

# DiaPex Plus Material 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

Restrictions on use of the product

Ointment type root canal filling material

Use by specialists

C. Supplier Information

#### Manufacturer:

DiaDent Group International

16-gil Osong saengmyung 4-ro, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do,

Republic of Korea 28161

Tel: + 82 43 266 2315

#### Importer:

Ivoclar Vivadent Ltd.

12 Omega St, Rosedale, Auckland

New Zealand

Tel: + 64 9 914 9999 / Fax: + 64 9 914 9990

· Further information obtainable from :

Regulatory Affairs

sds@ivoclarvivadent.com · Emergency telephone number: 0800 764 766

(National Poison Centre - 24 hours/7days)

#### 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

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 (%)
lodoform	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. 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 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

B. Conditions to avoid

Not applicable

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. Not a regulated substance.

DOT, ADR, IMDG, IATA

B. Proper shipment name Not a regulated substance.

DOT, ADR, IMDG, IATA

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 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

A. Regulations according to the Industrial Safety and Health Act N/A B. Regulations according to the Toxic Chemicals Control Act N/A C. Regulations according to the Safety Control of Dangerous Substances Act N/A

D. Regulations according to the Wastes Control Act N/A

E. Other regulations according to domestic and foreign laws

- Follow the regulations of the FDA.

F. Safety, health and environmental regulations/legislation specific for the substance or mixture.

- Classified as Hazardous according to the criteria of the National Occupational Health and Safety Commission (NOHSC) approved criteria for the classifying hazardous substances [NOHSC: 1008] 3rd edition.

- Standard for the Uniform Scheduling of Medicines and Poisons.

- Carcinogen classification under WHS Regulation 2011, Schedule 10.

- Notification status in accordance with section 3 and current national legislation.

- HSNO Approva I: HSR003008, HSR006510, HSR006679

- EPA NZ Classes of hazardous properties:

Classification 6.1D (All) Substances that are acutely toxic

Classification 6.3A Substances that are irritating to the skin

Classification 6.4A Substances that are irritating to the eye

Classification 9.1B (All) Substances that are very ecotoxic in the aquatic environment

Classification 9.3B Substances that are ecotoxic to terrestrial vertebrates

Classification 8.2C Substances that are corrosive to dermal tissue

Classification 8.3A Substances that are corrosive to ocular tissue

Classification 9.1D (All) Substances that are slightly harmful in the aquatic environment or are otherwise designed for biocidal action

# 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

C. Others

1

Date of final revision 2020-06-01

Dia Dent

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○ 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.