



SAFETY DATA SHEET

according to Regulation (EU) 2015/830

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OrthoStone dental stone (Draft)

Revision 5 (Draft)
Revision date

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

1.1. Product identifier

Product name OrthoStone dental stone

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

Description Foundry material.

1.3. Details of the supplier of the safety data sheet

Company	Ransom & Randolph
Address	3535 Briarfield Boulevard, PO Box 1570 Maumee, Ohio 43537 USA
Web	www.ransom-randolph.com
Telephone	+1 (419) 865-9497
Fax	+1 (419) 865-9997
Email	RR.SDS@dentsply.com
Email address of the competent person	RR.SDS@dentsply.com

1.4. Emergency telephone number

Emergency telephone number	USA +1 419 865 9497
Company	Ransom & Randolph Co. 08:00-17:00 (US Eastern Std. / GMT minus 5)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

2.1.2. Classification - EC 1272/2008 Carc. 2: H351;

2.2. Label elements

Hazard pictograms This substance / mixture has been classified in accordance with the US Federal OSHA Hazard Communication Standard 29CFR 1910.1200. Substance concentration band-ranges are presented, and minor ingredient composition maybe withheld, to protect trade secrets.



Signal Word

Warning

Hazard Statement

Carc. 2: H351 - Suspected of causing cancer inhalation.

Precautionary Statement: Prevention

P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P280 - Wear protective gloves/protective clothing/eye protection/face protection.

Precautionary Statement: Response

P308+P313 - IF exposed or concerned: Get medical advice/attention.

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2.2. Label elements

Precautionary Statement: Storage	P405 - Store locked up.
Precautionary Statement: Disposal	P501 - Dispose of contents/container to local and national regulations

2.3. Other hazards

Other hazards	Product contains crystalline silica.
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Further information

	Not applicable. PBT and vPvB assessment.
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SECTION 3: Composition/information on ingredients

3.2. Mixtures

EC 1272/2008

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration Number	Conc. (%w/w)	Classification
Calcium sulfate (Plaster of Paris)		26499-65-0				
Titanium dioxide USA (Titanium dioxide)		13463-67-7				Carc. 2: H351;

Further information

	Full text for all Risk Phrases mentioned in this section are displayed in Section 16.
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SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation	Move the exposed person to fresh air.
Eye contact	Rinse immediately with plenty of water for 15 minutes holding the eyelids open.
Skin contact	Wash with soap and water.
Ingestion	Drink 1 to 2 glasses of water. DO NOT INDUCE VOMITING.

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

Inhalation	May cause irritation to respiratory system.
Eye contact	May cause irritation to eyes.
Skin contact	May cause irritation to skin.
Ingestion	May cause irritation to mucous membranes.

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

Inhalation	Seek medical attention if irritation or symptoms persist.
Eye contact	Seek medical attention if irritation or symptoms persist.
Skin contact	Seek medical attention if irritation or symptoms persist.
Ingestion	Seek medical attention if irritation or symptoms persist.

SECTION 5: Firefighting measures

5.1. Extinguishing media

	Use extinguishing media appropriate to the surrounding fire conditions.
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5.2. Special hazards arising from the substance or mixture

	Burning produces irritating, toxic and obnoxious fumes.
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5.3. Advice for firefighters

	Self-contained breathing apparatus. Wear suitable protective clothing.
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SECTION 6: Accidental release measures

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6.1. Personal precautions, protective equipment and emergency procedures

Avoid raising dust. Wear suitable respiratory equipment when necessary.

6.2. Environmental precautions

No environmental requirements.

6.3. Methods and material for containment and cleaning up

Avoid raising dust. Clean the area using a vacuum cleaner. Transfer to suitable, labelled containers for disposal.

6.4. Reference to other sections

See section [2, 8 & 13] for further information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid raising dust. Ensure adequate ventilation of the working area. In case of insufficient ventilation, wear suitable respiratory equipment.

