

Safety Data Sheet

1. PRODUCT AND MANUFACTURER INFORMATION

- A. Product Name DIA-ROOT BIO Sealer
- B. Recommended use of the product and restrictions on its use
- Recommend use of the product Root canal filler, endodontic, sealer
 - Restrictions on use of the product **For Dental Professional Use Only**
- 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, Osongsaengmyeong 4-ro, Osong-Eup, Heungdeok-Gu,
Cheongju-Si, Chungcheongbuk-Do,
Republic of Korea
 - Emergency contact number 82-43-266-2315
- D. Importer Information
- Name of Company **DiaDent Group International Inc.**
 - Address **#380 - 8210 Ross Street
Vancouver, BC, Canada, V5X 0L1**
 - Emergency contact number **1-604-451-8851**
 - Email **diadent@diadent.com**

2. HAZARDS IDENTIFICATION

- A. Type of Hazard-Danger Serious eye damage / eye irritation : Class2
- B. Warning sign items including preventive action statements
- Pictorial symbol 
 - Signal words Danger(GHS07)
 - Hazard Statement H302 Harmful if swallowed

2. HAZARDS IDENTIFICATION

H317 May cause an allergic skin reaction

H319 Causes serious eye irritation

- Precautionary Statements

- Prevention

P270 Do not eat, drink or smoke when using this product.

P280 Wear protective gloves / protective clothing / eye protection / face protection.

- Response

P301+P312 If swallowed, get medical attention.

P305+P351+P338 If in eyes : Rinse cautiously with water for several minutes. If possible, remove the contact lenses. Keep washing.

P330 Rinse mouth.

P337+P313 If eye irritation persists, get medical advice / attention.

- Storage

Store in a dry, cool place (15-25 °C/ 59-77 °F)

- Disposal

P501 Dispose of contents container (according to the description in the related regulation)

C. Other hazards

- Calcium silicate

Health

1

Fire

0

Responsive

0

- Calcium aluminate

Health

1

Fire

N/A

Responsive

0

- Ytterbium trifluoride

Health

N/A

Fire

N/A

2. HAZARDS IDENTIFICATION

Responsive	N/A
- Zirconium dioxide	
Health	0
Fire	1
Responsive	0
- Polyethylene glycol	
Health	0
Fire	1
Responsive	0

3. COMPOSITION/INFORMATION ON INGREDIENT

Names of ingredients	Synonym	CAS No.	Content (%)
Calcium silicate	-	-	0 ~ 5
Calcium aluminate	-	65997-16-2	20 ~ 50
Ytterbium trifluoride	-	13760-80-0	10 ~ 40
Zirconium dioxide	-	1314-23-4	0 ~ 10
Polyethylene glycol	-	25322-68-3	5 ~ 20

4. FIRST AID MEASURES

A. When entered into eyes	If in eyes : Rinse cautiously with water for several minutes. If possible, remove the contact lenses. If eye irritation persists, get medical advice / attention.
B. When contacted with skin	Get urgent medical attention In case of contact with material, rinse skin and eyes immediately with running water for at least 20 minutes. Prevent spread of contaminated areas in case of minor skin contact
C. When inhaled	Move to fresh air. If you do not feel well, consult a doctor.

4. FIRST AID MEASURES

	Keep warm and stable
D. When eaten	If swallowed, get medical attention. Rinse mouth. In case of inhalation or inhalation of substances, do not use artificial respiration by oral cavity method and use appropriate respiratory medical equipment.
E. Other medical precautions	Ensure medical personnel are aware of the material and take protective measures.

5. FIRE FIGHTING MEASURES

A. suitable (improper) extinguishing agent	Use alcohol foam, carbon dioxide or water spray. Use dry sand or earth for asphyxiation.
B. Specific hazards arising from chemicals	Pyrolysis or combustion may produce irritating and very toxic gases while burning. Container may explode when heated Some can burn but do not ignite easily. Inflammable, the material itself does not burn, but may decompose on heating to produce corrosive / toxic fumes
C. Special protective equipment and precautions for firefighters	Rescuers should wear appropriate protective equipment. Extinguish area to keep safe

6. ACIDENTAL RELEASE MEASURES

Avoid inhalation and wipe up spills.

7. HANDLING AND STORAGE

Safe handling and storage	Store in a dry, cool place Store at 15~25°C/59~77°F. Use sanitary gloves and tools at the treatment site. Do not eat or inhale this product.
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7. HANDLING AND STORAGE

Only use by professionals.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

A. Appropriate engineering management	In case of generating dust, fume or mist, ventilate to keep air pollution below exposure standard.
B. Personal protective equipment	Wear respiratory protection and gloves.

9. PHYSICAL/CHEMICAL PROPERTIES

A. External	
- Composition	Paste
- Color	White
B. Odor	Odorless
C. Odor Threshold	No data
D. pH	> 10
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	0.95%
M. Vapor density	No data
N. Specific gravity	2.5
O. n-octanol / water partition coefficient	No data
P. Natural ignition temperature	No data
Q. Decomposition temperature	No data

9. PHYSICAL/CHEMICAL PROPERTIES

R. Viscosity	57cP(at 25°C)
S. Molecular Weight	No data

10. STABILITY AND REACTIVITY

A. Chemical Stability and Possibility of Hazardous Reaction	No data
B. Conditions to avoid	Avoid direct moisture exposure.

11. TOXICOLOGICAL INFORMATION

A. Oral mucosa irritation	No significant clinical signs was observed(hamster).
B. Maximization Sensitization	No significant clinical signs was observed.
C. Acute systemic toxicity	No significant clinical signs was observed(Mouse).
D. Bacterial reverse mutation	No significant clinical signs was observed.
E. Mammalian erythrocyte micronucleus	No significant clinical signs was observed.
F. In vitro mammalian chromosomal aberration	No significant clinical signs was observed.
G. Pyrogen	No significant clinical signs was observed.
H. Oral mucosa irritation	No significant clinical signs was observed(hamster).

12. ECOLOGICAL INFORMATION

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

13. DISPOSAL CONSIDERATION

A. Disposal methods	Dispose of contents container (according to the description in the related regulation).
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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.

14. TRANSPORT INFORMATION

C. Risk level in transportation	Not a regulated substance.
DOT, ADR, IMDG, IATA	
D. Container level	Not a regulated substance.
DOT, ADR, IMDG, IATA	
E. Marine pollutants	No data
F. Special safety measures required or required by the user to know regarding transport or means of transport	Protect from water. Product is not classified as a dangerous good for transport.

15. REGULATORY INFORMATION

- **The product is a medical device according to the Medical Device Regulation (MDR) (EU 2017/745)**
- This product is classified as a medical device under KFDA, **FDA. Health Canada**
- 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	Nov 02, 2019
B. Number of revisions and date of final revision	
- Number of revisions	04
- Date of final revision	Nov. 20, 2025
C. Others	Not applicable.

○ **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.**