Dentsply Sirona

Safety Data Sheet
According to 1907/2006/EC, Article 31

SECTION 1: Identification

1.1 Product identifier: AH Plus® Bioceramic Sealer
Trade name: AH Plus® Bioceramic Sealer

1.2 Relevant identified uses of the substance or mixture
For Dental use only.
Application of the substance / the preparation
Root Canal Treatment

1.3 Details of Distributor:
Maillefer Instruments Holding Sàrl
Chemin du Verger 3
CH-1338 Ballaigues
Switzerland
Tel: +41 (0)21 843 92 92
email: www.dentsplysirona.com

EC REP
BIOGERI
Am Pfeilshof 12, 22393
Hamburg, Germany
Tel: +49 176 4967 3648

Details of Manufacturer:
Maruchi
2 208, Medical Industry Complex Bldg.,
42 10,Taejanggongdan-gil,
Wonju si, Gangwon do,
26311, Republic of Korea

Information department:
Customer Care

1.4 Emergency telephone number: Contact your local emergency medical institution

SECTION 2: Hazard(s) Identification

2.1 Classification of the substance or mixture
NA: The product is not classified.,

Information concerning hazards for human and environment:
NA: No hazards for human or environment
Classification system:
The classification is according to the latest editions of the EU-lists and GHS specifications, and extended by company and literature data. Not applicable

2.2 Label elements
This product is a medical device and does not require a hazard label.
- E UH210 Safety data sheet available on request.

GHS label elements This product is classified and labeled according to the Globally Harmonized System (GHS).

Hazard pictograms:
Not applicable

Signal word: Not applicable

Hazardous Statement:
Not applicable

Precautionary Statements:
Not applicable.

Hazard-determining components of labelling:
Not applicable

Special labelling of certain preparations:
Not applicable.

2.3 Other hazards
Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable

SECTION 3: Composition/Information on Ingredients

3.1 Mixtures
- CLP

Chemical name	wt %	CAS No.	EC No.	REACH Reg. No.	Hazard classification	Notes
Zirconium Dioxide	50~70	1314-23-4	-	-	-	-
Tricalcium silicate	5~15	12168-85-3	-	-	-	-
Dimethyl sulfoxide	10~30	67-68-5	-		Aquatic Chronic 4; H413	-
Lithium carbonate	< 0.5		-		Acute Tox. 4; H302 Skin Irrit.2; H315 Eye irrit. 2; H319	-
Thickening agents, etc.	< 6	-	-	-	-	-

-Note : The substance has been assigned an exposure limit.
-References: The full text for all hazard statements is displayed in section 16.

SECTION 4: First-Aid Measures

4.1 Description of first aid measures general notes
After 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.

After 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.

After eye contact:
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.

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.

4.2 Most important symptoms and effects, both acute and delayed
See section 11 for more detailed information on health effects and symptoms.

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

SECTION 5: Fire-Fighting Measures

5.1 Extinguishing media
Suitable extinguishing agents
This product is not flammable. Use fire extinguishing media appropriate for surrounding materials.
5.2 Special hazards arising from the substance or mixture
During fire, gases hazardous to health may be formed
5.3 Advice for firefighters
Protective equipment: Selection of respiratory protection for firefighting: follow the general fire precautions indicated in the workplace.

SECTION 6: Accidental Release Measures

6.1 Personal precautions, protective equipment, and emergency procedures
Follow precautions for safe handling described in this safety data sheet.
6.2 Environmental precautions:
Avoid discharge into water courses or onto the ground.
6.3 Methods and material for containment and cleaning up:
IF DRY: Collect residues and place in a suitable container. IF WET Wear appropriate protective equipment and Collect residues.
6.4 Reference to other sections
For personal protection, see section 8. For waste disposal, see section 13

SECTION 7: Handling and Storage

7.1 Precautions for safe handling
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.

7.2 Conditions for safe storage, including any incompatibilities
Store in dry area. Normal temperatures and pressures do not affect the material. Store away from food and drinks.

7.3 Specific end use(s)
No further relevant information available.

SECTION 8: Exposure Controls/Personal Protection

Additional information about design of technical facilities: No further data.
8.1 Control parameters
- Occupational exposure limits

Chemical name	CAS No.	As:	Exposure limits	Type	Notes	References
Zirconium Dioxide Zirconium compounds	1314-23-4	-	5 mg/m³	TWA	-	EH40
			10 mg/m³	STEL		

Notes: EH40: EH40/2005
DNEL/PNEC: Not available.

