

SAFETY DATA SHEET

Updated according to Reg. (EC) 1907/2006 and Reg. (EU) 2017/745 (MDR)

Revision Date 11/11/2025
Previous release date 30/03/2023

IMPORTANT NOTE: The product is declared by the manufacturer as a MEDICAL DEVICE pursuant to Regulation (EU) 2017/745 (MDR). This data sheet is provided only to support the safety information for the substances it contains, where applicable.

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

1.1 PRODUCT IDENTIFIER

ORODENT WHITE MATT – ORODENT HIGH TRANSLUCENT – ORODENT PRESHADED – ORODENT GOLD – ORODENT BLEACH – ORODENT THOR – ORODENT EOS – ORODENT VENUS – ORODENT ERA – ORODENT HECTOR – ORODENT LUX – ORODENT KD3Y – ORODENT KD4Y

1.2 IDENTIFIED RELEVANT USES OF THE SUBSTANCE OR MIXTURE AND DISCOURAGED USES

RECOMMENDED USES DENTAL USE MDR CERTIFIED MEDICAL DEVICE

1.3 SAFETY DATA SHEET PROVIDER INFORMATION

Manufacturer ORODENT Srl
Via Maria Gaetana Agnesi n.8/10
37014 Castelnuovo del Garda (VR)
ITALY
Tel. +39 0456450635

1.4 EMERGENCY TELEPHONE NUMBER

Poison Control Centre, Department of Clinical Toxicology of Rome Tel. +39 06 305 43 43

SECTION 2: HAZARD IDENTIFICATION

2.1 CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

Classification (Reg. (EC) 1272/2008)

The product is not classified as hazardous

Classification according to EU Directives 67/548/EEC or 1999/45/EC

Unclassified

2.2 LABEL ELEMENTS

None

2.3 OTHER HAZARDS

Not known

SECTION 3: COMPOSITION/INGREDIENT INFORMATION

3.2 BLEND

CHEMICAL NAME	NO. CE	NO. CAS	% BY WEIGHT	CLASSIFICATION (67/548/EEC)	CLASSIFICATION (REG. (EC) 1272/2008	REACH REGISTRATION NUMBER
Zirconia	215-227-2	1314-23-4	88-96	-	Unclassified	No data available
Yttrium oxide	215-233-5	1314-36-9	5-10	-	Unclassified	No data available
Hafnium dioxide	235-013-2	12055-23-1	<5	-	-	No data available
Aluminum oxide	215.691-6	1344-28-1	<1	-	-	No data available

For the full text of the R-phrases mentioned in this section, refer to section 16.

For the full text of the H-declarations mentioned in this paragraph, see paragraph 16.

SECTION 4: FIRST AID MEASURES

4.1 DESCRIPTION OF FIRST AID MEASURES

General information	There are no dangers that require special first aid measures.
Eye contact	Rinse immediately with plenty of water, including under the eyelids, for at least 15 minutes. Seek medical attention immediately if symptoms occur.
Skin contact	Wash immediately with plenty of soap and water, removing all clothing and shoes contaminated. Seek medical attention immediately if symptoms occur.
Ingestion:	Rinse your mouth. Seek medical attention immediately if symptoms occur.
Inhalation	Take to fresh air. Seek medical attention immediately if symptoms occur.
Protecting rescuers	Use personal protective equipment. Avoid contact with skin, eyes and Clothing.

4.2 MAIN SYMPTOMS AND EFFECTS, BOTH IMMEDIATE AND SUBSEQUENT

Main symptoms	No immediate symptoms are observed that follow
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4.3 INDICATION OF THE NEED FOR IMMEDIATE MEDICAL ATTENTION OR SPECIAL TREATMENT

Notes to the physician	Treating symptomatically
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SECTION 5: FIRE PROTECTION

5.1 MEANS OF EXTINGUISHING

Suitable extinguishing means	The product itself does not burn. Use fire extinguishing systems that are compatible with the local situation, and with the surrounding environment
Suitable extinguishing means that must not be used for security reasons	No means known based on the information provided.

5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE

Exceptional danger Hazardous decomposition products in the event of fire: Carbon oxides and metal oxides.

5.3 RECOMMENDATIONS FOR FIREFIGHTERS

Special protective equipment for Fire extinguishing workers Wear a self-contained respirator and protective clothing.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

Evacuate unnecessary personnel. Avoid contact with skin, eyes and clothing. Do not breathe dust. See Section 8 for personal protective equipment.

6.2 ENVIRONMENTAL PRECAUTIONS

They must not be abandoned in the environment.

6.3 METHODS AND MATERIALS FOR CONTAINMENT AND REMEDIATION

Sweep away and store in suitable containers for disposal.

6.4 REFERENCE TO OTHER SECTIONS

See sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 SAFE HANDLING PRECAUTIONS

Handle in accordance with good industrial hygiene and proper safety practices. Avoid contact with skin, eyes and clothing. Wear protective clothing. Avoid dust formation. Provide adequate ventilation. Wear protective masks in case of insufficient ventilation. Do not eat, drink, or smoke using this product.