Do not eat, drink or smoke in areas where this product is used or stored. Wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Keep containers tightly closed.

7.3. Specific end use(s)

Foundry material.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

exposure limits - calcium sulfate - 10 mg/m³ TWA ACGIH TLV (inhalable fraction); 5 mg/m³ 8 hr -TWA PEL (respirable fraction).all respirable crystalline silica - sum of all types - quartz + cristobalite TWA PEL OSHA (respirable fraction) 0.050 mg/m³Action Level OSHA (respirable fraction) 0.025 mg/m³.

8.1.1. Exposure Limit Values

Calcium sulfate (Plaster of Paris)	WEL 8-hr limit ppm: -	WEL 8-hr limit mg/m ³ : -
	WEL 15 min limit ppm: -	WEL 15 min limit mg/m ³ : -
	WEL 8-hr limit mg/m ³ total 10 inhalable dust:	WEL 15 min limit mg/m ³ total - inhalable dust:
	WEL 8-hr limit mg/m ³ total 4 respirable dust:	WEL 15 min limit mg/m ³ total - respirable dust:
Titanium dioxide USA (Titanium dioxide)	WEL 8-hr limit ppm: -	WEL 8-hr limit mg/m ³ : -
	WEL 15 min limit ppm: -	WEL 15 min limit mg/m ³ : -
	WEL 8-hr limit mg/m ³ total 10 inhalable dust:	WEL 15 min limit mg/m ³ total - inhalable dust:
	WEL 8-hr limit mg/m ³ total 4 respirable dust:	WEL 15 min limit mg/m ³ total - respirable dust:

8.2. Exposure controls



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8.2. Exposure controls

8.2.1. Appropriate engineering controls	Ensure adequate ventilation of the working area.
8.2.2. Individual protection measures	Protective clothing.
Eye / face protection	In case of splashing, wear:.. Approved safety goggles. safety glasses with side-shields.
Skin protection - Handprotection	Wear suitable gloves.
Respiratory protection	Suitable respiratory equipment.
8.2.3. Environmental exposure controls	Not normally required.
Occupational exposure controls	Appropriate local exhaust ventilation is required.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Powder
Colour	White
Odour	Mild
pH	6 - 8
Melting point	1450 °C
Freezing Point	Not applicable.
Initial boiling point	Not applicable.
Evaporation rate	Not applicable.
Flammability (solid, gas)	Not applicable.
Vapour pressure	Not applicable.
Vapour density	Not applicable.
Relative density	3 (H ₂ O = 1 @ 20 °C)
Fat Solubility	Not applicable.
Partition coefficient	No data available
Autoignition temperature	Not applicable.
Viscosity	No data available
Explosive properties	Not applicable.
Oxidising properties	Not applicable.
Solubility	Slightly soluble in water

9.2. Other information

Conductivity	No data available
Surface tension	No data available
Gas group	Not applicable.
Benzene Content	Not applicable.
Lead content	Not applicable.
VOC (Volatile organic compounds)	Not applicable.

SECTION 10: Stability and reactivity

10.1. Reactivity

	Not applicable.
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10.2. Chemical stability

	Stable under normal conditions.
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10.3. Possibility of hazardous reactions

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10.3. Possibility of hazardous reactions

No Significant Hazard.

10.4. Conditions to avoid

When mixed with water, this product can become very hot. Do not make moulds of any body part.

10.5. Incompatible materials

mixing water and acids must be supervised, due to large amounts of heat produced.

