


DiaFil, DiaFil Capsule

Safety Data Sheet

1. PRODUCT AND MANUFACTURER INFORMATION

A. Product Name	DiaFil, DiaFil Capsule
B. Recommended use of the product and restrictions on its use	
Recommend use of the product	Composite resin for dental aesthetic restoration
Restrictions on use of the product	Use by specialists
C. Supplier Information (For imported goods, enter the information of the domestic supplier that can be contacted urgently)	
Name of Company	DiaDent Group International
Address	16-gil Osong saengmyung 4-ro, Heungdeok-gu, Chungbuk Cheongju
Emergency contact number	043-266-2315

2. HAZARDS IDENTIFICATION

A. Type of Hazard/Danger	The material is contraindicated if a person is known to be allergic to any of the ingredients of the product.
B. Warning sign items including preventive action statements	
Pictorial symbol	
Signal words	Danger(GHS07)
Hazard Statement	H317 May cause an allergic skin reaction H335 May cause respiratory irritation H413 May cause long-lasting harmful effects to aquatic life

3. COMPOSITION/INFORMATION ON INGREDIENT

Names of ingredients	Synonym	CAS No.	Content (%)
Urethane dimethacrylate	UDMA(Urethane dimethacrylate)	Proprietary	8 ~ 12
Bisphenol A glycidyl methacrylate	Bis-GMA	1565-94-2	6 ~ 10
Triethylene glycol dimethacrylate	TEGDMA	109-16-0	1 ~ 4
Barium alumino silicate	Barium aluminosilicate	Proprietary	65 ~ 75
Silicon dioxide	Silicon dioxide	112945-52-5	5 ~ 10
Camphorquinone	7,7-trimethyl-3-dione(+/-)-bicyclo[2.2.1]heptane-1(C amphorquinone))	10373-78-1	0.01 ~ 0.2
Dibutyl hydroxy toluene	2,6-di-butyl-4-Methylphenol(BHT)	128-37-0	0.001 ~ 0.02
Iron oxide	Iron Oxide	-	0.0001~0.01

4. FIRST AID MEASURES

A. When entered into eyes	Remove contact lenses and wash with plenty of water. If symptoms persist, seek medical attention. In case of contact with substance, immediately wash skin and eyes with running water for more than 20 minutes.
B. When contacted with skin	Wash the skin with soap and water.
C. When inhaled	Move to a place with fresh air. If you are not feeling well, consult a doctor.
D. When consumed	Rinse your mouth and get medical attention if you are not feeling well.
E. Other medical precautions	Have medical personnel perceive the material and take protective measures.

5. FIRE FIGHTING MEASURES

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| A. a suitable (improper) extinguishing agent | A fire extinguishing agent suitable for common combustible materials, such as water or foam. |
| B. specific hazards arising from chemicals | Does not occur |

6. ACCIDENTAL RELEASE MEASURES

Use an absorbent material to wipe clean.

7. HANDLING AND STORAGE

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| Safe handling and storage | Use for only professional personnel.
Use sanitary gloves and tools at the place of treatment.
Do not consume or inhale the product.
Store at 2~27°C/35~80°F
Avoid direct sunlight. |
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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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| A. Appropriate engineering management | Use local exhaust or do other engineering management to control the air level below the exposure standard. |
| B. Personal protective equipments | safety goggles and gloves |

9. PHYSICAL/CHEMICAL PROPERTIES

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|--|-------------------|
| A. External | |
| Composition | Paste |
| Color | Tooth Colored |
| B. Odor | Mild acrylic odor |
| C. Odor Threshold | No data |
| D. pH | No data |
| E. Melting point / Freezing point | No data |
| F. Initial boiling point and boiling point range | No data |
| G. Flash point | No data |
| H. Evaporation rate | No data |
| I. Flammability (solid, gas) | No data |
| J. Upper / lower limit of ignition or explosion | No data |
| K. Vapor pressure | No data |
| L. Solubility | No data |
| M. Vaport density | No data |
| N. Specific gravity | 2.073~2.075 |
| O. n-octanol / water partition coefficient | No data |
| P. Natural ignition temperature | No data |
| Q. Decomposition temperature | No data |
| R. Viscosity | No data |
| S. Molecular Weight | No data |

10. STABILITY AND REACTIVITY

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|---|---------------------------------------|
| A. Chemical Stability and Possibility of Hazardous Reaction | Not applicable |
| B. Conditions to avoid | Avoid direct light or water exposure. |

11. TOXICOLOGICAL INFORMATION

Oral mucosa irritation	No significant clinical signs was observed(hamster)
Maximization Sensitization	No significant clinical signs was observed
Acute systemic toxicity	No significant clinical signs was observed(Mouse)

12. ECOLOGICAL INFORMATION

No ecological problems to be anticipated if properly handled and used.

13. DISPOSAL CONSIDERATION

A. Disposal methods	Dispose of contents and containers in accordance with the regulations, if specified in the Waste Management Act. Discard the container (as specified in the applicable regulations).
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14. TRANSPORT INFORMATION

A. UN No. DOT, ADR, IMDG, IATA	Not a regulated substance.
B. Proper shipment name DOT, ADR, IMDG, IATA	Not a regulated substance.
C. Risk level in transportation DOT, ADR, IMDG, IATA	Not a regulated substance.
D. Container level DOT, ADR, IMDG, IATA	Not a regulated substance.
E. Marine pollutants	Not applicable.
F. Special safety measures required or required by the user to know regarding transport or means of transport	Protect from water, heat or light.

Product is not classified as a dangerous good for transport.

15. REGULATORY INFORMATION

The product is a medical device according to the EC-directive 93/42/EEC.

This product is classified as a medical device under KFDA, FDA.

This product does not require classification as Dangerous Goods.

16. OTHER INFORMATION

The above mentioned data correspond to our present state of knowledge and experience. The safety data sheet serves as description of the products in regard to necessary safety measures. The indications do not have the meaning of guarantees on properties.

A. Date of initial preparation	2018-10-04
B. Number of revisions and date of final revision	
Number of revisions	2
Date of final revision	2020-05-06

C. Others

○ The information and recommendations are taken from sources (raw material SDS(s) and manufacturer's knowledge) believed to be accurate and reliable. It is intended to describe the product according to various safety requirements; however, the manufacturer makes no warranty with respect to the accuracy and completeness of the information or the suitability of the recommendation and assumes no liability to any user thereof.