

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU)

2015/830

Date of issue: 1/18/2018 Version :

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

1.1. Product identifier

Product form : Mixture

Product name : O.V.S. (Ortho Veneer System) Pastes

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

1.2.1. Relevant identified uses

Use of the substance/mixture : For RX only

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Manufacturer

Reliance Orthodontic Products, Inc. 1540 West Thorndale Ave. Itasca, IL 60143 USA

630-773-4009, during normal business hours

www.relianceorthodontics.com

EC Representative:

Emergo Europe, Prinsessgracht 20 2514 AP The Hague, The Netherlands

Australian Sponsor: Emergo Australia, 201 Sussex St.

Darling Park, Tower II, Level 20 Sydney, NSW 2000 Australia

1.4. Emergency telephone number

Emergency number : CHEMTREC - 24-Hour Hazmat Emergency Communications Center

Domestic: 1-800-424-9300 Outside the U.S.: 1-703-527-3887, collect calls accepted

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Skin corrosion/irritation, Category 2 H315
Serious eye damage/eye irritation, Category H319
2
Skin sensitisation, Category 1 H317

Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

Causes skin irritation. May cause an allergic skin reaction. Causes serious eye irritation.

2.2. Label elements

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

Hazard pictograms (CLP)



GHS07

Signal word (CLP) : Warning Hazardous ingredients : BisGMA

Hazard statements (CLP) : H315 - Causes skin irritation

H317 - May cause an allergic skin reaction H319 - Causes serious eye irritation

Precautionary statements (CLP) : P261 - Avoid breathing vapours

P264 - Wash hands thoroughly after handling

P272 - Contaminated work clothing should not be allowed out of the workplace

P280 - Wear eye protection, face protection, protective gloves P302+P352 - IF ON SKIN: Wash with plenty of soap and water

P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove

contact lenses, if present and easy to do. Continue rinsing

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P321 - Specific treatment (see First aid measures on this label)

P332+P313 - If skin irritation occurs: Get medical advice/attention

P333+P313 - If skin irritation or rash occurs: Get medical advice/attention

P337+P313 - If eye irritation persists: Get medical advice/attention

P362+P364 - Take off contaminated clothing and wash it before reuse

P501 - Dispose of contents and container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation, a licensed hazardous-waste disposal contractor or collection site except for empty clean containers which can be disposed of as non-hazardous waste, a hazardous or special waste collection point.

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

| Name | Product identifier | % | Classification according to Regulation (EC) No. 1272/2008 [CLP] |
|------------------------------------|---|---------------|---|
| Ytterbium Fluoride | (CAS-No.) 13760-80-0 | <= 10.65 | Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335 |
| BisGMA | (CAS-No.) 1565-94-2 | 1.35 - 7.25 | Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317 |
| Urethane Dimethacrylate | (CAS-No.) Proprietary | 6.75 - 7.25 | Eye Irrit. 2, H319 STOT SE 3, H336 |
| Tetrahydrofurfuryl Methacrylate | (CAS-No.) 2455-24-5 | 2.362 - 2.537 | Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335 |
| Trimethylolpropane Trimethacrylate | (CAS-No.) 3290-92-4 (EC-No.) 221-950-4 | 1.012 - 1.087 | Skin Irrit. 2, H315 Eye Irrit. 2, H319 |

Full text of H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.

First-aid measures after skin contact : Wash skin with plenty of water. Take off contaminated clothing. If skin irritation or rash occurs:

Get medical advice/attention.

First-aid measures after eye contact : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to

do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

First-aid measures after ingestion : Call a poison center or a doctor if you feel unwell.

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

Symptoms/effects after skin contact : Irritation. May cause an allergic skin reaction.

Symptoms/effects after eye contact : Eye irritation.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Water spray. Dry powder. Foam.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of : Toxic fumes may be released.

fire

5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing

apparatus. Complete protective clothing.

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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area. Avoid contact with skin and eyes. Avoid breathing mist, vapours.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information

refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Mechanically recover the product.

Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Avoid contact with skin and eyes. Wear personal

protective equipment. Avoid breathing mist, vapours.

Hygiene measures : Wash contaminated clothing before reuse. Contaminated work clothing should not be allowed

out of the workplace. Do not eat, drink or smoke when using this product. Always wash hands

after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

Hand protection:

Protective gloves

Eye protection:

Protective goggles

Skin and body protection:

Wear suitable protective clothing

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Solid

Appearance : Viscous paste.

Colour : Tooth.

Odour : Acrylic.

