DiaDent

Safety Data Sheet

1. PRODUCT AND MANUFACTURER INFORMATION

A. Product Name — Dia-X Sil Bite

B. Recommended use of the product and restrictions on its use

- Recommend use of the product — Dental impression materials
- 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 — 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

2. HAZARDS IDENTIFICATION

	H335 May cause respiratory irritation
- Precautionary Statements	
- Prevention	P262 Do not get in eyes, on skin, or on clothing.
	P264 Wash thoroughly after handling

3. COMPOSITION/INFORMATION ON INGREDIENT

	Names of ingredients	Synonym	CAS No.	Content (%)
Catalyst	Siloxanes and Silicones, di-Me, vinyl group-terminated	Polydimethylsiloxane, vinyldimethylsiloxy terminated	68083-19-2	35 ~ 55
	Silica (Crystalline Quartz)	Crystalline Silica in the form of Quartz	14808-60-7	50 ~ 70
	Platinum, 1,3-diethenyl-1,1,3,3-tetramethyldisiloxane complexes	-	68478-92-2	0.1 ~ 3
Base	Siloxanes and Silicones, di-Me, vinyl group-terminated	Polydimethylsiloxane, vinyldimethylsiloxy terminated	68083-19-2	25 ~ 45
	Silica (Crystalline Quartz)	Crystalline Silica in the form of Quartz	14808-60-7	50 ~ 70
	Siloxanes and silicones, Di-Me, Me Hydrogen	Siloxane and silicone, dimethyl, methyl hydrogen	68037-59-2	1 ~ 10
	Yellow pigment	-	-	~ 1

4. FIRST AID MEASURES

A. When entered into eyes	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. ACIDENTAL RELEASE MEASURES

Use an absorbent material to wipe clean.

7. HANDLING AND STORAGE

Safe handling and storage	After use, store the cartridge with the protective cap securely attached. The cap functions as a seal for the cartridge. Store in a cool, shaded place at 2 ~ 25°C Storage temperature may affect product performance. For optimal results, allow the product to reach room temperature before use. After use, seal the product securely and dispose of it as regulated medical waste in accordance with local regulations.

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 equipment	safety goggles and gloves

9. PHYSICAL/CHEMICAL PROPERTIES

A. Appearance	
- Physical state	Rubber-Crepe
- Color	White(Catalyst), Yellow(Base)
B. Odor	No data

9. PHYSICAL/CHEMICAL PROPERTIES

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	>100°C (Seta Closed Cup)
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	Insoluble
M. Vapor density	No data
N. Specific gravity	1.55 – 1.65
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

A. Chemical Stability and Possibility of Hazardous Reaction	Stable under normal conditions.
B. Conditions to avoid	May release formaldehyde above 150°C.

11. TOXICOLOGICAL INFORMATION

A. Cytotoxicity(MTT assay)	No significant clinical signs was observed
B. Skin Sensitization Test(GPMT)	No significant clinical signs was observed
C. Oral Mucosa Irritation Test	No significant clinical signs was observed(Syrian Hamster)

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.

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. 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, **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	May. 21, 2025
B. Number of revisions and date of final revision	
- Number of revisions	01

16. OTHER INFORMATION

- Date of final revision	Feb. 13, 2026
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.**