

SAFETY DATA SHEETS

This SDS packet was issued with item:

071253079

N/A


DiaFil Flow

Safety Data Sheet

1. PRODUCT AND MANUFACTURER INFORMATION

| | |
|---|---|
| A. Product Name | DiaFil Flow |
| 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 | 15~20 |
| Bisphenol A Ethoxylates Dimethacrylate | Ethoxylates (4) Bisphenol A Dimethacrylate | 41637-38-1 | 15~20 |
| Barium alumino silicate | Barium aluminosilicate | Proprietary | 50 ~ 60 |
| 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 | - | 0.0001~0.05 |

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

- | | |
|--|--|
| 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

- | | |
|---------------------------|--|
| 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. |
|---------------------------|--|

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

- | | |
|---------------------------------------|--|
| 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

- | | |
|--|-------------------|
| 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 |
| O. Gravity | 1.81~1.82 |
| P. n-octanol / water partition coefficient | No data |
| Q. Natural ignition temperature | No data |
| R. Decomposition temperature | No data |
| S. Viscosity | No data |
| T. Molecular Weight | No data |

10. STABILITY AND REACTIVITY

- | | |
|---|---------------------------------------|
| 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).

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
- 2017-11-22
- 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.