

ZINC OXIDE - ART.11430/31/32/33



SAFETY DATA SHEET

(REACH regulation (EC) n° 1907/2006 - n° 2020/878)

SECTION 1 : IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product name : ZINC OXIDE

Product code : ART.11430/31/32/33.

UFI : AVY4-D0UN-E007-DWMD

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

For dental professional use only.

Reactive powder for the preparation of ZOE cement.

1.3. Details of the supplier of the safety data sheet

Registered company name : PRODUITS DENTAIRE SA.

Address : Rue des Bosquets 18 .1800 .Vevey .Switzerland.

Telephone : +41 21 921 26 31. Fax : .

info@pd-dental.com

https://pd-dental.com

1.4. Emergency telephone number : +41 21 921 26 31.

Association/Organisation : .

SECTION 2 : HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

In compliance with EC regulation No. 1272/2008 and its amendments.

Hazardous to the aquatic environment - Acute hazard, Category 1 (Aquatic Acute 1, H400).

Hazardous to the aquatic environment - Chronic hazard, Category 1 (Aquatic Chronic 1, H410).

This mixture does not present a physical hazard. Refer to the recommendations regarding the other products present on the site.

This mixture does not present a health hazard with the exception of possible occupational exposure thresholds (see paragraphs 3 and 8).

2.2. Label elements

In compliance with EC regulation No. 1272/2008 and its amendments.

Hazard pictograms :



GHS09

Signal Word :

WARNING

Product identifiers :

EC 215-222-5 ZINC OXIDE

Hazard statements :

H410

Very toxic to aquatic life with long lasting effects.

Precautionary statements - Prevention :

P273

Avoid release to the environment.

Precautionary statements - Response :

P391

Collect spillage.

Precautionary statements - Disposal :

P501

Dispose of contents/container according to the hygienic rules in force in dental surgeries and according to the legislation in force.

ZINC OXIDE - ART.11430/31/32/33**2.3. Other hazards**

In use, may form flammable/explosive dust-air mixture.

The mixture does not contain substances classified as 'Substances of Very High Concern' (SVHC) $\geq 0.1\%$ published by the European Chemicals Agency (ECHA) under article 57 of REACH: <http://echa.europa.eu/fr/candidate-list-table>

The mixture fulfils neither the PBT nor the vPvB criteria for mixtures in accordance with annexe XIII of the REACH regulations EC 1907/2006.

The mixture does not contain substances $\geq 0.1\%$ with endocrine disrupting properties in accordance with the criteria of the Delegated Regulation (EU) 2017/2100 of the Commission or Regulation (EU) 2018/605 of the Commission.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS**3.2. Mixtures****Composition :**

Identification	Classification (EC) 1272/2008	Note	%
CAS: 1314-13-2 EC: 215-222-5 REACH: 01-2119463881-32 ZINC OXIDE	GHS09 Wng Aquatic Acute 1, H400 M Acute = 1 Aquatic Chronic 1, H410 M Chronic = 1	[1]	100%

Information on ingredients :

(Full text of H-phrases: see section 16)

[1] Substance for which maximum workplace exposure limits are available.

SECTION 4 : FIRST AID MEASURES

As a general rule, in case of doubt or if symptoms persist, always call a doctor.

NEVER induce swallowing by an unconscious person.

4.1. description of first aid measures**In the event of exposure by inhalation :**

In the event of massive inhalation, remove the person exposed to fresh air. Keep warm and at rest.

If the person is unconscious, place in recovery position. Notify a doctor in all events, to ascertain whether observation and supportive hospital care will be necessary.

In the event of splashes or contact with eyes :

Wash thoroughly with fresh, clean water for 15 minutes holding the eyelids open.

If there is any redness, pain or visual impairment, consult an ophthalmologist.

In the event of splashes or contact with skin :

Wash the skin thoroughly with soap and fresh water.

Be careful with product which can remain between the skin and the clothes, the watch, the jewels.

In the event of an allergic reaction, seek medical attention.

In the event of swallowing :

Seek medical attention, showing the label.

Do not induce vomiting.

4.2. Most important symptoms and effects, both acute and delayed

Breathing system irritation.

Severe eyes irritation.

