DiaPex Plus
Safety Data Sheet

1. PRODUCT AND MANUFACTURER INFORMATION

A. Product Name	DiaPex Plus
B. Recommended use of the product and restrictions on its use	
Recommend use of the product	Oinment type root canal filling material
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, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Korea, 28161
Emergency contact number	+82-43-266-2315

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 — Warning(GHS07, GHS08))

3. COMPOSITION/INFORMATION ON INGREDIENT

Names of ingredients	Synonym	CAS No.	Content (%)
Iodoform	Triiodomethane	75-47-8	35-40
Calcium hydroxide		1305-62-0	20-30
Polydimethylsiloxane		63148-62-9	20-30

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	Water fog, Dry powder, 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	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℃/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	Yellow
B. Odor	mild 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	1.7~1.8
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	Not applicable
B. Conditions to avoid	Avoid direct light or water exposure. If exposed to light, yellowing may occur.

11. TOXICOLOGICAL INFORMATION

Cytotoxicity	No significant clinical signs was observed(MTT)
Maximization Sensitization	No significant clinical signs was observed(Guinea pig)
Acute systemic toxicity	No significant clinical signs was observed(Mouse)
Pyrogen	No significant clinical signs was observed(rabbit)

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	2018-03-19
B. Number of revisions and date of final revision	
Number of revisions	1
Date of final revision	2020-01-30
C. Others	

○ The information and recommendations are taken from sources (raw material SDS(s) and manufacturer's knowledge) belived 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.