## **Dentsply International**

**Prosthetics** 

## Safety Data Sheet

Safety Data Sheet conforms to Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 2015/830, US 29CFR1910.1200, Canada Hazardous Products Regulation Date Issued: 7 July 1997 Document Number: 152 Date Revised:20 November 2017 Revision Number: 8

# 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product Identifier:

Trade Name (as labeled): Al-Cote® Separating Agent

Part/Item Number: 652500, 652502

1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against:

Recommended Use: Used in fabrication of dentures.

**Restrictions on Use:** For Professional Use Only

1.3 Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier Name: Dentsply Sirona Prosthetics

Manufacturer/Supplier Address: 570 West College Ave.

York, PA 17401

Manufacturer/Supplier Telephone Number: 717-845-7511 (Product Information)

Email address: Prosthetics\_MSDS@dentsplysirona.com

1.4 Emergency Telephone Number:

**Emergency Contact Telephone Number:** 800-243-1942

#### 2. HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture:

GHS Classification: Not classified as hazardous

2.2 Label Elements: Not required

2.3 Other Hazards: None known.

#### 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.2 Mixture:

Hazardous Components	C.A.S. #	EINECS # / REACH Registration #	Classification	WT %
Water	7732-18-5	231-791-2 /	Not Applicable	95-100

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Non-hazardous Ingredients	Proprietary	Proprietary	Not Applicable	1-5
Potassium Aliginate	9005-36-1	635-886-3/	Eye Irrit Cat 2 (H319)	1-2

The exact concentration is being withheld as a trade secret.

Refer to Section 16 for the full text of the GHS Classifications.

#### 4. FIRST AID MEASURES

4.1 Description of	4.1 Description of First Aid Measures:				
Eye	Flush eyes with plenty of water, while holding the eyelids apart. Seek medical attention if irritation develops or persists.				
Skin	Thoroughly wash skin with soap and water. Seek medical attention if irritation develops or persists.				
Inhalation	Remove victim to fresh air. Get medical attention if irritation develops.				
Ingestion	Rinse out mouth with water. Do not induce vomiting unless directed by physician. Get medical attention if symptoms develop.				
4.2 Most Important Symptoms and Effects, Both Acute and Delayed:					
May cause slight eye irritation. Ingestion may cause gastrointestinal irritation.					
4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:					
Immediate medic	al attention is not required.				

#### 5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media:	Use media appropriate for the surrounding fire.			
5.2 Special Hazards Arising from the Substance or Mixture:				
None known				
5.3 Advice for Fire-Fighters:				
Fire Fighting Procedures/Precautions for Fire Fighters:	Cool fire exposed containers and structures with water. Firefighters should wear full emergency equipment and approved positive pressure self-contained breathing apparatus. Do not enter fire area without proper protection			

#### 6. ACCIDENTAL RELEASE MEASURES

#### 6.1 Personal Precautions, Protective Equipment and Emergency Procedures:

Avoid contact with skin, eyes, or clothing. Wear appropriate protective clothing as described in Section 8. Avoid breathing vapors or mists.

#### **6.2 Environmental Precautions:**

Do not allow spills to be released into the environment. Report releases as required by local and national authorities.

#### 6.3 Methods and Material for Containment and Cleaning up:

Collect with absorbent material and place in appropriate, labeled container for disposal.

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#### **6.4 Reference to Other Sections:**

Refer to Section 8 for Personal Protective Equipment and Section 13 for Disposal information.

#### 7. HANDLING AND STORAGE

#### 7.1 Precautions for Safe Handing:

Avoid contact with the eyes, skin and clothing. Use with adequate ventilation. Wash thoroughly with soap and water after handling.

- 7.2 Conditions for Safe Storage, Including Any Incompatibilities: Store in a cool, dry, well-ventilated area away. Keep container tightly closed when not in use. Protect from physical damage.
- **7.3 Specific End Use (s):** For professional use only.

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:				
Occupational Exposure Limits:				
Water	None Established			
Non-hazardous Ingredients	None Established			
Potassium Aliginate	None Established			
Biological Exposure Limits: None Established				

#### **8.2 Exposure Controls:**

Appropriate Engineering Controls: No special ventilation normally required. If airborne concentrations are excessive, use adequate general or local exhaust ventilation to minimize exposures.

