

# Safety Data Sheet

According to 1907/2006/EC, Article 31

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## **1. Identification of the substance/preparation and of the company/undertaking**

### **Product details**

Trade name: Unolux Seal F (PSU020)

Relevant identified uses of the substance or mixture and uses advised against:

No further relevant information available.

Application of the substance / the mixture: fissure sealant

### **Details of the supplier of the safety data sheet**

#### **Manufacturer/Supplier**

Manufacturer/supplier: Made for UnoDent Ltd. Tel: 01376 500582

Address: 10 Perry Way, Witham, Essex CM8 3SX, UK Fax: 01376 500581

Information sector: Technical Department Tel: 01376 500582

Emergency information: Technical Department

Emergency e-mail: [info@unodent.com](mailto:info@unodent.com)

## **2. Hazards identification**

Classification of the substance or mixture

· Classification according to Regulation (EC) No 1272/2008 Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

Skin Sens. 1 H317 May cause an allergic skin reaction.

Label elements

· Labelling according to Regulation (EC) No 1272/2008

As a medical device the product is not subject to labelling regulations under 1272/2008/EC.

· Hazard pictograms GHS07

· Hazard statements

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

Precautionary statements

Wear protective gloves / eye protection.

Wear protective clothing.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

If skin irritation occurs: Get medical advice/attention.

If eye irritation persists: Get medical advice/attention.

Dispose of contents/container in accordance with local/regional/national/international regulations.

Other hazards Use only for intended scope of application

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

### **3. Composition/information on ingredients**

#### **Chemical characterization: Mixtures**

**Description: Mixture of substances listed below with non-hazardous additions.**

<i>Dangerous components:</i>		
<i>CAS: 1565-94-2</i>	<i>BIS-GMA</i> <i>Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317</i>	<i>25-50%</i>
<i>CAS: 6606-59-3</i>	<i>HEDMA</i> <i>Aquatic Chronic 2, H411</i> <i>Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335</i>	<i>10-25%</i>
<i>CAS: 72869-86-4</i> <i>EINECS: 276-957-5</i>	<i>Urethanedimethacrylate</i> <i>Aquatic Chronic 3, H412</i>	<i>10-25%</i>
	<i>fumed silica</i> <i>Acute Tox. 2, H330</i>	<i>5-10%</i>
<i>CAS: 7681-49-4</i> <i>EINECS: 231-667-8</i>	<i>sodium fluoride</i> <i>Acute Tox. 3, H301</i> <i>Skin Irrit. 2, H315; Eye Irrit. 2, H319</i>	<i>2.5-5%</i>
	<i>Catalyst</i> <i>Aquatic Acute 1, H400</i> <i>Acute Tox. 4, H302; Acute Tox. 4, H332; Skin Irrit. 2, H315; Eye Irrit. 2, H319</i>	<i>≤ 2.5%</i>

### **4. First aid measures**

Description of first aid measures

After inhalation: Seek medical treatment in case of complaints.

After skin contact: Immediately wash with water and soap and rinse thoroughly.

After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

After swallowing: If symptoms persist consult doctor.

Most important symptoms and effects, both acute and delayed No further relevant information available.

Indication of any immediate medical attention and special treatment needed No further relevant information available.

### **5. Fire-fighting measures**

Extinguishing media

· Suitable extinguishing agents:

CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

Special hazards arising from the substance or mixture No further relevant information available.

Advice for firefighters

Protective equipment: No special measures required.

## **6. Accidental release measures**

Personal precautions, protective equipment and emergency procedures Not required.

Environmental precautions: Do not allow to enter sewers/ surface or ground water.

Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

## **7. Handling and storage**

Precautions for safe handling For dental use only.

Information about fire - and explosion protection: No special measures required.

Conditions for safe storage, including any incompatibilities

Storage:

Requirements to be met by storerooms and receptacles: See storage instructions on package

Information about storage in one common storage facility: Not required.

