

	<b>APPENDIX 11- MATERIAL SAFETY DATA SHEET</b>	<b>MSDS-6</b> <i>Date of Issue:</i> <b>1.08.2017</b>
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## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1 Product identifiers

Products name: **Create**

**SHADES: A1, A2, A3, A3.5, OA2, OA3, B1, B2, C2, D2, D3, T**

Producer: DENTAL LIFE SCIENCES (mfg) Ltd.

Unit A3, Wigan Enterprise Court, Unit A3, Wigan Enterprise Park  
Ince, Wigan, Wn2 2 LE, United Kingdom

Application: Dental composite

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

**Create** is a light-cured microhybrid dental restorative material. The product undergoes a free-radical polymerization, combined with cross-linking, under the influence of the visible radiation from the blue region (at the wavelength of 400 to 500 nm). **Create** is originally packaged in 6 g black syringes.

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

Producer: DENTAL LIFE SCIENCES (mfg) Ltd.

Unit A3, Wigan Enterprise Court, Unit A3, Wigan Enterprise Park  
Ince, Wigan, Wn2 2 LE, United Kingdom

Telephone: (+44) 1942 324 700

E-mail address: [info@rxdls.co.uk](mailto:info@rxdls.co.uk)

### 1.4 Emergency telephone number

Emergency Phone #: 999, 112

## 2. HAZARDS IDENTIFICATION

### 2.1 Classification of the substance or mixture

#### Classification according to Regulation (EC) No 1272/2008

H317 May cause an allergic skin reaction

H318 Causes serious eye damage

H319 Causes serious eye irritation

H335 May cause respiratory irritation.

H400 Very toxic to aquatic life

H410 Very toxic to aquatic life with long-lasting effects.

#### Classification according to Regulation 1999/45/EC

Xi Irritant

R36/37/38 Irritating to eyes, respiratory system and skin.

R41 Risk of serious damage to eyes

R43 May cause sensitisation by skin contact

### 2.2 Label elements

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

Pictogram

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Signal word: Warning

Hazard statement(s)

H315 Causes skin irritation

Precautionary statement(s)

P280 Wear protective gloves/protective clothing/eye protection/face protection. [As modified by IV ATP]

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

P261 Avoid breathing dust/fumes/gas/mist/vapours/spray. [As modified by IV ATP]

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

P302+P352 IF ON SKIN: Wash with plenty of water/... [As modified by IV ATP]

P273 Avoid release to the environment.

P501 Dispose of contents/ container to an approved waste disposal plant.

### 2.3 Other hazards - none

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Mixture of Bis-GMA, Bisphenol A ethoxylate dimethacrylate, TEGDMA, UDMA, inorganic pigments, bariumborosilicate glasses with initiators, stabilizers and UV absorber.

Hazardous ingredients according to Regulation (EC) No 1272/2008

No	Component	Classification	CAS #
1	Bis-GMA (Bisphenol A glycerolate dimethacrylate)	H318	1565-94-2
2	Ethoxylated Bisphenol A dimethacrylate	H315, H317, H319, H335	41637-38-1
3	TEGDMA - Triethylene glycol dimethacrylate	H315, H319, H335	109-16-0
4	UDMA (Diurethane dimethacrylate)	H317	72869-86-4
5	Camphorquinone (CQ)	-----	10373-78-1
6	BHT	H400, H410	128-37-0

Hazardous ingredients according to Regulation 1999/45/WE

No	Component	Classification	CAS #
1	Bis-GMA (Bisphenol A glycerolate dimethacrylate)	Xi, R41	1565-94-2
2	Ethoxylated Bisphenol A dimethacrylate	Xi, R36/37/38, R43	41637-38-1
3	TEGDMA - Triethylene glycol dimethacrylate	Xi, R36/37/38, R43	109-16-0
4	UDMA (Diurethane dimethacrylate)	Xi, R43	72869-86-4
5	Camphorquinone (CQ)	-----	10373-78-1

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6	BHT (2,6-Di-tert-butyl-4-methylphenol)	-----	128-37-0
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For the full text of the H-Statements and R-Phrases mentioned in this Section, see Section 16.

#### 4. FIRST AID MEASURES

##### 4.1 Description of first aid measures

###### General advice

Consult a physician. Show this safety data sheet to the doctor in attendance.

###### If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

###### In case of skin contact

Wash off with soap and plenty of water. Consult a physician.

###### In case of eye contact

Flush eyes with water as a precaution.

###### If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

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

The most important known symptoms and effects are described in the labelling and/or in section 11

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

no data available

#### 5. FIRE-FIGHTING MEASURES

##### 5.1 Extinguishing media

###### Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

##### 5.2 Special hazards arising from the substance or mixture

no data available

##### 5.3 Advice for firefighters

Wear self contained breathing apparatus for fire fighting if necessary.