Odour threshold : No data available pH : No data available Relative evaporation rate (butylacetate=1) : No data available

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Melting point

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: No data available

: No data available

Freezing point : Not applicable
Boiling point : No data available
Flash point : > 55 °C
Auto-ignition temperature : Not applicable
Decomposition temperature : No data available
Flammability (solid, gas) : Non flammable.
Vapour pressure : No data available

Relative density : > 1

Solubility : No data available
Log Pow : No data available
Viscosity, kinematic : Not applicable
Viscosity, dynamic : No data available
Explosive properties : No data available
Oxidising properties : No data available
Explosive limits : Not applicable

9.2. Other information

Relative vapour density at 20 °C

No additional information available

SECTION 10: Stability and reactivity

10.1 Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

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 (oral) : Not classified
Acute toxicity (dermal) : Not classified
Acute toxicity (inhalation) : Not classified

| Ytterbium Fluoride (13760-80-0) | |
|---|-------------|
| LD50 oral rat | N/A |
| LD50 dermal rat | N/A |
| LD50 dermal rabbit | N/A |
| LC50 inhalation rat (ppm) | N/A |
| LC50 inhalation rat (Dust/Mist - mg/l/4h) | N/A mg/l/4h |
| LC50 inhalation rat (Vapours - mg/l/4h) | N/A mg/l/4h |

| Urethane Dimethacrylate (Proprietary) | |
|---|-------------|
| LD50 oral rat | N/A |
| LD50 dermal rat | N/A |
| LD50 dermal rabbit | N/A |
| LC50 inhalation rat (ppm) | N/A |
| LC50 inhalation rat (Dust/Mist - mg/l/4h) | N/A mg/l/4h |
| LC50 inhalation rat (Vapours - mg/l/4h) | N/A mg/l/4h |

| Trimethylolpropane Trimethacrylate (3290-92- | 4) |
|--|------------------|
| LD50 oral rat | 5660 mg/kg (Rat) |

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| Trimethylolpropane Trimethacrylate (3290-92-4) | | |
|---|---|--|
| LD50 dermal rabbit | 17120 mg/kg (Rabbit) | |
| Skin corrosion/irritation | : Causes skin irritation. | |
| Serious eye damage/irritation | : Causes serious eye irritation. | |
| Respiratory or skin sensitisation | : May cause an allergic skin reaction. | |
| Germ cell mutagenicity | : Not classified | |
| Carcinogenicity | : Not classified | |
| Reproductive toxicity | : Not classified | |
| STOT-single exposure | : Not classified | |
| Ytterbium Fluoride (13760-80-0) | | |
| LOAEL (oral, rat) | N/A mg/kg bodyweight | |
| LOAEL (dermal, rat/rabbit) | N/A mg/kg bodyweight | |
| LOAEC (inhalation, rat, gas) | N/A ppmv/4h | |
| LOAEC (inhalation, rat, vapour) | N/A mg/l/4h | |
| LOAEC (inhalation, rat, dust/mist/fume) | N/A mg/l/4h | |
| Urethane Dimethacrylate (Proprietar | ry) | |
| LOAEL (oral, rat) | N/A mg/kg bodyweight | |
| LOAEL (dermal, rat/rabbit) | N/A mg/kg bodyweight | |
| LOAEC (inhalation, rat, gas) | N/A ppmv/4h | |
| LOAEC (inhalation, rat, vapour) | N/A mg/l/4h | |
| LOAEC (inhalation, rat, dust/mist/fume) | N/A mg/l/4h | |
| STOT-repeated exposure | : Not classified | |
| Vttorbium Eluorido (12760 90 0) | | |
| Ytterbium Fluoride (13760-80-0) LOAEL (oral, rat, 90 days) | N/A ma/ka hadvuojaht/day | |
| LOAEL (dermal, rat/rabbit, 90 days) | N/A mg/kg bodyweight/day N/A mg/kg bodyweight/day | |
| LOAEC (inhalation, rat, gas, 90 days) | N/A ppmv/6h/day | |
| LOAEC (inhalation, rat, gas, 90 days) LOAEC (inhalation, rat, vapour, 90 days) | N/A mg/l/6h/day | |
| LOAEC (inhalation, rat, vapour, 90 days) | N/A mg/l/6h/day | |
| days) | N/A mg///on/day | |
| Urethane Dimethacrylate (Proprietal | ny) | |
| LOAEL (oral, rat, 90 days) | N/A mg/kg bodyweight/day | |
| LOAEL (dermal, rat/rabbit, 90 days) | N/A mg/kg bodyweight/day | |
| LOAEC (inhalation, rat, gas, 90 days) | N/A ppmv/6h/day | |
| LOAEC (inhalation, rat, vapour, 90 days) | N/A mg/l/6h/day | |
| LOAEC (inhalation, rat,dust/mist/fume, 90 | N/A mg/l/6h/day | |
| days) Aspiration hazard | : Not classified | |
| Aspiration nazaru | . Not diassined | |
| SECTION 12: Ecological information | | |
| 12.1. Toxicity | | |
| Ecology - general | : The product is not considered harmful to aquatic organisms nor to cause long-term adverse | |
| | effects in the environment. | |
| Acute aquatic toxicity | : Not classified | |
| Chronic aquatic toxicity | : Not classified | |
| Ytterbium Fluoride (13760-80-0) | | |
| EC50 Daphnia 1 | 190 mg/l | |
| Tetrahydrofurfuryl Methacrylate (2455-24-5) | | |
| LC50 fish 1 | 34.7 mg/l (LC50; 96 h; Pimephales promelas) | |
| 40.0 Parallet | | |
| 12.2. Persistence and degradability | | |
| Tetrahydrofurfuryl Methacrylate (2455-24-5) | | |
| Persistence and degradability | Biodegradability in water: no data available. No (test)data on mobility of the substance available. | |
| Trimethylolpropane Trimethacrylate (3290-9 | 12-4) | |
| Persistence and degradability | Not readily biodegradable in water. | |
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Bioaccumulative potential

