

# SAFETY DATA SHEET

according to Regulation (EU) 2015/830

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## Universal Composite.

Revision 2  
Revision date 2020-01-15

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

#### 1.1. Product identifier

Product name	Universal Composite.
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#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

Product Use	[SU22] Professional uses: Public domain (administration, education, entertainment, services, craftsmen);
Restricted use	[SU21] Consumer uses: Private households (= general public = consumers);
Description	Dental product.

#### 1.3. Details of the supplier of the safety data sheet

Company	Unodent Ltd
Address	10 Perry Way, Witham, Essex,  CM8 3SX, UK
Web	www.Unodent.com
Telephone	(01376) 500582      Use for Emergency also
Fax	
Email	feedback@unodent.com
Email address of the competent person	feedback@unodent.com

#### 1.4. Emergency telephone number


Emergency telephone number	(01376) 500582 (9.00 am – 5.00 pm Mon - Fri)
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### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

2.1.2. Classification - EC 1272/2008	Skin Sens. 1: H317;
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#### 2.2. Label elements

Hazard pictograms	
Signal Word	Warning
Hazard Statement	Skin Sens. 1: H317 - May cause an allergic skin reaction.
Precautionary Statement: Prevention	P272 - Contaminated work clothing should not be allowed out of the workplace. P280 - Wear protective gloves/protective clothing/eye protection/face protection.

#### 2.2. Label elements

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<b>Precautionary Statement:</b>	<b>P302+P352 - IF ON SKIN: Wash with plenty of water/ .</b>
<b>Response</b>	<b>P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.</b>

## 2.3. Other hazards

<b>Other hazards</b>	<b>PBT. vPvB. Not applicable.</b>
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## Further information

	Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.
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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
Glass Powder		65997-18-4	266-047-6		60 - 70%	
Aluminium Oxide (Aluminium oxides)		1344-28-1	215-691-6		1 - 10%	
3-Methacryloxypropyltrimethoxysilane		2530-85-0			1 - 10%	
Bisphenol A glycerolate dimethacrylate		1565-94-2	216-367-7		1 - 10%	Skin Irrit. 2: H315; Skin Sens. 1: H317; Eye Irrit. 2: H319;
Triethylene Glycol Dimethacrylate		109-16-0	203-652-6	01-2119969287-21	1 - 10%	Skin Sens. 1: H317;
Silica		112945-52-5	231-545-4	01-2119379499-16	1 - 10%	
Dibutyltin dilaurate		77-58-7			0 - 0.5%	Skin Corr. 1B: H314; Eye Dam. 1: H318; Muta. 2: H341; Repr. 1B: H360FD; STOT RE 1: H372; Aquatic Acute 1: H400; Aquatic Chronic 1: H410;

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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 off immediately with plenty of soap and water. Remove contaminated clothing.
Ingestion	Do NOT induce vomiting.

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

Inhalation	May cause irritation to mucous membranes.
Eye contact	May cause irritation to eyes.
Skin contact	May cause irritation to skin. May cause allergic reactions in susceptible people.
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.

### General information

	If you feel unwell, seek medical advice (show the label where possible).
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## 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

	Wear suitable respiratory equipment when necessary.
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## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

	Ensure adequate ventilation of the working area. Wear suitable protective equipment.
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### 6.2. Environmental precautions

	Do not allow product to enter drains. Prevent further spillage if safe.
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### 6.3. Methods and material for containment and cleaning up

	Sweep up. Transfer to suitable, labelled containers for disposal. Clean spillage area thoroughly with plenty of water.
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### 6.4. Reference to other sections

	See Section 13 for disposal information. See Section 8 for exposure controls/personal protection.
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## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Avoid contact with eyes and skin. Ensure adequate ventilation of the working area. Adopt best Manual Handling considerations when handling, carrying and dispensing.

### 7.2. Conditions for safe storage, including any incompatibilities

Keep in a cool, dry, well ventilated area. Keep containers tightly closed. Store in original container.

### 7.3. Specific end use(s)

See section 1.2. Relevant identified uses of the substance or mixture and uses advised against for further information.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### 8.1.1. Exposure Limit Values

Aluminium Oxide (Aluminium oxides)	WEL 8-hr limit ppm: -	WEL 8-hr limit mg/m3: -
	WEL 15 min limit ppm: -	WEL 15 min limit mg/m3: -
	WEL 8-hr limit mg/m3 total 10 inhalable dust:	WEL 15 min limit mg/m3 total inhalable dust:
	WEL 8-hr limit mg/m3 total 4 respirable dust:	WEL 15 min limit mg/m3 total respirable dust:

### 8.2. Exposure controls



8.2.1. Appropriate engineering controls Ensure adequate ventilation of the working area.

#### 8.2. Exposure controls

##### 8.2.2. Individual protection measures

Wear chemical protective clothing.

##### Eye / face protection

Approved safety goggles.

##### Skin protection -

##### Handprotection

Chemical resistant gloves.