##### 5.4 Further information

no data available

#### 6. ACCIDENTAL RELEASE MEASURES

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

Use personal protective equipment. Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Avoid breathing dust.

##### 6.2 Environmental precautions

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Do not let product enter drains.

### **6.3 Methods and materials for containment and cleaning up**

Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

### **6.4 Reference to other sections**

For disposal see section 13.

## **7. HANDLING AND STORAGE**

### **7.1 Precautions for safe handling**

Avoid contact with skin, eyes and clothing. Wash hands before and immediately after using this product.

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

Store in cool place. Keep container tightly closed in a dry and well-ventilated place.

Recommended storage temperature: 3 - 28°C

### **7.3 Specific end use(s)**

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

## **8. EXPOSURE CONTROL/PERSONAL PROTECTION**

### **8.1 Control parameters**

**Components with workplace control parameters**

### **8.2 Exposure controls**

#### **Appropriate engineering controls**

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

#### **Personal protective equipment**

#### **Eye/face protection**

Safety glasses with side-shields conforming to EN166 Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

#### **Skin protection**

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

#### **Body Protection**

Impervious clothing. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

#### **Respiratory protection**

Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator

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cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

**Control of environmental exposure**

Do not let product enter drains.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

**9.1 Information on basic physical and chemical properties**

- |  |                                       |                                      |
|--|---------------------------------------|--------------------------------------|
| a) Appearance                                    | Form: paste<br>Colors: Various shades |                                      |
| b) Odour:  |                                       | practically odourless, acrylate odor |
| c) Odour Threshold:                              |                                       | no data available                    |
| d) pH  |                                       | no data available                    |
| e) Melting point/freezing point                  |                                       | no data available                    |
| f) Initial boiling point and boiling range       |                                       | no data available                    |
| g) Flash point:                                  |                                       | no data available                    |
| h) Evaporation rate:                             |                                       | no data available                    |
| i) Flammability (solid, gas)                     |                                       | no data available                    |
| j) Upper/lower flammability or explosive limits: |                                       | no data available                    |
| k) Vapour pressure:                              |                                       | no data available                    |
| l) Vapour density:                               |                                       | no data available                    |
| m) Relative density                              |                                       | 1.95-2.05 g/cm <sup>3</sup> (20°C)   |
| n) Water solubility                              |                                       | insoluble                            |
| o) Partition coefficient: noctanol/water:        |                                       | no data available                    |
| p) Autoignition temperature:                     |                                       | no data available                    |
| q) Decomposition temperature:                    |                                       | no data available                    |
| r) Viscosity:                                    |                                       | no data available                    |
| s) Explosive properties:                         |                                       | no data available                    |
| t) Oxidizing properties:                         |                                       | no data available                    |

**9.2 Other safety information**

no data available

**10. STABILITY AND REACTIVITY**

**10.1 Reactivity**

no data available

**10.2 Chemical stability**

Stable under recommended storage conditions.

**10.3 Possibility of hazardous reactions**

no data available

**10.4 Conditions to avoid**

no data available

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### 10.5 Incompatible materials

Strong oxidizing agents

### 10.6 Hazardous decomposition products

Other decomposition products - no data available

## 11. TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

#### Acute toxicity

LD50 Oral - rat - 5000 mg/kg

#### Skin corrosion/irritation

Uncured material: prolonged or frequently repeated skin contact may cause allergic skin reactions in some individuals

#### Serious eye damage/eye irritation

no data available

#### Respiratory or skin sensitisation

no data available

#### Germ cell mutagenicity

no data available

#### Carcinogenicity

#### Reproductive toxicity

no data available

#### Specific target organ toxicity - single exposure

Inhalation - May cause respiratory irritation.

#### Specific target organ toxicity - repeated exposure

no data available

#### Aspiration hazard

no data available

## 12. ECOLOGICAL INFORMATION

### 12.1 Toxicity

no data available

### 12.2 Persistence and degradability

no data available

### 12.3 Bioaccumulative potential

no data available

### 12.4 Mobility in soil

no data available

### 12.5 Results of PBT and vPvB assessment

no data available

### 12.6 Other adverse effects

no data available

## 13. DISPOSAL CONSIDERATIONS



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H335 *May cause respiratory irritation.*  
 H400 *Very toxic to aquatic life*  
 H410 *Very toxic to aquatic life with long-lasting effects*

Xi Irritant  
 R36/37/38 Irritating to eyes, respiratory system and skin.  
 R41 Risk of serious damage to eyes  
 R43 May cause sensitisation by skin contact

**Further information**

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Prepared by Robert Chilczuk	I approve of its use on: <div style="text-align: right; margin-top: 10px;">  </div>
	1.08.2017