7.2 CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

Store in the original containers. Keep the container in a clean and dry place.

7.3 SPECIFIC END USES

Exposure Scenario Not available.

Additional information Not available.

SECTION 8: EXPOSURE CONTROL/PERSONAL PROTECTION

8.1 CONTROL PARAMETERS

Exposure limits Does not contain substances with occupational exposure limit value

CHEMICAL NAME	EUROPEAN UNION	UNITED KINGDOM	FRANCE	SPAIN	GERMANY
Zirconia		TWA: 5 mg/m ³ as Zr STEL: 10 mg/m ³ as Zr		VLA-ED: 5 mg/m ³ as Zr VLA-EC: 10 mg/m ³ as Zr	MAK: 1 mg/m ³ inh AGW: 1 mg/m ³ inh
Yttrium oxide				VLA-ED: 1 mg/m ³	

Hafnium dioxide				VLA-ED: 0.5 mg/m ³	
Aluminum oxide		TWA: 10 mg/m ³ inh TWA: 4 mg/m ³ resp	VME: 10 mg/m ³ resp	VLA-ED: 10 mg/m ³ inh VLA-ED: 5 mg/m ³ resp	

CHEMICAL NAME	ITALY	PORTUGAL	NETHERLANDS	DENMARK	POLAND
Zirconia		VLE-MP: 5 mg/m ³ as Zr VLE-CD: 10 mg/m ³ as Zr		GV: 5 mg/m ³ as Zr	MAK: 1 mg/m ³ inh AGW: 1 mg/m ³ inh
Yttrium oxide		VLE-MP: 1 mg/m ³		GV: 1 mg/m ³	
Hafnium dioxide		VLE-MP: 0.5 mg/m ³			
Aluminum oxide		VLE-MP: 10 mg/m ³		GV: 5 mg/m ³ inh GV: 2 mg/m ³ resp	

Derived No Effect Level (DNEL)

No information available.

CHEMICAL NAME	LONG-TERM EXPOSURE -SYSTEMIC EFFECTS - INHALATION	LONG-TERM EXPOSURE -SYSTEMIC EFFECTS - DERMAL	ACUTE / SHORT-TERM EXPOSURE – SYSTEMIC EFFECTS - INHALATION	ACUTE / SHORT-TERM EXPOSURE – SYSTEMIC EFFECTS - DERMAL
Zirconia	5 mg/m ³	15.75 mg/kg bw/d		

The predictable concentration without EFFECT (PNEC)

No information available

CHEMICAL NAME	FRESH WATER	SEA WATER	INTERMITTENT RELEASE	WASTEWATER TREATMENT PLANT	FRESHWATER SEDIMENT	MARINE SEDIMENT	SOIL	ORAL
Zirconia						9.5 mg/kg dw	7.9 mg/kg dw	

8.2 EXPOSURE CONTROLS**Suitable roadworthiness tests**

Ensure adequate ventilation, especially in enclosed areas.

**Personal protective measures, such as
Personal protective equipment****Eye protection**

Tight-fitting safety glasses.

Hand protection

Protective gloves.

Skin and body protection

Wear suitable protective clothing.

Respiratory protection

In case of insufficient ventilation, wear suitable respiratory equipment.

Hygiene measures

Handle in accordance with good industrial hygiene and proper safety practices.

Environmental exposure controls

Do not contaminate the water supply with the material.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**9.1 INFORMATION ON THE FUNDAMENTAL PHYSICAL AND CHEMICAL PROPERTIES**

Physical state at 20°C

solid

Appearance

Block

Color

White

Odor

odorless

pH

No information available

Melting/freezing point

No information available

Boiling point/range

No information available

Flash point

No information available

Evaporation rate

No information available

Flammability (solids, gases)	No information available
Flammability limits in air	No information available
Vapor pressure	Negligible
Vapor density	No information available
Solubility (Water Solubility)	No information available
Partition coefficient: n-octanol/water	No information available
Self-flammability temperature	No information available
Decomposition Temperature	No information available
Viscosity, dynamics	No information available
Explosive properties	No information available
Oxidizing properties	No information available

9.2 OTHER INFORMATION

Density	6 gr/cm3
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SECTION 10: PHYSICAL AND CHEMICAL PROPERTIES

10.1 RESPONSIVENESS

Inert, non-reactive

10.2 CHEMICAL STABILITY

Stable under normal conditions.

10.3 POSSIBILITY OF DANGEROUS REACTIONS

No dangerous polymerization takes place.

10.4 CONDITIONS TO AVOID

No information available.

10.5 INCOMPATIBLE MATERIALS

No information available.