8.2 Exposure controls
- **Engineering measures:** Observe occupational exposure limits and minimize the risk of inhalation of vapors
- **Personal protection**: Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.
- **Respiratory equipment:** Under normal conditions of use respiration protection should not be required. In case of inadequate ventilation use suitable respirator.
- Hand protection: Risk of contact: Wear protective gloves. The most suitable glove must be chosen in consultation with the glove's supplier, who can inform about the breakthrough time of the glove material.
- **Eye protection:** Risk of splashes: Wear approved safety goggles
- **Skin protection:** Wear appropriate clothing to prevent repeated or prolonged skin contact
- **Hygiene measures:** Wash hands after handling. Wash contaminated clothing before reuse.

SECTION 9: Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

General Information	
Appearance:	
• **Form**	Paste
• **Color**	White
Odor	Amine like
Odor threshold	Not available.
pH-value	12 to 13
Change in condition:	
• **Melting point/Melting range**	Not available.
• **Boiling point/Boiling range**	Not available.
Flash point	Not available.
Flammability (solid, gaseous)	Not available.
Ignition temperature:	
• **Decomposition temperature**	Not available
Self-igniting	Not available
Danger of explosion	Not available
Explosion limits	
• **Lower**	Not available
• **Upper**	Not available
Vapor pressure	Not available
Density	Not available
Relative density	Not available
Vapor density	Not available
Evaporation rate	Not available
Solubility	3%
Partition coefficient (n-octanol/Water)	Not available
Viscosity	
• **dynamic**	Not available
• **kinematic**	Not available
Solvent content:	
• **Organic solvents**	0,0 %

9.2 Other information No further relevant information available

SECTION 10: Stability and Reactivity

10.1 Reactivity - Hardened by reacting with moisture
10.2 Chemical stability - Stable under normal temperature conditions. (2 years)
10.3 Possibility of hazardous reactions None known
10.4 Conditions to avoid Extremes of temperatures. (>25°C 15 °)
10.5 Incompatible materials: Strong oxidizing substances
10.6 Hazardous decomposition products: None under normal conditions

SECTION 11: Toxicological Information

11.1. Information on toxicological effects

- 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. When 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 mg kg
Lithium carbonate: LD50 525 mg kg
LD50(dermal rabbit)
Dimethyl sulfoxide: LD50 20000~40000 mg kg
LC50(Dust, rat)
Lithium carbonate: LC50 2.17 mg /ℓ 4hr

11.2 Information on other hazards

- Endocrine disrupting properties: None

SECTION 12: Ecological Information

12.1 Toxicity - Ecotoxicity: Not classified as dangerous to the environment.
Dimethyl sulfoxide:
LC50(Fish)32300mg/L96hr
EC50(Crustaceans)24600mg/L48hr
EC50(Algae)12350~25500mg/L96hr
Lithium carbonate:
LC50(Fish)8.1mg/ℓ96hr

12.2 Persistence and degradability: This product mainly consists of inorganic compounds which are not biodegradable. The remaining compounds of the product are expected to be easily biodegradable.

12.3 Bioaccumulative potential Not applicable
12.4 Mobility in soil Not applicable

Additional ecological information:
12.5 Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.
12.6 Other adverse effects None known

SECTION 13 Disposal Considerations

13.1 Waste treatment methods
Recommendation
Dispose of waste and residues in accordance with local authority requirements. - Waste from residues: EWC code: 18 01 07
European waste catalogue: Not applicable
Recommendation: Observe the general safety regulations when handling chemicals. The product is not subject to identification regulations according to directives on hazardous materials. Completely emptied packaging's can be recycled.

SECTION 14: Transport Information

14.1 UN-Number: Not applicable

14.2 UN proper shipping name Not applicable
14.3 Transport hazard class(es): Not applicable
14.4 Packing Group: Not applicable
14.5 Environmental hazards: Not applicable
14.6 Special precautions for user: Not applicable
14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code

SECTION 15: Regulatory Information

15.1 Safety, health and environmental regulations / specific legal regulation for the substance or mixture

National regulation:

Regulation (No 1907/2006 of the European Parliament and of the Council of 18 December 2006- 28 May 2021 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (No 793/93 and Commission Regulation (No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC,

93/105/EC and 2000/21/EC, with amendments. Regulation (No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (No 1907/2006 with amendments. The Control of Substances Hazardous to Health Regulations 2002 (S.I 2002 No. 2677) with amendments. EH40/2005, Workplace exposure limits 2005, with amendments. The List of Wastes ((Regulations 2005. (SI 2005 No. 895). Globally Harmonized System of Classification and Labelling of Chemicals.

15.2 Chemical safety assessment: - CSA status Not applicable

SECTION 16: Other Information

Relevant phrases

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, Bioaccumulative and Toxic. VPvB = very Persistent and very Bioaccumulative. LD50=LethalDose50%. EC50=EffectiveConcentration50%. LC50=LethalConcentration50%. 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

Date of SDS Preparation/Revision: 01/14/2022
Data Sources: Supplier

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