



Orthodontic Glass Ionomer Powder

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Revision date: 07/10/2014 Date of issue: 07/10/2014

Version: 1.0

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

1.1. Product identifier

Product form : Mixture
Product Name : Orthodontic Glass Ionomer Powder

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

1.2.1. Relevant identified uses

Industrial/Professional use spec : For professional dental use only

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Septodont, Inc.
416 S. Taylor Ave.
Louisville, CO 80027
T 303-665-7535
email: usregulatoryaffairs@septodont.com
www.septodontusa.com

1.4. Emergency telephone number

Emergency number : 800-424-9300 CHEMTREC; 1-703-527-3887 CHEMTREC - Outside USA

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

STOT RE 2 H373

Full text of H-phrases: see section 16

Classification according to Directive 67/548/EEC or 1999/45/EC

Xn; R48/20/21/22

Full text of R-phrases: see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS08

Signal word (CLP) :

Warning

Hazardous ingredients :

Frits, chemicals

Hazard statements (CLP) :

H373 - May cause damage to organs through prolonged or repeated exposure

Precautionary statements (CLP) :

P260 - Do not breathe dust.

P314 - Get medical advice/attention if you feel unwell.

P501 - Dispose of contents/container according to local, regional, national, and international regulations.

2.3. Other Hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

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3.2. Mixture

Name	Product identifier	%	Classification according to Directive 67/548/EEC
Frits, chemicals	(CAS No) 65997-18-4 (EC no) 266-047-6	85 - 95	Xn; R48/20/21/22
Silica, vitreous	(CAS No) 60676-86-0 (EC no) 262-373-8;424-440-1	10 - 15	Not classified

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Frits, chemicals	(CAS No) 65997-18-4 (EC no) 266-047-6	85 - 95	STOT RE 2, H373
Silica, vitreous	(CAS No) 60676-86-0 (EC no) 262-373-8;424-440-1	10 - 15	Not classified

Full text of R- and H-phrases: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

- First-aid measures general : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
- First-aid measures after inhalation : Using proper respiratory protection, move the exposed person to fresh air at once. Encourage exposed person to cough, spit out, and blow nose to remove dust. Immediately call a poison center, physician, or emergency medical service.
- First-aid measures after skin contact : Remove contaminated clothing. Drench affected area with water for at least 15 minutes. Wash contaminated clothing before reuse. Seek medical attention if ill effect or irritation develops.
- First-aid measures after eye contact : Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.
- First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER or doctor/physician.

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

- Symptoms/injuries : Dust may cause mechanical irritation to eyes, nose, throat, and lungs.
- Symptoms/injuries after inhalation : Dust may cause severe irritation to the mouth, throat, and lungs. Repeated or prolonged inhalation may cause lung damage and difficulty breathing.
- Symptoms/injuries after skin contact : Skin contact with large amounts of dust may cause mechanical irritation.
- Symptoms/injuries after eye contact : Contact may cause irritation due to mechanical abrasion. Direct contact may result in corneal injury.
- Symptoms/injuries after ingestion : Ingestion is likely to be harmful or have adverse effects.
- Chronic symptoms : Repeated or prolonged inhalation may cause lung damage.

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

If exposed or concerned, get medical advice and attention.

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire.
- Unsuitable extinguishing media : Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : Not considered flammable but may burn at high temperatures.
- Explosion hazard : Product is not explosive.
- Reactivity : No reactivity hazard.

5.3. Advice for firefighters

- Precautionary measures fire : Exercise caution when fighting any chemical fire.

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- Firefighting instructions : Use water spray or fog for cooling exposed containers.
Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- General measures : Avoid all contact with skin, eyes, or clothing. Avoid generating dust. Do not breathe dust.

6.1.1. For non-emergency personnel

- Protective equipment : Use appropriate personal protection equipment (PPE).
Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

- Protective equipment : Equip cleanup crew with proper protection.
Emergency procedures : Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

- For containment : Sweep spilled substance into containers; if appropriate, moisten first to prevent dusting. Avoid generation of dust during clean-up of spills.
Methods for cleaning up : Clear up spills immediately and dispose of waste safely.

6.4. Reference to other sections

See heading 8, Exposure Controls and Personal Protection. Concerning disposal elimination after cleaning, see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Additional hazards when processed : Good housekeeping is needed during storage, transfer, handling, and use of this material to avoid excessive dust accumulation.
Hygiene measures : Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking, or smoking and again when leaving work.

