Dentsply Sirona Tulsa Dental Specialties
Safety Data Sheet
Conforms with OSHA Hazard Communication Standard (CFR 29 1910.1200) HazCom 2012

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1. PRODUCT IDENTIFICATION

Trade Name (as labeled):	AH and PLUS® BIOCERAMIC ROOT CANAL SEALER
Chemical Name/Classification:	NA
Product Identifier (Part/Item Number):	AH and Plus Bioceramic Sealer Syringe Refill: AHPBIOREFILL AH and Plus Bioceramic Sealer Starter Kit: AHPBIOSEAL
U.N. Number:	NA
U.N. Dangerous Goods Classification:	NA
Recommended Use:	Permanent root canal obturation. Permanent root canal obturation. product is only to be used in a clinical or hospital environment by qualified dentists.
Restrictions on Use:	Do not use in patients allergic to any of the components of AH Plus® Bioceramic Sealer
Manufactured For:	Dentsply Sirona Tulsa Dental Specialties
Address:	608 Rolling Hills Dr. Johnson City, TN 37601
Supplier Telephone Number:	1-800-924-7393 (Product Information)
Manufacturer Name:	Maruchi
Emergency Contact Telephone Number:	1-800-262-8200
Email address:	chemtrec@chemtrec.com

2. HAZARD(s) IDENTIFICATION

Hazard Statements	Precautionary Statements

2.1. Classification of the substance or mixture
- CLP : The product is not classified.
2.2. Label elements
This product is a medical device and does not require a hazard label. The information which would have appeared on the label is shown here.
2.3. Other hazards
- PBT/vPvB PBT or vPvB

EU Classification: NA

EU Risk (R) and Safety (S) Phrases: NA

Refer to Section 16 for the full text of the EU Classifications and R Phrases.

3. COMPOSITION AND INFORMATION ON INGREDIENTS

3.1. Mixtures -CLP

Hazardous Components	C.A.S. # EC# NA	IUPAC Name	Hazard classification	WT %
Zirconium Dioxide	1314-23-4	NA	NA	50 -70
Tricalcium silicate	12168-85-3	NA	NA	5 -15
Dimethyl sulfoxide	67-68-5	NA	Aquatic Chronic 4; H413	10 -30
Lithium carbonate	NA	NA	Acute Tox. 4; H302 Skin Irrit.2; H315 Eye irrit. 2; H319	< 0.5
Thickening agents, etc.	NA	NA	NA	< 6

Refer to Section 16 for the full text of the GHS and H phrases and EU Classifications and R Phrases.

4. FIRST-AID MEASURES

Routes of Exposure	First Aid Instructions
Eye	Do not rub 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 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.
Skin	Wash off with cool water and PH-neutral soap. 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.
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. In case of inhalation of gross amounts of product, immediate medical attention shall be required.
Ingestion	Do not induce vomiting. If the person is conscious, rinse the mouth with water and give the person 1 or 2 classes of water. Call a doctor immediately or an anti-poison center. (Never give anything by mouth to an unconscious person.
Most important symptoms and effects, both acute and delayed	See section 11 for more detailed information on health effects and symptoms.
Other	NA
Note to Physicians (Treatment, Testing, and Monitoring) Indication of any immediate medical attention and special treatment needed: Medical attention/ treatments: Treat symptomatically.	

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media:	This product is not flammable. Use fire-extinguishing media appropriate for surrounding materials.
Fire Fighting Procedures:	Protective equipment for firefighters
Specific Hazards Arising from the Chemical:	During fire, gases hazardous to health may be formed
Precautions for Fire Fighters:	Selection of respiratory protection for firefighting: follow the general fire precautions indicated in the workplace.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, PPE, and Emergency Procedures: Follow precautions for safe handling described in this safety data sheet. For personal protection, see section 8.

Environmental Precautions: Avoid discharge into water courses or onto the ground.

