

Material Safety Data Sheet

– ENDOSEAL MTA –

Rev.1
27 April, 2018

1. Product and Company Identification

- Product name : Endoseal MTA
- Chemical Name/Classification : Root Canal Filling Material
- Manufacturer : MARUCHI
- Manufacturer/Supplier Address : 2-208, 42-10, Taejanggongdan-gil, Wonju-si, Gangwon-do, Korea 26311
- Manufacturer/Supplier Phone Number : +82-33-734-0330
- Manufacturer/Supplier e-mail Address : help@endocem.com

2. Composition and Information on Ingredients

Components	CAS No.	wt %
Natural Pure Cement	-	27.81
Zirconium Dioxide Bismuth Trioxide	1314-23-4 1304-76-3	47.28
Thickening agents	-	24.91

3. Hazards Identification

- Most Important Hazard : When product comes into contact with the skin, a strongly alkaline solution is produce.
- Inhalation : Frequent inhalation of large quantities of product over a long period increases the risk of the onset of respiratory disease. Some components of product may cause headache, nausea, dizziness and drowsiness.
- Skin : Some components of product may cause eye irritation with direct contact.
- Ingestion : Some components of product may be harmful if swallowed.
- Hazard Statements : According to CLP regulation, this product is classified as :
H315 - Causes skin irritation
H317 - May cause an allergic skin reaction
H318 - May cause serious eye damage
H335 - May cause respiratory irritation

4. First-Aid Measures

- Inhalation : Take the individual into the fresh air. Consult a doctor if persistent irritation occurs, or in case of the subsequent appearance of discomfort, coughing or any other symptoms. And in case of inhalation of gross amounts of product, immediate medical attention shall be required.

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- Ingestion : Do not induce vomiting. If the person is conscious, rinse the mouth with water and give the person 1 or 2 glasses of water. Call a doctor immediately or an anti-poison center. (Never give anything by mouth to an unconscious person.
- Skin Contact : Wash off with cool water and PH-neutral soap. And contact with wet skin leads to thickening of the skin and the appearance of fissures or cracks. Prolonged contact combined with abrasions may cause severe burns. In case of irritation, redness and burns, consult a doctor.
- Eye Contact : Do not rub in order to avoid further damage. If need be, remove contact lenses, then Immediately flush eyes thoroughly with plenty of clean water for at least 15 minutes, keeping the eyelids wide apart in order to eliminate any residue. And direct contact with eyes may damage the cornea due to rubbing, and cause immediate or subsequent irritation or inflammation. Consult an occupational doctor or ophthalmologist.

5. Fire-fighting Measures

- Fire-fighting Procedures : Wear breathing apparatus plus protective gloves for fire only. Prevent, by any means available, spillage from entering drains or water courses. Use fire-fighting procedures suitable for surrounding area.
- Specific Hazards Arising from the chemical : Most of components in product are neither combustible, nor explosive and will not aid or feed the combustion of other materials. But one component is combustible material. Therefore containers may explode when overheated. Keep product away from heat and sources of ignition.
- Hazardous combustion products : No information available
- Unusual fire and explosion hazards : No information available
- Suitable Extinguishing Media : Use water spray, alcohol-resistant foam, and dry chemical of carbon dioxide.
- Precautions for Fire Fighters : Thermal decomposition can lead to release of irritating gases and vapors

6. Accidental Release Measures

- Personal Precautions : Avoid inhalation and contact with skin and eyes. Use suitable personal protective equipment as described in section 8. Ensure adequate ventilation. Remove all sources of ignition.

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- Environmental Precautions : Clean up significant quantities and place in an appropriate container.
Allow the material to “dry” before disposal.
Do not allow product to spread into the environment.
Do not pour down the drains, into the sewer system or into watercourses.
- Methods for Cleaning up : Dispose of waste material in accordance with local, state and federal regulations.
IF DRY: Use dry clean up procedures and avoid generating dust. Collect residues and place in a suitable container.
IF WET: Vacuum/shovel up and place in a suitable container.
ALWAYS: Wash contaminated area down with large amounts of water by preventing runoff into drains.

7. Handling and Storage

- Handling : Avoid all personal contact, including inhalation.
Wear protective clothing when risk of exposure occurs.
Use in a well-ventilated area.
Promptly remove dusty or wet clothing.
Launder before reuse.
Use local exhaust ventilation to minimize airborne dusts.
Avoid contact with ammonia, ammonia nitrate and chlorine or chlorine containing items.
- Storage : Store in dry area.
Normal temperatures and pressures do not affect the material.
Store away from food and drinks.
Do not store near ammonia, ammonia nitrate and chlorine or chlorine containing items.