4.3. Indication of any immediate medical attention and special treatment needed

No data available.

SECTION 5 : FIREFIGHTING MEASURES

Non-flammable.

5.1. Extinguishing media**Suitable methods of extinction**

ZINC OXIDE - ART.11430/31/32/33

In the event of a fire, use :

- carbon dioxide (CO₂)

The product is not combustible itself. Adapt the measures of extinction in the middle surrounding.

Unsuitable methods of extinction

In the event of a fire, do not use :

- water jet

5.2. Special hazards arising from the substance or mixture

A fire will often produce a thick black smoke. Exposure to decomposition products may be hazardous to health.

Do not breathe in smoke.

In the event of a fire, the following may be formed :

- carbon monoxide (CO)
- carbon dioxide (CO₂)
- metallic oxide smokes

5.3. Advice for firefighters

Wear self-contained breathing apparatus.

Avoid generating dusts.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Consult the safety measures listed under headings 7 and 8.

For non first aid worker

Avoid generating dusts.

For first aid worker

First aid workers will be equipped with suitable personal protective equipment (See section 8).

Avoid generating dusts.

6.2. Environmental precautions

Prevent any material from entering drains or waterways.

6.3. Methods and material for containment and cleaning up

Retrieve the product by mechanical means (sweeping/vacuuming) : do not generate dust.

6.4. Reference to other sections

No data available.

SECTION 7 : HANDLING AND STORAGE

Respect storage precautions mentioned on the label.

7.1. Precautions for safe handling

Always wash hands after handling.

The persons who have medical histories of cutaneous reactions must use this product with all the required precautions.

Avoid any contact with skin and eyes.

Fire prevention :

Prevent access by unauthorised personnel.

Recommended equipment and procedures :

For personal protection, see section 8.

Packages which have been opened must be reclosed carefully and stored in an upright position.

7.2. Conditions for safe storage, including any incompatibilities

Keep the container tightly closed

Storage

Respect storage precautions mentioned on the label.

Packaging

Always conserve in the original packaging.

ZINC OXIDE - ART.11430/31/32/33

7.3. Specific end use(s)

Consult instructions for use enclosed.

SECTION 8 : EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Occupational exposure limits :

- ACGIH TLV (American Conference of Governmental Industrial Hygienists, Threshold Limit Values, 2010) :

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
1314-13-2	2 (R) mg/m3	10 (R) mg/m3			

- France (INRS - Outils 65 / 2021-1849, 2021-1763, decree of 09/12/2021) :

CAS	VME-ppm :	VME-mg/m3 :	VLE-ppm :	VLE-mg/m3 :	Notes :	TMP No :
1314-13-2	-	5	-	-	-	-

8.2. Exposure controls

Personal protection measures, such as personal protective equipment

Pictogram(s) indicating the obligation of wearing personal protective equipment (PPE) :



- Eye / face protection

Avoid contact with eyes.

- Hand protection

Wear gloves according to the hygienic rules in force in dental surgeries.

- Body protection

After contact with the product, all parts of the body that have been soiled must be washed.

- Respiratory protection

Avoid inhaling dust.

SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state

Physical state : Powder or dust.

Colour

White

Odour

Odour threshold : Not stated.

Melting point

Melting point/melting range : Not relevant.

Freezing point

Freezing point / Freezing range : Not stated.

Boiling point or initial boiling point and boiling range

Boiling point/boiling range : Not relevant.

Flammability

Flammability (solid, gas) : Not stated.

Lower and upper explosion limit

Explosive properties, lower explosivity limit (%) : Not stated.

Explosive properties, upper explosivity limit (%) : Not stated.

Flash point

Flash point interval : Not relevant.

Auto-ignition temperature

Self-ignition temperature : Not relevant.

ZINC OXIDE - ART.11430/31/32/33

Decomposition temperature

Decomposition point/decomposition range : Not relevant.

pH

pH (aqueous solution) : Not stated.

pH : Not relevant.

Kinematic viscosity

Viscosity : Not stated.

Solubility

Water solubility : Insoluble.

Fat solubility : Not stated.

Partition coefficient n-octanol/water (log value)

Partition coefficient: n-octanol/water : Not stated.

Vapour pressure

Vapour pressure (50°C) : Not relevant.