Methods and Materials for Containment and Clean-up: F DRY: Collect residues and place in a suitable container. If WET: Wear appropriate protective equipment and Collect residues

Recommended Personal Protective Equipment for Containment and Clean-up: For personal protection, see section 8. For waste disposal, see section 13

7. HANDLING AND STORAGE

Precautions for Safe Handing: Avoid contact with eyes and prolonged skin contact. Observe good chemical hygiene practices. Ventilate well. Wash hands before breaks and before smoking, eating, or drinking.

Conditions for Safe Storage: Keep the workplace clean. Environmental precautions: Store in dry area. Normal temperatures and pressures do not affect the material. Store away from food and drinks.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational exposure limits

Chemical name	C.A.S. #	As:	Exposure Limits	Types	Notes	References
Zirconium Dioxide Zirconium compounds	1314-23-4	-	5 mg/m³ 10 mg/m³	TWA STEL	-	EH40

Occupational Exposure Limits: Control parameters
Biological Exposure Limits: NA
Appropriate Engineering Controls: Observe occupational exposure limits and minimize the risk of inhalation of vapors.
Individual Protection Measures (PPE) **Specific Eye/face Protection:** Wear goggles, safety glasses, or a face shield. **Specific Skin Protection:** Wear latex or nitrile gloves. Wear impervious protective clothing, lab coat, apron, or coveralls, as appropriate to prevent skin contact. **Specific Respiratory Protection:** Handle the product in a well-ventilated area. **Specific Thermal Hazards: NA**
Environmental Exposure Controls: DO NOT discharge into sewer or waterways.
General Hygiene Considerations and Work Practices: NA
Protective Measures During Repair and Maintenance of Contaminated Equipment: NA

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Paste / White	**Explosive limits:**	Not available
Odor:	Amine-like	**Vapor pressure:**	Not available
Odor threshold:	Not available	**Vapor density:**	Not available
pH:	12 to 13	**Relative density:**	Not available
Melting/freezing point:	Not available	**Solubility:**	<3%
Initial boiling point and range:	Not available	**Partition coefficient: n-octanol/water:**	Not available
Flash point:	Not available	**Auto-ignition temperature:**	Not available
Evaporation rate:	Not available	**Decomposition temperature:**	Not available
Flammability:	Not available	**Viscosity:**	Not available
Explosive Properties:	Not available	**Oxidizing Properties:**	Not available

10. STABILITY AND REACTIVITY

Reactivity: Hardened by reacting with moisture
Chemical Stability: Stable under normal temperature conditions. (2years)
Possibility of Hazardous Reactions: None known
Conditions to Avoid: Extremes of temperatures. (>25°C - <15°C)
Incompatible materials: Strong oxidizing substances.
Hazardous Decomposition Products: None under normal conditions.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity (Oral) Based on available data, the classification criteria are not met.
- Acute Toxicity (Dermal) Based on available data, the classification criteria are not met.
- Acute Toxicity (Inhalation) Based on available data, the classification criteria are not met.
- Skin Corrosion/Irritation Strong alkali
-Serious eye damage/irritation Based on available data; the classification criteria are not met.
- Respiratory or skin sensitization Based on available data, the classification criteria are not met.
- Germ cell mutagenicity Based on available data; the classification criteria are not met.
- Carcinogenicity Based on available data, the classification criteria are not met.
- Reproductive Toxicity Based on available data, the classification criteria are not met.
- STOT - Single exposure Based on available data, the classification criteria are not met.
- STOT - Repeated exposure Based on available data, the classification criteria are not met.
- Aspiration hazard Based on available data; the classification criteria are not met.
- Inhalation Not relevant at normal room temperatures. heated, irritating vapors may be formed.
- Skin contact Strong alkali. The product contains a small amount of sensitizing substance which may provoke an allergic reaction among sensitive individuals.
- Eye contact Strong alkali. May irritate and cause redness and pain.