8. Exposure Controls / Personal Protection

- Respiratory Protection : Under conditions of frequent use or heavy exposure, respiratory protection may be needed
Use suitable anti-dust mask.
Use local exhaust ventilation to control dust levels below applicable exposure limits and to minimize airborne dusts.
- Skin : Wear latex or nitrile gloves.
Wear impervious protective clothing, including lab coat, apron or coveralls, as appropriate to prevent skin contact.
Promptly remove clothing with dry product or clothing dampened with moisture mixed with the product.
Laundry before reuse.
- Eyes : Wear safety glasses with the eyes.
In extremely dusty environments, wear tight-fitting unvented or indirectly vented goggles to avoid eye irritation or injury.
Contact lenses should not be worn when handling product.

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9. Physical and Chemical Properties

- Physical State	: Paste Type	- Solubility	: 0.7%
- Color	: Gray	- PH	: 12 to 13
- Odor	: Amine-like	- Flash Point	: N/A
- Boiling Point	: N/A	- Auto Ignition Tem.	: N/A
- Melting Point	: N/A	- Lower Explosive Limit	: N/A
- Vapor Pressure	: N/A	- Upper Explosive Limit	: N/A
- Vapor Density	: N/A	- Evaporation rate	: N/A

10. Stability and Reactivity

- Stability	: Stable
- Conditions to Avoid	: Avoid unintentional contact with air to prevent premature setting.
- Incompatibility	: Product mixed with water is alkaline (caustic/basic). Therefore It is incompatible with acids, ammonia, ammonia nitrate, ammonium salts, aluminum metal and chlorine.
- Hazardous Decomposition	: Addition of water to product results in hydration reaction and produces (caustic) calcium hydroxide.
- Hazardous Polymerization	: Hazardous polymerization will not occur.

11. Toxicological information

- Cytotoxicity(MTT) ISO10993-5(2009)	: Cell vitality should be more than 70%. Result - Cell vitality of 50% extract: ≥74%, Cell vitality of 100% extract: ≥11%
- Acute Systemic Toxicity Test Report (Acute Oral Route Application) ISO10993-11(2006)	: There shall be no abnormality or death during the observation period. Result - All animal do not show symptoms of toxicity or death, and large weight decrease. OK.
- Local Lymph Node Assay, LLNA(Skin Senization) ISO10993-10(2010)	: Do not show any hypersensitivity (SI<1.6). Result - Do not show any hypersensitivity (SI<1.6). OK.
- Bacterial Reverse Mutation Test (AMES test) ISO10993-03(2003)	: The results shall be conformed to OECD guideline 471, OECD guideline for testing of chemicals – bacterial reverse mutation test (<2.0). Result - No evidence of bacterial reverse mutation by the samples. TA100 0.7-1.2, TA98 0.7-1.1. OK

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- Bone Implantation Test
ISO10993-06(2007) : There shall be no evidence of inflammation, foreign body reactions or other biological abnormalities when tested according to the standard.
Result - There was no evidence of inflammation or foreign body reaction in histological observation while the implanted specimen was compatible with surrounding tissue with adequate bone formation. OK
- Mammalian Erythrocyte
Micronucleus
ISO10993-3 : The results shall be conformed to OECD guideline 474, OECD guideline for testing of chemicals – mammalian erythrocyte micronucleus test.
Result - No evidence of influence in mammalian erythrocyte micronucleus formation by the samples. OK.

12. Ecological information

- No unusual toxicity to plants or animals has been recognized.

13. Disposal Considerations

- Disposal of Product : Do not allow product to spread into the environment.
Do not pour down the drains, into the sewer system or into watercourses.
Dispose of waste material in accordance with local, state and federal regulations.
- Disposal of Product Package : Dispose of packaging in an approved landfill or incinerator.

14. Transport information

- Shipping Name : Same as product name
- Dangerous Goods Class : None
- UN / NA Number : Not restricted
- EMS Number : None
- Packing Group : None
- Additional Shipping Information : None

15. Regulatory information

- Regulations : This Product, Endoseal MTA, is subject to declaration according to medical device directive 93/42/ECC, Australian Register of Therapeutic Goods Certificate and KGMP.
Cement clinker(Endoseal MTA Main Content) is exempt from registration (Art 2.7 (b) and Annex V.10 of REACH)

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- Date of previous MSDS : None
- MSDS Number : None

16. Other information

- Prepared by / Authorized by : Kim, Tae Ho / Byun, Won Gil
- Issue date : 27 April, 2018
- MSDS Number : None

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