10.6 HAZARDOUS DECOMPOSITION PRODUCTS

Carbon oxides, metal oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 INFORMATION ON TOXICOLOGICAL EFFECTS

Acute toxicity

Ingestion

No known effect

Skin contact

No known effect

Inhalation

No known effect

CHEMICAL NAME	LD50 ORAL	LD50 DERMAL	CL50 INHALATION
Zirconia	> 5000 mg/kg bw (Rat)		> 4.3 other: mg/L (Rat) 4h
Yttrium oxide	> 5000 mg/kg bw (Rat)		> 5.09 mg/L air (Rat) 4h
Hafnium dioxide	> 5000 mg/kg bw (Rat)		

Aluminum oxide			7.6 mg/L air (Rat) 1h > 2.3 mg/L air (Rat) 4h
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Skin corrosion/irritation	No known effect
Serious eye damage/irritation severe eye pieces	No known effect Contact of the dust with the eyes can provoke irritation
Respiratory sensitization or skin	No known effect
Germ cell mutagenicity	It is known that it does not cause hereditary genetic lesions
Carcinogenicity products.	It does not contain ingredients included in the list of carcinogenic
Reproductive toxicity	It is not known to cause birth defects or that it can have any effect deleterious for the unborn. Not known to negatively influence organs and reproductive functions.
Organ Specific Toxicity target (STOT) — exposure single room	No known effect.
Organ Specific Toxicity target (STOT) — exposure repeated	No known effect.
Danger in the event of suction	No known effect.
Other harmful effects	No known effect.

SECTION 12: ECOLOGICAL INFORMATION

12.1 TOXICITY

It does not contain substances recognized as hazardous to the environment.

CHEMICAL NAME	ALGAE TOXICITY	TOXICITY TO FISH	TOXICITY FOR MICRO-ORGANISMS	TOXICITY TO DAPHNIA AND OTHER AQUATIC INVERTEBRATES
Zirconia		LC50: > 100 mg/L 96h static Brachydanio rerio		
Yttrium oxide		LC50: > 100 mg/L 96h static Brachydanio rerio		

12.2 PERSISTENCE AND DEGRADABILITY

No information available.

12.3 BIOACCUMULATION POTENTIAL

No information available

12.4 MOBILITY IN THE SOIL

No information available

12.5 RESULTS OF THE PBT AND VPVB ASSESSMENT

No information available

12.6 OTHER ADVERSE EFFECTS

No information available

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 WASTE TREATMENT METHODS

Waste from waste/products
regulations.

Dispose of as non-hazardous waste in accordance with local and national

Unused

CER 06 03 16

Contaminated containers

Empty containers should be transported to an authorised site for the recycling or disposal.

SECTION 14: TRANSPORTATION INFORMATION

Second: ADR, RID, ADN, IMDG, ICAO.

14.1 UN NUMBER

Unregulated.

14.2 UN SHIPPING NAME

Unregulated.

14.3 CLASSES OF TRANSPORT HAZARD

Unregulated.

14.4 PACKAGING ASSEMBLY

Unregulated.

14.5 HAZARDS TO THE ENVIRONMENT

Not applicable.

14.6 SPECIAL PRECAUTIONS FOR USERS

Not applicable.

14.7 CARRIAGE OF BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE

Not applicable.

SECTION 15: REGULATORY INFORMATION

15.1 HEALTH, SAFETY AND ENVIRONMENTAL STANDARDS AND LEGISLATION SPECIFIC TO THE SUBSTANCE OR MIXTURE

Limitations on Use

No information available:

Other legislation

No information available.

15.2 CHEMICAL SAFETY ASSESSMENT

No information available.

SECTION 16: OTHER INFORMATION

Full text of the R-phrases quoted in Chapters 2 and 3

Not applicable

References to H-Declarations in Text Form under paragraphs 2 and 3

Not applicable

Abbreviations/Acronyms

EC(E): European Commission

REACH: Registration, Evaluation, Authorisation and Restriction of Chemical substances (The Registration, Evaluation, Authorisation and Restriction of Chemicals)

STOT: Specific Target Organ Toxicity

PBT: Persistent, Bioaccumulative or Toxic vPvB: very Persistent and very Bioaccumulating (very Persistent and very Bioaccumulative)

ADR: Accord européen relatif au transport international des marchandises Dangereuses par Route

RID: Regulations for the International Transport of Dangerous Goods by Rail

ADN: Accord européen relatif au transport international des marchandises Dangereuses par voies de Navigation intérieures

IMDG: International Maritime Dangerous Goods Code

ICAO: International Civil Aviation Organization

Review Date

11/11/2025

Revision Note:

Product name. Composition/ingredient information.

This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006. Labelling according to Regulation (EC) No. 1272/2008.

Denial

The information in this Safety Data Sheet is correct to our best knowledge of the product at the time of publication. This information is provided with the sole purpose of allowing the use, storage, transport and disposal of the product in the most correct and safe way. This information should not be considered a guarantee or specification of the quality of the product. They refer only to the material specifically indicated and are not valid for the same when used in combination with other materials or in other processes not specifically indicated in the text of the Material Safety Data Sheet.

End of Safety Data Sheet