7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Store in a dry, cool and well-ventilated place. Keep container closed when not in use.
Incompatible products : Strong acids. Strong bases. Strong oxidizers.

7.3. Specific end use(s)

For professional dental use only.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Silica, vitreous (60676-86-0)		
Austria	MAK (mg/m ³)	0,3 mg/m ³ (respirable fraction)
Belgium	Limit value (mg/m ³)	0,1 mg/m ³ (alveolar dust)
Bulgaria	OEL TWA (mg/m ³)	0,07 mg/m ³ (respirable fraction)
Germany	TRGS 900 Occupational exposure limit value (mg/m ³)	0,3 mg/m ³ (The risk of damage to the embryo or fetus can be excluded when AGW and BGW values are observed-respirable fraction)
United Kingdom	WEL TWA (mg/m ³)	0,08 mg/m ³ (respirable dust)
United Kingdom	WEL STEL (mg/m ³)	0,24 mg/m ³ (calculated-respirable dust)
Denmark	Grænseværdie (langvarig) (mg/m ³)	0,1 mg/m ³ (respirable)
Ireland	OEL (8 hours ref) (mg/m ³)	0,08 mg/m ³ (respirable dust)
Ireland	OEL (15 min ref) (mg/m ³)	0,24 mg/m ³ (calculated-respirable dust)

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Silica, vitreous (60676-86-0)		
Poland	NDS (mg/m ³)	2,0 mg/m ³ (total inhalable dust) 1,0 mg/m ³ (respirable dust)

8.2. Exposure controls

Appropriate engineering controls : Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Maintain sufficient mechanical or natural ventilation to assure concentrations remain below PEL/TLV. Use local exhaust if necessary. Power equipment should be equipped with properly designed dust collection devices.

Personal protective equipment : Gloves. Protective clothing. Dust formation: dust mask. Protective goggles.



Hand protection : Protective Gloves.

Eye protection : Chemical goggles or safety glasses.

Skin and body protection : Wear suitable protective clothing.

Respiratory protection : Wear a NIOSH approved respirator that is properly fitted and is in good condition when exposed to dust above exposure limits.

Other information : When using, do not eat, drink or smoke.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: No data available
Odour	: No data available
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting/Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative Density	: No data available
Solubility	: No data available
Partition coefficient: n-octanol/water	: No data available
Viscosity	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: Not applicable

9.2. Other information

Not applicable

SECTION 10: Stability and reactivity

10.1. Reactivity

No reactivity hazard.

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10.2. Chemical stability

Product is stable.

10.3. Possibility of hazardous reactions

Hazardous polymerization will not occur.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Strong acids. Strong bases. Strong oxidizers.

10.6. Hazardous decomposition products

Silicon oxides.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Frits, chemicals (65997-18-4)

LD50 oral rat	> 2000 mg/kg
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Skin corrosion/irritation : Not classified

Serious eye damage/irritation : Not classified

Respiratory or skin sensitisation : Not classified

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

Reproductive toxicity : Not classified

Specific target organ toxicity (single exposure) : Not classified

Specific target organ toxicity (repeated exposure) : May cause damage to organs through prolonged or repeated exposure.

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

Other information : Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose of waste material in accordance with all local, regional, national, and international regulations.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

14.1. UN number

Not regulated for transport

14.2. UN proper shipping name

Not applicable

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14.3. Transport hazard class(es)

Not applicable

14.4. Packing group

Not applicable

14.5. Environmental hazards

Other information : No supplementary information available.

14.6. Special precautions for user

14.6.1. Overland transport

Transport category (ADR) 3

14.6.2. Transport by sea

No additional information available

14.6.3. Air transport

No additional information available

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

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

The following restrictions are applicable according to Annex XVII of the REACH Regulation (EC) No 1907/2006:

3. Liquid substances or mixtures which are regarded as dangerous in accordance with Directive 1999/45/EC or are fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008	Orthodontic Glass Ionomer Powder
3.b. Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10	Frits, chemicals

Contains no REACH candidate substance

Other information, restriction and : This substance is for use in medicinal products, and as such, is exempt from prohibition regulations REACH registration requirements.

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Revision date : 07/10/2014

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

Full text of R-, H- and EUH-phrases

STOT RE 2	Specific target organ toxicity — Repeated exposure, Category 2
H373	May cause damage to organs through prolonged or repeated exposure
R48/20/21/22	Harmful: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed
Xn	Harmful

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.