Further information about storage conditions: Keep container tightly sealed.

Specific end use(s) No further relevant information available.

## **8. Exposure controls/personal protection**

Additional information about design of technical facilities: No further data; see item 7.

Control parameters

Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

Additional information: The lists valid during the making were used as basis.

Exposure controls

Personal protective equipment:

General protective and hygienic measures: Avoid contact with the eyes and skin.

Protection of hands:



Protective gloves

Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

Eye protection: Safety glasses

## **9. Physical and chemical properties**

Information on basic physical and chemical properties

· General Information

- **Appearance:**

*Form: Fluid*

*Colour: Whitish*

- **Odour:** *Characteristic*

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- **pH-value:** *Not determined.*

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- **Change in condition**

*Melting point/Melting range: Undetermined.*

*Boiling point/Boiling range: Undetermined.*

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- **Flash point:** *Not applicable.*

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- **Self-igniting:** *Product is not selfigniting.*

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- **Danger of explosion:** *Product does not present an explosion hazard.*

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- **Density:** *Not determined.*

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- **Solubility in / Miscibility with water:**

*Not miscible or difficult to mix.*

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- **Viscosity:**

*Dynamic: Not determined.*

*Kinematic: Not determined.*

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Other information - No further relevant information available.

## **10. Stability and reactivity**

Reactivity

Chemical stability

Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

Possibility of hazardous reactions No dangerous reactions known.

Conditions to avoid No further relevant information available.

Incompatible materials: No further relevant information available.

Hazardous decomposition products: No dangerous decomposition products known.

## **11. Toxicological information**

Information on toxicological effects

· Acute toxicity:

LD/LC50 values relevant for classification:

7681-49-4 sodium fluoride

Oral LD50 52 mg/kg (rat)

Primary irritant effect:

on the skin:

Testing according to ISO 10993-1/10993-10 showed no skin irritation for this product when fully cured Irritant to skin and mucous membranes.

on the eye: Irritating effect.

Sensitization: Sensitization possible through skin contact.

Additional toxicological information:

The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:

Irritant

## **12. Ecological information**

Toxicity

Aquatic toxicity: No further relevant information available.

Persistence and degradability No further relevant information available.

Bioaccumulative potential No further relevant information available.

Mobility in soil No further relevant information available.

Additional ecological information:

General notes:

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

Other adverse effects No further relevant information available.

## **13. Disposal considerations**

Waste treatment methods

Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

Uncleaned packaging:

Recommendation: Disposal must be made according to official regulations.

## **14. Transport information**

- <b>14.1 UN-Number</b> - <i>ADR, ADN, IATA</i>	<i>Void</i>
- <b>14.2 UN proper shipping name</b> - <i>ADR, ADN, IATA</i>	<i>Void</i>
- <b>14.3 Transport hazard class(es)</b> - <i>ADR, ADN, IATA</i> - <i>Class</i>	<i>Void</i>
- <b>14.4 Packing group</b> - <i>ADR, IATA</i>	<i>Void</i>
- <b>14.5 Environmental hazards:</b> - <i>Marine pollutant:</i>	<i>No</i>
- <b>14.6 Special precautions for user</b>	<i>Not applicable.</i>
- <b>14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	<i>Not applicable.</i>

## **15. Regulatory information**

Safety, health and environmental regulations/legislation specific for the substance or mixture No further relevant information available.

## **16. Other information**

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

Acute Tox. 3: Acute toxicity, Hazard Category 3

Acute Tox. 4: Acute toxicity, Hazard Category 4

Acute Tox. 2: Acute toxicity, Hazard Category 2

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3

Aquatic Acute 1: Hazardous to the aquatic environment - Acute Hazard, Category 1

Aquatic Chronic 2: Hazardous to the aquatic environment - Chronic Hazard, Category 2

Aquatic Chronic 3: Hazardous to the aquatic environment - Chronic Hazard, Category 3