| Tetrahydrofurfuryl Methacrylate (2455-24-5) | | |
|--|--|--|
| Log Pow | 1.3 | |
| Bioaccumulative potential | Low potential for bioaccumulation (Log Kow < 4). | |
| Trimethylolpropane Trimethacrylate (3290-92-4) | | |

4.39 Log Pow

12.4. Mobility in soil

No additional information available

Results of PBT and vPvB assessment

No additional information available

Other adverse effects

No additional information available

SECTION 13: Disposal considerations

Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

SECTION 14: Transport information

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

UN number 14.1.

UN-No. (ADR) : Not applicable UN-No. (IMDG) : Not applicable UN-No. (IATA) : Not applicable UN-No. (ADN) : Not applicable UN-No. (RID) : Not applicable

UN proper shipping name

Proper Shipping Name (ADR) : Not applicable Proper Shipping Name (IMDG) : Not applicable Proper Shipping Name (IATA) : Not applicable Proper Shipping Name (ADN) : Not applicable Proper Shipping Name (RID) : Not applicable

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR) : Not applicable

IMDG

Transport hazard class(es) (IMDG) : Not applicable

IATA

Transport hazard class(es) (IATA) : Not applicable

ADN

Transport hazard class(es) (ADN) : Not applicable

RID

Transport hazard class(es) (RID) : Not applicable

Packing group

: Not applicable Packing group (ADR) : Not applicable Packing group (IMDG) Packing group (IATA) : Not applicable Packing group (ADN) : Not applicable : Not applicable Packing group (RID)

Environmental hazards

Dangerous for the environment : No Marine pollutant : No

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Other information : No supplementary information available

14.6. Special precautions for user

- Overland transport

No data available

- Transport by sea

No data available

- Air transport

No data available

- Inland waterway transport

No data available

- Rail transport

No data available

14.7. Transport in bulk according to Annex II of Marpol 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

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

15.1.2. National regulations

Germany

VwVwS Annex reference : Water hazard class (WGK) 3, severe hazard to waters (Classification according to VwVwS,

Annex 4)

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV

: Is not subject of the 12. BlmSchV (Hazardous Incident Ordinance)

Netherlands

SZW-lijst van kankerverwekkende stoffen

SZW-lijst van mutagene stoffen

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding

NIET-limitatieve lijst van voor de voortplanting

giftige stoffen – Vruchtbaarheid

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling

None of the components are listedNone of the components are listed

: None of the components are listed

: None of the components are listed

: None of the components are listed

Denmark

Classification remarks : Emergency management guidelines for the storage of flammable liquids must be followed

Recommendations Danish Regulation : Young people below the age of 18 years are not allowed to use the product

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

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SECTION 16: Other information

Full text of H- and EUH-statements:

| Eye Irrit. 2 | Serious eye damage/eye irritation, Category 2 |
|---------------|--|
| Skin Irrit. 2 | Skin corrosion/irritation, Category 2 |
| Skin Sens. 1 | Skin sensitisation, Category 1 |
| STOT SE 3 | Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation |
| STOT SE 3 | Specific target organ toxicity — Single exposure, Category 3, Narcosis |
| H315 | Causes skin irritation |
| H317 | May cause an allergic skin reaction |
| H319 | Causes serious eye irritation |
| H335 | May cause respiratory irritation |
| H336 | May cause drowsiness or dizziness |

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.

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