Density and/or relative density

Density : 5.61

Relative vapour density

Vapour density : Not stated.

9.2. Other information

Enthalpy of melting : 1975°C

9.2.1. Information with regard to physical hazard classes

No data available.

9.2.2. Other safety characteristics

No data available.

SECTION 10 : STABILITY AND REACTIVITY**10.1. Reactivity**

No data available.

10.2. Chemical stability

This mixture is stable under the recommended handling and storage conditions in section 7.

Do not use if the expiry date is exceeded.

10.3. Possibility of hazardous reactions

No data available.

10.4. Conditions to avoid

Avoid :

- formation of dusts
- exposure to light

10.5. Incompatible materials

Keep away from :

- acids
- alkalis

10.6. Hazardous decomposition products

The thermal decomposition may release/form :

- carbon monoxide (CO)
- carbon dioxide (CO₂)
- metallic oxide smokes

ZINC OXIDE - ART.11430/31/32/33**SECTION 11 : TOXICOLOGICAL INFORMATION****11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008**

No data available.

11.1.1. Substances**Acute toxicity :**

ZINC OXIDE (CAS: 1314-13-2)

Oral route :

LD50 > 5000 mg/kg bodyweight/day

Species : Rat

OECD Guideline 401 (Acute Oral Toxicity)

Dermal route :

LD50 > 2000 mg/kg bodyweight/day

Species : Rat

OECD Guideline 402 (Acute Dermal Toxicity)

Inhalation route (Dusts/mist) :

LC50 > 5.7 mg/l

Species : Rat

11.1.2. Mixture**Acute toxicity :**

Oral route :

No observed effect.

Species : Rat

LD50 > 5000 mg/kg

Species : Rat

LD50 > 2000 mg/kg

Species : Rat

LC50 > 5.7 mg/l

11.2. Information on other hazards**SECTION 12 : ECOLOGICAL INFORMATION**

Very toxic to aquatic life with long lasting effects.

The product must not be allowed to run into drains or waterways.

12.1. Toxicity**12.1.1. Substances**

ZINC OXIDE (CAS: 1314-13-2)

Crustacean toxicity :

EC50 = 0.122 mg/l

Factor M = 1

Species : Daphnia magna

Duration of exposure : 48 h

OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test)

Algae toxicity :

ECr50 = 0.136 mg/l

Factor M = 1

Species : Pseudokirchnerella subcapitata

Duration of exposure : 72 h

OECD Guideline 201 (Alga, Growth Inhibition Test)

12.1.2. Mixtures

EC50 < 0.66 mg/l

Duration of exposure : 48 h

ECr50 = 0.136 mg/l

Duration of exposure : 72 h

ZINC OXIDE - ART.11430/31/32/33

OECD Guideline 201 (Alga, Growth Inhibition Test)

12.2. Persistence and degradability

12.2.1. Substances

ZINC OXIDE (CAS: 1314-13-2)

Biodegradability :

no degradability data is available, the substance is considered as not degrading quickly.

12.2.2. Mixtures

Biodegradation :

No data on decomposition is available, the mixture is not considered to decompose rapidly.

12.3. Bioaccumulative potential

12.3.2. Mixtures

Octanol/water partition coefficient :

log K_{ow} = 2.2

Does not have the potential for bioconcentration.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

No data available.

12.6. Endocrine disrupting properties

No data available.

12.7. Other adverse effects

No data available.

SECTION 13 : DISPOSAL CONSIDERATIONS

Proper waste management of the mixture and/or its container must be determined in accordance with Directive 2008/98/EC.

13.1. Waste treatment methods

Do not pour into drains or waterways.

Waste :

Waste management is carried out without endangering human health, without harming the environment and, in particular without risk to water, air, soil, plants or animals.

Recycle or dispose of waste in compliance with current legislation, via a certified collector or company.

Do not contaminate the ground or water with waste, do not dispose of waste into the environment.

Soiled packaging :

Empty container completely. Keep label(s) on container.

Give to a certified disposal contractor.

SECTION 14 : TRANSPORT INFORMATION

Transport product in compliance with provisions of the ADR for road, RID for rail, IMDG for sea and ICAO/IATA for air transport (ADR 2023 - IMDG 2020 [40-20] - ICAO/IATA 2023 [64]).

