

1. Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name : Metapex

Product code : D1MPX00

1.2. Relevant identified uses of the substance or mixture and uses advised against

Temporary filling material for infected root canals

1.3. Details of the supplier of the safety data sheet

Registered company name : METABIOMED CO., LTD.

Address : Head Office & Osong Factory) 270, Osongsaengmyeong1-ro, Osong-eup, Heungdeok-gu,
Cheongju-si, Chungcheongbuk-do, Korea

Telephone : (82-43) 216-0433, 0434

Fax : (82-43) 216-0438

e-mail : info@meta-biomed.com

Manufacturer : METABIOMED CO., LTD.

1.4. Emergency telephone number

(82-43) 216-0433, 0434

2. Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

Eye irritation, Category 2(Eye Irrit. 2, H319)

Skin irritation, Category 2(Skin Irrit. 2, H315)

2.2. Label elements

Labelling according to Regulation (EC) No 1272/2008

* GHS label elements including precautionary statements

- Hazard Pictograms



GHS07

- Signal word : Warning

- Hazard statement(s) : H315 Causes skin irritation.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation

- Precautionary Statement(s) : P261 Avoid breathing vapours.



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- Prevention P264 Wash...thoroughly after handling
P271 Use only outdoors or in a well-ventilated area
P280 Wear protective gloves/protective clothing/eye protection/ face protection
- Response : P302+P352 IF ON SKIN: Wash with plenty of water.
P304+P340 IF INHALED: Remove victim to fresh air and keep at rest in apposition comfortable for breathing.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.
P310 Immediately call a POISON CENTER or doctor/physician.
P321 Provide specific treatment according to the situation.
P363 Wash contaminated clothing before reuse.
P405 Store locked up
- Disposal : P501 Dispose of contents/container according to the related regulations

2.3. Other hazards (according to the NFPA Rating System)

- Health : 2
- Flammability : 1
- Reactivity : 1

3. Composition/information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

Chemical Name	CAS No.	EC No.	Wt.%	Classification according to Directive 67/548/EEC	Classification according to Regulation(EC) No 1272/2008[CLP]
Iodoform	75-47-8	200-874-5	<37	R20/21/22 R36/37/38	H315, H319, H335
Calcium hydroxide	1305-62-0	215-137-3	<36	C;R34	H319, H317, H412, H335, H314, H370, H290, H302, H312
Polydimethylsiloxane	63148-62-		<27		



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4. First aids measures

4.1. Description of first aid measures

- Eyes : Get medical aid immediately if discomfort or irritation persists
- Skin : Consult physician immediately if you feel discomfort.
- Inhalation : Remove patient from exposure to fresh air immediately. Administer approved oxygen supply if breathing is difficult and get medical aid immediately.
- Ingestion : Seek immediate medical help.

4.2. Most important symptoms and effects, both acute and delayed

- Eyes : Causes eye irritation.
- Skin : Causes skin irritation.
- Inhalation : None expected for this product
- Ingestion : Ingestion of this material can cause mouth, throat, esophageal, and gastrointestinal tract irritation.

4.3. Indication of any immediate medical attention and special treatment needed

- Notes to physician : Corrosive

5. Fire fighting measures

5.1. Extinguishing media

- Extinguishing media : Please see Fire Fighting Equipment under Section 5.3.

5.2. Special hazards arising from the substance or mixture

- Hazardous combustion products : None Known.
- Explosion hazards : Not Determined
- Fire explosion : Not Determined
- Sensitive to static discharge : Not Determined
- Sensitivity to impact : Not Determined

5.3. Advice for firefighters

- Fire fighting procedures : General: Evacuate all personnel; use protective equipment for fire-fighting. Use self-contained breathing apparatus when product is involved in fire.
- Fire fighting equipment : Non-combustible

6. Accidental release measures



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6.1. Personal precautions, protective equipment and emergency procedures

Give special attention to chemical materials and conditions that must be avoided.

6.2. Environmental precautions

Prevent the inflow of this product to waterways, drains, basements, and confined spaces.

