Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 07.06.2017 *Version number 9* *Revision: 31.01.2017*

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

· **1.1 Product identifier**

· **Trade name: Unolux BCS Composite (FLU650-696)**
· **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
· **Application of the substance / the mixture** Dental filling material

· **1.3 Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
UnoDent Lts, 10 Perry Way, Witham, Essex, CM8 3SX – info@unodent.com

· **Further information obtainable from:** Scientific department tel. 01376 500582
· **1.4 Emergency telephone number:** Scientific department tel. 01376 500582

SECTION 2: Hazards identification

· **2.1 Classification of the substance or mixture**
· **Classification according to Regulation (EC) No 1272/2008**
Skin Sens. 1 H317 May cause an allergic skin reaction.

· **2.2 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**
May cause an allergic skin reaction.
· **Precautionary statements**
Wear protective gloves / eye protection.
Wear protective gloves.
If skin irritation or rash occurs: Get medical advice/attention.
IF ON SKIN: Wash with plenty of water.
Dispose of contents/container in accordance with local/regional/national/international regulations.
· **2.3 Other hazards** Use only for intended scope of application
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

· **3.2 Chemical characterisation: Mixtures**
· **Description:**
Mixture of non-hazardous substances.
Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**		
CAS: 1565-94-2	BIS GMA Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	10-25%
CAS: 72869-86-4 EINECS: 276-957-5	Urethanedimethacrylate Aquatic Chronic 3, H412	10-25%

· **Additional information:** For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

· **4.1 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.

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· ***After swallowing:*** *If symptoms persist consult doctor.*

· ***4.2 Most important symptoms and effects, both acute and delayed*** *No further relevant information available.*
· ***4.3 Indication of any immediate medical attention and special treatment needed***
No further relevant information available.

SECTION 5: Firefighting measures

· ***5.1 Extinguishing media***
· ***Suitable extinguishing agents:*** *Use fire extinguishing methods suitable to surrounding conditions.*
· ***5.2 Special hazards arising from the substance or mixture*** *No further relevant information available.*
· ***5.3 Advice for firefighters***
· ***Protective equipment:*** *No special measures required.*

SECTION 6: Accidental release measures

· ***6.1 Personal precautions, protective equipment and emergency procedures*** *Not required.*
· ***6.2 Environmental precautions:*** *Do not allow to enter sewers/ surface or ground water.*
· ***6.3 Methods and material for containment and cleaning up:*** *Pick up mechanically.*
· ***6.4 Reference to other sections***
No dangerous substances are released.
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

· ***7.1 Precautions for safe handling*** *For dental use only.*
· ***Information about fire - and explosion protection:*** *No special measures required.*

· ***7.2 Conditions for safe storage, including any incompatibilities***
· ***Storage:***
· ***Requirements to be met by storerooms and receptacles:*** *No special requirements.*
· ***Information about storage in one common storage facility:*** *Not required.*
· ***Further information about storage conditions:*** *See storage instructions on package*
· ***7.3 Specific end use(s)*** *No further relevant information available.*

SECTION 8: Exposure controls/personal protection

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

· ***8.1 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.*

· ***8.2 Exposure controls***
· ***Personal protective equipment:***
· ***General protective and hygienic measures:***
The usual precautionary measures are to be adhered to when handling chemicals.
· ***Respiratory protection:*** *Not required.*
· ***Protection of hands:***

Protective gloves

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· ***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*

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
Form:	Solid
Colour:	According to product specification
· **Odour:**	Characteristic
· **Odour threshold:**	Not determined.
· **pH-value:**	Not applicable.
· **Change in condition**	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
· **Flash point:**	169 °C
· **Flammability (solid, gaseous):**	Not determined.
· **Decomposition temperature:**	Not determined.
· **Self-igniting:**	Product is not selfigniting.
· **Danger of explosion:**	Product does not present an explosion hazard.
· **Density:**	Not determined.
· **Relative density**	Not determined.
· **Vapour density**	Not applicable.
· **Evaporation rate**	Not applicable.
· **Solubility in / Miscibility with water:**	Insoluble.
· **Partition coefficient (n-octanol/water):**	Not determined.
· **Viscosity:**	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
Solids content:	73.4 %
· **9.2 Other information**	No further relevant information available.

SECTION 10: Stability and reactivity

· **10.1 Reactivity** No further relevant information available.
· **10.2 Chemical stability**
· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
· **10.3 Possibility of hazardous reactions** No dangerous reactions known.
· **10.4 Conditions to avoid** No further relevant information available.
· **10.5 Incompatible materials:** No further relevant information available.
· **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

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SECTION 11: Toxicological information

· **11.1 Information on toxicological effects**
· **Acute toxicity** Based on available data, the classification criteria are not met.
· **Primary irritant effect:**
· **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
· **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
· **Respiratory or skin sensitisation**
May cause an allergic skin reaction.
· **CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)**
· **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
· **Carcinogenicity** Based on available data, the classification criteria are not met.
· **Reproductive toxicity** Based on available data, the classification criteria are not met.
· **STOT-single exposure** Based on available data, the classification criteria are not met.
· **STOT-repeated exposure** Based on available data, the classification criteria are not met.
· **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

· **12.1 Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **12.2 Persistence and degradability** No further relevant information available.
· **12.3 Bioaccumulative potential** No further relevant information available.
· **12.4 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.
· **12.5 Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

· **13.1 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.

SECTION 14: Transport information

· **14.1 UN-Number**	
· **ADR, ADN, IMDG, IATA**	Void
· **14.2 UN proper shipping name**	-
· **ADR, ADN, IMDG, IATA**	Void
· **14.3 Transport hazard class(es)**	-
· **ADR, ADN, IMDG, IATA**	
· **Class**	Void
· **14.4 Packing group**	-

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· **ADR, IMDG, IATA**	Void
· **14.5 Environmental hazards:**	
· **Marine pollutant:**	No
· **14.6 Special precautions for user**	Not applicable.
· **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**	Not applicable.
· **UN "Model Regulation":**	Void

*
SECTION 15: Regulatory information

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

· **Directive 2012/18/EU**
· **Named dangerous substances - ANNEX I** None of the ingredients is listed.

*
SECTION 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.

· **Department issuing SDS:** Scientific department
· **Contact:** Tel.: 01376 500582
· **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)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised 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)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
Skin Sens. 1: Skin sensitisation – Category 1
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3
· *** Data compared to the previous version altered.**