

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

#### 1.1. Product identifier

Product name : MD-Cleanser

Product code : D1MCL00

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

Root Canal Cleaning and Smear Layer Removing Solution

#### 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**

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

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

#### 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.

- Precautionary Statement(s) : P305+P351+P338 IF IN EYES: Rinse cautiously with water for several  
Prevention minutes. Remove contact lenses if present and easy to do. Continue  
rinsing.



# Material Safety Data Sheet

- MD-Cleanser -

METABIOMED CO., LTD.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

- Response

- Disposal : P501 Dispose of contents/container according to the related regulations

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

- Health : 1
- Flammability : 0
- Reactivity : 0

## 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]
EDTA(Ethylene diamine tetraacetic acid)	60-00-4		17	Xi;R36/37/38	GHS07 Warning H315,H319

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



# Material Safety Data Sheet

- MD-Cleanser -

METABIOMED CO., LTD.

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

No further relevant information available

## 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

### 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.



# Material Safety Data Sheet

- MD-Cleanser -

METABIOMED CO., LTD.

## 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                                   | : liquid          | - Vapor pressure            | : 1 atm   |
| - Odor   | : Odorless:       | - Vapor density             | : N/A     |
| - Color  | : Colorless       | - Relative density          | : 0.976   |
| - pH   | : 6 to 8(at 25°C) | - Solubility(ies)           | : Soluble |
| - Melting/freezing point                       | : -3°C            | - Partition coefficient :   | : N/A     |
| - Initial boiling point and boiling range      | : 103°C           | n-octanol/water             |           |
| - Flash point                                  | : N/A             | - Auto-ignition temperature | : N/A     |
| - Evaporation rate                             | : N/A             | - Decomposition temperature |           |
| - Flammability(solid, gas)                     | : N/A             | - Viscosity                 | : 1~2 cps |
| - Upper/lower flammability or explosive limits | : N/A             | - Explosive properties      | : 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.



# Material Safety Data Sheet

- MD-Cleanser -

METABIOMED CO., LTD.

## 10.3. Possibility of hazardous reactions

None

## 10.4. Conditions to avoid

Heat

## 10.5 Incompatible materials

Strong oxidizing agents

## 10.6. Hazardous decomposition products

None known

## 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, Reproductive toxicity	None known
Empirical data	N/A
Clinical experience	EDTA, 17% Solution has been on the market in the US and internationally for more than 15 years. Using EDTA 17% Solution as part of root canal treatment is a well-established (20+ years), industry-accepted, endodontic practice. EDTA is considered to be safe and effective treatment in the hands of a dental professional.

## 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



# Material Safety Data Sheet

- MD-Cleanser -

METABIOMED CO., LTD.

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

Classification information on transportation of hazardous materials not available

### 14.2. UN proper shipping name

N/A

### 14.3. Transport hazard class(es)

N/A

### 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



# Material Safety Data Sheet

- MD-Cleanser -

METABIOMED CO., LTD.

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 : 4
  - \* Date of last revision : 02-01-2023
- **Prepared by** : META BIOMED CO., LTD.