##### Respiratory protection

Wear suitable respiratory equipment when necessary.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Appearance	Paste
Odour	Slight
Odour threshold	No data available

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pH	No data available
Melting point	No data available
Freezing Point	No data available
Initial boiling point	No data available
Flash point	No data available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Vapour pressure	No data available
Vapour density	No data available
Relative density	No data available
Fat Solubility	No data available
Partition coefficient	No data available
Autoignition temperature	No data available
Viscosity	No data available
Oxidising properties	No data available
Solubility	No data available

## 9.2. Other information

Conductivity	No data available
Surface tension	No data available
Gas group	No data available
Benzene Content	No data available
Lead content	No data available
VOC (Volatile organic compounds)	No data available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

	No data available.
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### 10.2. Chemical stability

	Stable under normal conditions.
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### 10.3. Possibility of hazardous reactions

	No data is available on this product.
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### 10.4. Conditions to avoid

	Heat. Moisture. Direct sunlight.
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### 10.5. Incompatible materials

	Reducing agents. Strong acids. Strong bases. Strong oxidising agents.
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## 10.6. Hazardous decomposition products

	No data available.
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## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity	No data available.
Skin corrosion/irritation	May cause irritation to skin. May cause allergic reactions in susceptible people.
Serious eye damage/irritation	Causes serious eye irritation.
Respiratory or skin sensitisation	May cause irritation to mucous membranes.
Germ cell mutagenicity	No mutagenic effects reported.
Carcinogenicity	No carcinogenic effects reported.
Reproductive toxicity	No teratogenic effects reported.
STOT-single exposure	No data available.
STOT-repeated exposure	No data available.
Aspiration hazard	May cause irritation to mucous membranes.
Repeated or prolonged exposure	No data available.

### 11.1.4. Toxicological Information

Aluminium Oxide	Oral Rat LD50: >10000 mg/kg	Inhalation Rat LC50/4 h: >2.6 mg/l
Dibutyltin dilaurate	Oral Rat LD50: 2071 mg/kg	Dermal Rabbit LD50: 2000 mg/kg
Triethylene Glycol Dimethacrylate	Oral Rat LD50: 10837 mg/kg	

## SECTION 12: Ecological information

### 12.1. Toxicity

Dibutyltin dilaurate	Daphnia EC50/48h: 1.7000 mg/l	Algae IC50/72h: 1.0000 mg/l
Triethylene Glycol Dimethacrylate	Fish LC50/96h: 16.4000 mg/l	

### 12.2. Persistence and degradability

	No data is available on this product.
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### 12.3. Bioaccumulative potential

	No data is available on this product.
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### Partition coefficient

	Universal Composite. No data available
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### 12.4. Mobility in soil

	Dispose of in compliance with all. local and national regulations.
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	No data is available on this product.
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## 12.5. Results of PBT and vPvB assessment

	No data is available on this product.
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## 12.6. Other adverse effects

	No data is available on this product.
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## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

#### General information

	18 WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND /OR RELATED RESEARCH( except kitchen and restaurant wastes not arising from immediate health care). 18 01 wastes from natal care, diagnosis, treatment or prevention of disease in humans. 18 01 06 chemicals consisting of or containing dangerous substances.
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#### Disposal methods

	Do not empty into drains. For disposal within the EC, the appropriate code according to the European Waste Catalogue (EWC) should be used.
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#### Disposal of packaging

	Do NOT reuse empty containers. Empty containers can be sent for disposal or recycling.
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## SECTION 14: Transport information

### 14.1. UN number

	The product is not classified as dangerous for carriage.
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### 14.2. UN proper shipping name

	The product is not classified as dangerous for carriage.
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### 14.3. Transport hazard class(es)

	The product is not classified as dangerous for carriage.
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### 14.4. Packing group

	The product is not classified as dangerous for carriage.
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### 14.5. Environmental hazards

	The product is not classified as dangerous for carriage.
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### 14.6. Special precautions for user

	The product is not classified as dangerous for carriage.
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### 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.
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## SECTION 15: Regulatory information

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

#### Regulations

	COMMISSION REGULATION (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18
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December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

## 15.2. Chemical safety assessment

No data available.

## SECTION 16: Other information

### Other information

Revision	<p>This document differs from the previous version in the following areas:.</p> <ul style="list-style-type: none"> <li>2 - Precautionary Statement: Prevention.</li> <li>2 - Precautionary Statement: Response.</li> </ul>
<p>Other information</p> <p>Text of Hazard Statements in Section 3</p>	<ul style="list-style-type: none"> <li>2 - Precautionary Statement: Disposal.</li> <li>4 - Eye contact.</li> <li>11 - 11.1.4. Toxicological Information.</li> <li>12 - 12.1. Toxicity.</li> </ul> <hr/> <p>Skin Irrit. 2: H315 - Causes skin irritation.          Skin Sens. 1: H317 - May cause an allergic skin reaction.          Eye Irrit. 2: H319 - Causes serious eye irritation.          Skin Corr. 1B: H314 - Causes severe skin burns and eye damage.          Eye Dam. 1: H318 - Causes serious eye damage.          Muta. 2: H341 - Suspected of causing genetic defects .          Repr. 1B: H360FD - May damage fertility. May damage the unborn child.          STOT RE 1: H372 - Causes damage to organs through prolonged or repeated exposure .          Aquatic Acute 1: H400 - Very toxic to aquatic life.          Aquatic Chronic 1: H410 - Very toxic to aquatic life with long lasting effects.</p>
Further information	<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>