: Transport information

	ADR/RID	ADN	IMDG	IATA
14.1 UN number	UN3077	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)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O. S. (Zinc oxide)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O. S. (Zinc oxide)
14.3 Transport hazard class(es)	9 	9 	9 	9 
14.4 Packing group	III	III	III	III
14.5 Environmental hazards	Yes.	Yes.	Yes.	Yes.
Additional information	The environmentally hazardous substance mark is not required when transported in sizes of ≤5 L or ≤5 kg. Tunnel code (E)	The environmentally hazardous substance mark is not required when transported in sizes of ≤5 L or ≤5 kg.	The marine pollutant mark is not required when transported in sizes of ≤5 L or ≤5 kg. Emergency schedules (EmS) F-A, S-F	The environmentally hazardous substance mark is not required when transported in sizes of ≤5 L or ≤5 kg.

14.6 Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code : Not available.

SECTION 15: Regulatory information

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

EU Regulation (EC) No. 1907/2006 (REACH)

Annex XIV - List of substances subject to authorisation

Annex XIV

None of the components are listed.

Substances of very high concern

None of the components are listed.

Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles : Not applicable.

Other EU regulations

SECTION 15: Regulatory information

Europe inventory : All components are listed or exempted.

Seveso II Directive

This product is controlled under the Seveso II Directive.

Danger criteria

Category

E1: Hazardous to the aquatic environment - Acute 1 or Chronic 1
C9i: Very toxic for the environment

15.2 Chemical Safety Assessment : This product contains substances for which Chemical Safety Assessments are still required.

SECTION 16: Other information

Abbreviations and acronyms : ATE = Acute Toxicity Estimate
CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]
DMEL = Derived Minimal Effect Level
DNEL = Derived No Effect Level
EUH statement = CLP-specific Hazard statement
PBT = Persistent, Bioaccumulative and Toxic
PNEC = Predicted No Effect Concentration
RRN = REACH Registration Number
vPvB = Very Persistent and Very Bioaccumulative

Classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Aquatic Acute 1, H400
Aquatic Chronic 1, H410

Procedure used to derive the classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Classification	Justification
Aquatic Acute 1, H400 Aquatic Chronic 1, H410	Calculation method Calculation method

Full text of abbreviated H statements :	H400 H410	Very toxic to aquatic life. Very toxic to aquatic life with long lasting effects.
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Full text of classifications [CLP/GHS] :	Aquatic Acute 1, H400 Aquatic Chronic 1, H410	ACUTE AQUATIC HAZARD - Category 1 LONG-TERM AQUATIC HAZARD - Category 1
-------------------------------------------------	--------------------------------------------------	----------------------------------------------------------------------------

Full text of abbreviated R phrases : R50- Very toxic to aquatic organisms.
R50/53- Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Full text of classifications [DSD/DPD] : N - Dangerous for the environment

History

Date of issue (dd/mm/yyyy) : 15/10/2014

Date of previous issue : 15/02/2010

Version : 2

Revised Section(s) : Not applicable.

Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.



EP/BP - STANDARD	ZINC OXIDE
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FRENCH PROCESS ZINC OXIDE - PRODUCED FROM PRIMARY GRADE ZINC

DESCRIPTION

EP/BP is a zinc oxide extremely high in quality and purity to meet with all current EP/BP Pharmacopoeia standards as per EP 7.0 Edition and BP 2011 Edition.

USES

All pharmaceutical applications; salves, creams, lotions, ointments.

TYPICAL TECHNICAL VALUES**

CHEMICAL PROPERTIES		MAXIMUM	MINIMUM	TYPICAL
Description:	A very fine, amorphous, white or yellowish white powder free from gritty particles.	N/A	Passes	N/A
Identification:	a) When strongly heated, it assumes a yellow color that disappears on cooling. b. When 0.10g dissolved in 1.50 ml of dilute hydrochloric acid R and diluted to 5 ml with water R, the addition of 0.20 ml of strong sodium hydroxide R solution will form a white precipitate. When more sodium hydroxide is added the precipitate dissolves. Adding 10 ml of ammonium chloride solution R, the solution remains clear. Adding 0.10 ml of sodium sulphide R will form a white precipitate.	N/A	Passes	N/A
Alkalinity:	If a red color is produced, no more than 0.30 ml of 0.10 N hydrochloric acid is required to discharge the color of the indicator.	N/A	Passes	N/A
Loss on Ignition @ 500°C:	Maximum 1.0 percent, determined on 1 g by ignition to constant mass at 500 +/-50°C	1.0 %	N/A	N/A
Carbonate and substances insoluble in acids	No effervescence occurs and the resulting solution is clear and colorless. The solution is not more opalescent than the reference suspension.	N/A	Passes	N/A
Arsenic:	Maximum 5 ppm, determined on 0.20g	5ppm	n/a	< 1 ppm
Iron	Any pink color in the test solution is not more intense than the iron standard solution (1ppm Fe) R	N/A	Passes	N/A
Lead	Atomic Absorption Spectrometry	50 ppm	N/A	15 ppm
Cadmium	Atomic Absorption spectrometry	10 ppm	N/A	3 ppm
Assay – ZnO (ignited basis)	Dissolve 1.5g Zinc Oxide in 10 ml of dilute acetic acid R. Carry out the complexometric titration of zinc(2.5.11), 1ml of 0.10M sodium edetate is equivalent to 81.40 mg of ZnO	100.5	99.0	99.9