6.3. Methods and material for containment and cleaning up

Clean up spills immediately, observing precautions in Protective Equipment section.

6.4. Reference to other sections

Not Applicable

7. Handling and storage

7.1. Precautions for safe handling

Follow all prevention measures on the SDS/labels.

Handle and store with care.

Give special attention to chemical materials and conditions that must be avoided.

Wear personal protective equipment while handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Keep out of reach of children. Keep container closed. Store in cool place.

7.3. Specific end use(s)

Use only professional dentist

8. Exposure controls and personal protection

8.1. Control parameters

Not determined

8.2. Exposure controls

- Eye protection : Wear safety glasses.
- Skin protection : Wear suitable protective clothing and gloves.
- Respiratory protection : Good general ventilation should be sufficient to control airborne levels.

9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

- Appearance	: Paste	- Vapor pressure	: N/A
- Odor	: Slight odor of hospital	- Vapor density	: N/A
- Color	: Yellow	- Relative density	: 1.9~2.0g/cm ³
- pH	: N/A	- Solubility(ies)	: Soluble
		- Partition coefficient :	: N/A



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|--|-------|-----------------------------|-------|
| - Melting/freezing point | : N/A | n-octanol/water | |
| - Initial boiling point and boiling range | : N/A | - Auto-ignition temperature | : N/A |
| - Flash point | : N/A | - Decomposition temperature | |
| - Evaporation rate | : N/A | - Viscosity | : N/A |
| - Flammability(solid, gas) | : N/A | - Explosive properties | : N/A |
| - Upper/lower flammability or explosive limits | : N/A | - Oxidising properties | : N/A |

9.2. Other information

None

10. Stability and reactivity

10.1. Reactivity

Stable

10.2. Chemical stability

Stable when stored and handled under recommended conditions.

10.3. Possibility of hazardous reactions

None

10.4. Conditions to avoid

Extreme heat, direct light and humidity

10.5 Incompatible materials

N/A

10.6. Hazardous decomposition products

Iodine

11. Toxicological information

11.1. Information on toxicological effects

- | | |
|---|--|
| Acute toxicity | Device is biocompatible when used as directed by dental professionals per ISO 10993-1. |
| Irritation and corrosiveness | May be irritating to eyes or skin on contact |
| Sensitization | N/A |
| Sub-acute, sub chronic and prolonged toxicity | None known |
| Carcinogenicity, Mutagenicity, | None known |
| Reproductive toxicity | |



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Empirical data	None known
Clinical experience	None known

12. Ecological information

12.1. Toxicity

- Toxicity : Not determined
- Aquatic toxicity(acute) : Not determined

12.2. Persistence and degradability

Not determined

12.3. Bioaccumulative potential

Not determined

12.4. Mobility in soil

Not determined

12.5. Results of PBT and vPvB assessment

Not determined

12.6. Other adverse effects

None known

13. Disposal considerations

13.1. Waste treatment methods

Dispose of in compliance with governmental regulation.(Council Directive 75/442/EEC(1975))

14. Transport information

4.1. UN Number

N/A

14.2. UN proper shipping name

N/A

14.3. Transport hazard class(es)

N/A



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14.4. Packing Group

N/A

14.5. Environmental hazards

N/A

14.6. Special precautions for user

- ADR - road : N/A

- RID - rail : N/A

- IMDG - sea : N/A

- IATA - air : N/A

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Transport in bulk : N/A

15. Regulatory information

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

RoHS : Please refer to Medical Devices Directive 93/42/EEC

15.2. Chemical safety assessment

Chemical safety assessment : See Section 11

16. Other information

The information contained in the Safety data sheet is correct to the best of our knowledge at the date of issue. It is intended as a guide for the safe use, handling, disposal, storage and transportation and is not intended as warranty or as a specification. The information relates only to the product specified and may not be suitable for combinations with other materials or in processes other than those specifically described herein.

HISTORY

- **Date of creation** : 19-10-2015
- **Revision number and Revision date**
 - * Revision number : 6
 - * Date of last revision : 02-01-2023
- **Prepared by** : META BIOMED CO., LTD.