10.6. Hazardous decomposition products

calcium oxide. Sulphur oxides.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	Intended use. No Significant Hazard.
Skin corrosion/irritation	No irritation expected.
Serious eye damage/irritation	Causes eye irritation.
Respiratory or skin sensitisation	No sensitization effects reported.
Germ cell mutagenicity	No mutagenic effects reported.
Carcinogenicity	Carcinogen category 2.
Reproductive toxicity	No observed effect level. No observed effect concentration.
STOT-single exposure	No known adverse health effects.
STOT-repeated exposure	Chronic effects < 1% respirable crystalline silica Prolonged inhalation of respirable crystalline silica In 1997, the International Agency for Research on Cancer (IARC) concluded that crystalline silica inhaled from occupational sources can cause lung cancer in humans. However it pointed out that not all industrial circumstances, nor all crystalline silica types, were to be incriminated. (IARC Monographs on the evaluation of the carcinogenic risks of chemicals to humans, Silica, silicates dust and organic fibers, 1997, Vol. 68, IARC, Lyon, France). In June 2003, the European Commission's Scientific Committee for Occupational Exposure Limits (SCOEL) concluded: (SCOEL SUM Doc 94-final on respirable crystalline silica, June 2003) There is a body of evidence supporting the fact that increased cancer risk would be limited to people already suffering from silicosis. Worker protection against silicosis should be assured by respecting the existing regulatory occupational exposure limits and implementing additional risk management measures where required (see Section 16).
Aspiration hazard	No Significant Hazard.

11.1.4. Toxicological Information

No data available

SECTION 12: Ecological information

12.1. Toxicity

OrthoStone dental stone Fish LC50/96h: 1970.000 mg/l

12.2. Persistence and degradability

No data is available on this product.

12.3. Bioaccumulative potential

Does not bioaccumulate.

Partition coefficient

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Partition coefficient

OrthoStone dental stone No data available

12.4. Mobility in soil

Not determined.

12.5. Results of PBT and vPvB assessment

Not determined.

12.6. Other adverse effects

Not applicable.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Dispose of in compliance with all. local and national regulations.

Disposal methods

Contact a licensed waste disposal company.

Disposal of packaging

Empty containers can be sent for disposal or recycling.

SECTION 14: Transport information

14.1. UN number

The product is not classified as dangerous for carriage.

14.2. UN proper shipping name

The product is not classified as dangerous for carriage.

14.3. Transport hazard class(es)

The product is not classified as dangerous for carriage.

14.4. Packing group

The product is not classified as dangerous for carriage.

14.5. Environmental hazards

The product is not classified as dangerous for carriage.

14.6. Special precautions for user

The product is not classified as dangerous for carriage.

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

The product is not classified as dangerous for carriage.

Further information

The product is not classified as dangerous for carriage.

SECTION 15: Regulatory information

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

Regulations

U.S. FEDERAL REGULATIONS: Dental family of investments - OrthoStone.

CERCLA 103 Reportable Quantity: is not subject to CERCLA reporting requirements. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations.

Hazard Category For Section 311/312: Chronic health

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

	<p>Section 313 Toxic Chemicals: This product contains the following chemicals subject to Annual Release Reporting Requirements Under SARA Title III, Section 313 (40 CFR 372): None</p> <p>Section 302 Extremely Hazardous Substances (TPQ): None</p> <p>EPA Toxic Substances Control Act (TSCA) Status: All of the components of this product are listed on the TSCA inventory.</p> <p>U.S. STATE REGULATIONS California Proposition 65: This product can expose you to Titanium dioxide and Silica, crystalline (airborne particles of respirable size), which are known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.</p> <p>INTERNATIONAL REGULATIONS: Canadian Environmental Protection Act: All of the components in this product are listed on the Domestic Substances List (DSL).</p>
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15.2. Chemical safety assessment

	No data is available on this product.
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SECTION 16: Other information

Other information

Revision	This document differs from the previous version in the following areas: 11 - Carcinogenicity.
Text of Hazard Statements in Section 3	Carc. 2: H351 - Suspected of causing cancer .

Further information

	<p>Training Workers must be informed of the presence of crystalline silica and trained in the proper use and handling of this product as required under applicable regulations.</p> <p>The information supplied in this Safety Data Sheet is designed only as guidance for the safe use, storage and handling of the product. This information is correct to the best of our knowledge and belief at the date of publication however no guarantee is made to its accuracy. This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any other process.</p>
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