PHYSICAL PROPERTIES (Not EP/BP Requirement)		MAXIMUM	MINIMUM	TYPICAL
Surface Area (m ² /g)		6.00	3.00	4.50
Particle Size (microns)		0.36	0.18	0.24
Bulk Density (lb/cu. ft)				50
Apparent Density (lb/cu.ft)				18
Screen Test - Through 325 Mesh (%)			99.99	99.995
Specifications				ASTM D-79

REVISION 1: Nov. 18, 2011



ALLERGENS ZINC OXIDE

ALLERGENS	Product Free From YES/NO	Listed Item on Site at Manufacturer YES/NO	Where applicable, is there risk of cross-contamination? YES/NO or N/A
Free from Peanuts and Peanut Derivatives (including possible cross contamination)	Yes	Yes	Yes
Free from other Nut and Nut Derivatives <i>Almond (Amygdalus communis L.), Hazelnut (Corylus avellana), Walnut (Juglans regia), Cashew (Anacardium occidentale), Pecan nut (Carya illinoensis (Wangenh.) K. Koch), Brazil nut (Bertholletia excelsa), Pistachio nut (Pistacia vera), Macadamia nut and Queensland nut (Macadamia ternifolia)</i>	Yes	Yes	Yes
Free from Sesame Seeds and Sesame Seed Derivatives	Yes	Yes	Yes
Free from other Seeds and Seed Derivatives (Poppy Seeds, Cotton Seeds, Sunflower Seeds)	Yes	Yes	Yes
Free from Milk and Milk Derivatives (including lactose)	Yes	Yes	Yes
Free from Egg and Egg Derivatives	Yes	Yes	Yes
Free from Cereals and Derivatives containing OR POTENTIALLY CONTAMINATED WITH Gluten (<i>wheat, wheatgrass, faro, freekeh, spelt, kamut, rye, oats, barley, barley grass</i>)	Yes	Yes	Yes
Free from Soya and Soya Derivatives	Yes	Yes	Yes
Free from Lupin and Lupin Derivatives	Yes	Yes	Yes
Free from Mustard and Mustard Derivatives	Yes	Yes	Yes
Free from Celery or Celery Derivatives (including Celeriac)	Yes	Yes	Yes
Free from Fish and Fish Derivatives	Yes	Yes	Yes
Free from Molluscs and their Derivatives	Yes	Yes	Yes
Free from Crustaceans and their Derivatives	Yes	Yes	Yes
Free from Sulphur Dioxide and Sulphites (E220, E228) at levels > 10mg/kg or 10mg/litre	Yes	Yes	Yes

QM07/FOR09

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ALLERGENS ZINC OXIDE

ADDITIVES / CONTAMINANTS / DIETARY REQUIREMENTS	Product Free From YES/NO	Listed Item on Site at Manufacturer YES/NO	Where applicable, is there risk of cross-contamination? YES/NO or N/A
Free from Additives	Yes	Yes	Yes
Free from Antioxidants	Yes	Yes	Yes
Free from Ethylene Oxide	Yes	Yes	Yes
Free from Gelatine	Yes	Yes	Yes
Free from Flavourings (Artificial / Nature Identical / Natural / Smoked)	Yes	Yes	Yes
Free from Maize / Corn and any Derivatives	Yes	Yes	Yes
Free from Legumes / Pulses	Yes	Yes	Yes
Free from Rice and Rice Derivatives	Yes	Yes	Yes
Free from Added Salt	Yes	Yes	Yes
Free from Added Sugar / artificial or natural sweeteners	Yes	Yes	Yes
Free from Aspartame	Yes	Yes	Yes
Free from BHA / BHT (E320 / E321)	Yes	Yes	Yes
Free from Caffeine	Yes	Yes	Yes
Free from Colours (Artificial / Nature Identical / Natural / Smoked)	Yes	Yes	Yes
Free from Dextrose	Yes	Yes	Yes
Free from Dioxins	Yes	Yes	Yes
Free from MSG (Added and Naturally Occurring E621) or Glutamates (E620 to E625)	Yes	Yes	Yes
Free from Nucleotides (E627, E630, E631, E635)	Yes	Yes	Yes
Free from Polyols (sugar alcohols)	Yes	Yes	Yes
Free from Benzoates (E210 / E219)	Yes	Yes	Yes
Free from Sorbic Acid (E200, E203)	Yes	Yes	Yes
Free from any other Preservatives	Yes	Yes	Yes
Free from Ethanol	Yes	Yes	Yes
Free from Honey	Yes	Yes	Yes
Free from Lactose	Yes	Yes	Yes
Free from Yeast and Yeast Derivatives	Yes	Yes	Yes
Free from All Animal Products (Beef, Pork, Poultry or other) and Derivatives (which may include growth/yield hormones, antibiotics etc.)	Yes	Yes	Yes
Free from Bovine Products or Derivatives (which may include growth/yield hormones, antibiotics etc.)	Yes	Yes	Yes
Suitable for Ovo-Lacto Vegetarians	Yes	XXX	
Suitable for Vegans	Yes	XXX	
Kosher Certified	Yes	XXX	
Halal Certified	No	XXX	