14.1. UN number or ID number

3077

14.2. UN proper shipping name

UN3077=ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

(zinc oxide)

ZINC OXIDE - ART.11430/31/32/33

14.3. Transport hazard class(es)

- Classification :



9

14.4. Packing group

III

14.5. Environmental hazards

- Environmentally hazardous material :



14.6. Special precautions for user

ADR/RID	Class	Code	Pack gr.	Label	Ident.	LQ	Provis.	EQ	Cat.	Tunnel
	9	M7	III	9	90	5 kg	274 335 375 601	E1	3	-

Not subject to this regulation if Q ≤ 5 l / 5 kg (ADR 3.3.1 - DS 375)

IMDG	Class	2°Label	Pack gr.	LQ	EMS	Provis.	EQ	Stowage Handling	Segregation
	9	-	III	5 kg	F-A. S-F	274 335 966 967 969	E1	Category A SW23	-

Not subject to this regulation if Q ≤ 5 l / 5 kg (IMDG 3.3.1 - 2.10.2.7)

IATA	Class	2°Label	Pack gr.	Passager	Passager	Cargo	Cargo	note	EQ
	9	-	III	956	400 kg	956	400 kg	A97 A158 A179 A197 A215	E1
	9	-	III	Y956	30 kg G	-	-	A97 A158 A179 A197 A215	E1

Not subject to this regulation if Q ≤ 5 l / 5 kg (IATA 4.4.4 - DS A197)

For limited quantities, see part 2.7 of the OACI/IATA and chapter 3.4 of the ADR and IMDG.

For excepted quantities, see part 2.6 of the OACI/IATA and chapter 3.5 of the ADR and IMDG.

14.7. Maritime transport in bulk according to IMO instruments

No data available.

SECTION 15: Regulatory information

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

Classification and labelling information included in section 2:

The following regulations have been used:

- EU Regulation No. 1272/2008 amended by EU Regulation No. 2022/692 (ATP 18)

Container information:

No data available.

Restrictions applied under Title VIII of Regulation (EC) No. 1907/2006 (REACH):

The mixture does not contain any substance restricted under Annex XVII of Regulation (EC) No. 1907/2006 (REACH):
<https://echa.europa.eu/substances-restricted-under-reach>.

Explosives precursors :

The mixture does not contain any substance subject to Regulation (EU) 2019/1148 on the marketing and use of explosives precursors.

ZINC OXIDE - ART.11430/31/32/33

Particular provisions :

No data available.

15.2. Chemical safety assessment

No data available.

SECTION 16 : OTHER INFORMATION

Since the user's working conditions are not known by us, the information supplied on this safety data sheet is based on our current level of knowledge and on national and community regulations.

The mixture must not be used for other uses than those specified in section 1 without having first obtained written handling instructions.

It is at all times the responsibility of the user to take all necessary measures to comply with legal requirements and local regulations.

The information in this safety data sheet must be regarded as a description of the safety requirements relating to the mixture and not as a guarantee of the properties thereof.

Wording of the phrases mentioned in section 3 :

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

Abbreviations and acronyms :

LD50 : The dose of a test substance resulting in 50% lethality in a given time period.

LC50 : The concentration of a test substance resulting in 50% lethality in a given period.

EC50 : The effective concentration of substance that causes 50% of the maximum response.

ECr50 : The effective concentration of substance that causes 50% reduction in growth rate.

REACH : Registration, Evaluation, Authorization and Restriction of Chemical Substances.

UFI : Unique formulation identifier.

STEL : Short-term exposure limit

TWA : Time Weighted Averages

TMP : French Occupational Illness table

TLV : Threshold Limit Value (exposure)

AEV : Average Exposure Value.

ADR : European agreement concerning the international carriage of dangerous goods by Road.

IMDG : International Maritime Dangerous Goods.

IATA : International Air Transport Association.

ICAO : International Civil Aviation Organisation

RID : Regulations concerning the International carriage of Dangerous goods by rail.

GHS09 : Environment

PBT: Persistent, bioaccumulable and toxic.

vPvB : Very persistent, very bioaccumulable.

SVHC : Substances of very high concern.