-Ingestion May cause irritation to the mouth and throat.
Toxicological data LD50(oral, rat) Dimethyl sulfoxide: LD50 > 20000 ㎎/㎏ Lithium carbonate: LD50 525 ㎎/㎏, LD50(dermal rabbit) Dimethyl sulfoxide: LD50 20000~40000 ㎎/㎏ LC50(Dust, rat) Lithium carbonate: LC50 > 2.17 ㎎/ℓ 4hr
Information on other hazards - Endocrine disrupting properties: NA

12. ECOLOGICAL INFORMATION

Toxicity: - Ecotoxicity: Not classified as dangerous to the environment. Dimethyl sulfoxide: LC50(Fish) 32300 ㎎/L 96hr EC50(Crustaceans) 24600 ㎎/L 48hr EC50(Algae) 12350~25500 ㎎/L 96hr Lithium carbonate: LC50(Fish) 8.1 ㎎/ℓ 96 hr.
Persistence and Degradability: Degradability: This product mainly consists of inorganic compounds which are not biodegradable. The remaining compounds of the product are expected to be easily biodegradable.
Bio-accumulative Potential: No data available on bioaccumulation.
Mobility in Soil: No data available
Other Adverse Effects: None known
Results of PBT/vPvB Assessment: This product does not contain any PBT or vPvB substances.

13. DISPOSAL CONSIDERATIONS

Regulations: NA
Properties (Physical/Chemical) Affecting Disposal: NA
Waste Treatment Recommendations: Dispose of waste and residues in accordance with local authority requirements.

14. TRANSPORT INFORMATION

The product is not covered by international regulation on the transport of dangerous goods (IMDG, IATA, ADR/RID).

UN Identification Number: NA
UN Proper Shipping Name: NA
Transport hazard class(es): NA

Packing Group: NA
Special precautions for user: NA

15. REGULATORY INFORMATION

U.S. Federal Regulations

Comprehensive Environmental Response and Liability Act of 1980 (CERCLA): Not available

Toxic Substances Control Act (TSCA): Not available

Clean Water Act (CWA): Not available

Clean Air Act (CAA): Not available

Superfund Amendments and Reauthorization Act (SARA) Title III Information: Not available

SARA Section 311/312 (40 CFR 370) Hazard Categories: Not available

Immediate Hazard:	**NA**	**Pressure Hazard:**	**NA**
Delayed Hazard:	**NA**	**Reactivity Hazard:**	**NA**
Fire Hazard:	**NA**		

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372):

Components	C.A.S. #	WT %
NA	NA	NA

State Regulations

California: This product contains the following chemicals(s) known to the State of California to cause cancer, birth defects or reproductive harm:

Components	C.A.S. #	WT %
NA	NA	NA

International Regulations

Canadian Environmental Protection Act: NA

Canadian Workplace Hazardous Materials Information System (WHMIS): NA

European Inventory of Existing Chemicals (EINECS): NA

Chemical Safety Assessment: No chemical safety assessment has been carried out

16. OTHER INFORMATION

Full text of Classification abbreviations used in Section 2 and 3: The user must be instructed in the proper work procedure and be familiar with the contents of these instructions.

Abbreviations and acronyms used in the safety data sheet

PBT = Persistent, Bio accumulative and Toxic.

vPvB = very Persistent and very Bioaccumulative.

LD50 = Lethal Dose 50%.

EC50 = Effective Concentration 50%.

LC50 = Lethal Concentration 50%.

CSA= Chemical Safety Assessment.

Wording of H-statements

H302 Harmful if swallowed

H315 Causes skin irritation

H319 Causes serious eye irritation.

H413 May cause long-lasting harmful effects to aquatic life

The information in this Material Safety Data Sheet (MSDS) is believed to be correct as of the date issued. Manufacturer makes no warranties, expressed or implied, including, but not limited to, any implied warranty or merchantability or fitness for particular purpose of course of performance or usage of trade User is responsible for determining whether the manufacture's product is fit for a particular purpose and suitable for user's method of use or application. Given the variety of factors that can affect the use and application of is product, some of which are uniquely within the user's knowledge and control, it is essential that the user evaluate the product to determine whether it is fit for a particular purpose and suitable for user's method of use or application.

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Data Sources: Manufacturer