#### **Individual Protection Measures (PPE):**

Specific Eye/face Protection: None needed under normal use. Wear safety glasses with side shields as needed to avoid eye contact where splashing is possible.

Specific Skin Protection: None needed under normal use. Wear rubber gloves or nitrile gloves to avoid prolonged skin contact.

Specific Respiratory Protection: None should be needed during normal conditions. If the product is heated and ventilation is inadequate, wear an approved respirator appropriate for the exposure conditions. Respirator selection and use should be based on contaminant type, form and concentration. Use in accordance with applicable regulations and good Industrial Hygiene practice.

Specific Thermal Hazards: None required.

#### 9. PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on Basic Physical and Chemical Properties:

Appearance:	Pink liquid	Explosive limits:	LEL: Not applicable UEL: Not applicable
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Odor:	Slight odor	Vapor pressure (mmHg):	Same as water
Odor threshold:	Not determined	<b>Vapor density:</b> (Air = 1)	Same as water
рН:	Not applicable	Relative density:	1.009
Melting/freezing point:	Not determined	Solubility(ies):	Completely soluble in water
Initial boiling point and boiling range:	100°C ( 212°F)	Partition coefficient: n-octanol/water:	Not applicable
Flash point:	None	Auto-ignition temperature:	None
Evaporation rate: (n-BuAc = 1)	Same as water	Decomposition temperature:	Not available
Flammability (solid, gas):	Not flammable	Viscosity:	Not applicable
<b>Explosive Properties:</b>	Not explosive	Oxidizing Properties:	None

**9.2 Other Information:** None available

#### 10. STABILITY AND REACTIVITY

**10.1 Reactivity:** Polymerization will not occur.

**10.2 Chemical Stability:** Stable under normal conditions.

10.3 Possibility of Hazardous Reactions: None known.

**10.4 Conditions to Avoid:** Avoid high temperatures.

**10.5 Incompatible materials:** Oxidizing agents.

**10.6 Hazardous Decomposition Products:** None known.

#### 11. TOXICOLOGICAL INFORMATION

#### 11.1 Information on Toxicological Effects:

Eves: May cause slight irritation with blurred vision, redness and tearing.

Skin: May cause slight skin irritation.

<u>Ingestion:</u> Large amounts may cause gastrointestinal irritation.

<u>Inhalation:</u> Mists may cause slight respiratory tract irritation with coughing and shortness of breath.

Chronic Health Effects: None known.

<u>Irritation:</u> This product is not classified as an irritant. There are components that are irritants, but they aren't in concentrations high enough to effect classification.

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**Corrosivity:** This product is not corrosive.

**Sensitization:** None of the components have been shown to cause sensitization in animals or humans.

<u>Carcinogenicity:</u> None of the components of this product are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU CLP.

Mutagenicity: No data available.

Aspiration Hazard: Not an aspiration hazard

**Acute Toxicity Data:** 

Non-Hazardous Ingredients: Oral rat LD50 - >5000 mg/kg

Reproductive Toxicity Data: None of the components have been shown to cause reproductive or developmental toxicity.

Specific Target Organ Toxicity Single Exposure (STOT-SE): No data available.

Specific Target Organ Toxicity Repeated Exposure (STOT-RE): No data available.

#### 12. ECOLOGICAL INFORMATION

#### 12.1 Toxicity:

No data is currently available. Not expected to present and environmental hazard.

12.2 Persistence and Degradability: No data available

12.3 Bio-accumulative Potential: No data available

12.4 Mobility in Soil: No data available

12.5 Results of PBT and vPvB Assessment: Not required

**12.6 Other Adverse Effects:** None known

#### 13. DISPOSAL CONSIDERATIONS

#### 13.1 Waste Treatment Methods:

Waste Treatment Recommendations: Treat in accordance with national and local regulations.

#### 14. TRANSPORT INFORMATION

	14.1 UN Number	14.2 UN Proper Shipping Name	14.3 Hazard Class(s)	14.4 Packing Group	14.5 Environmental Hazards
DOT	None	Not Regulated	None	None	None
ADR/RID	None	Not Regulated	None	None	None

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IMDG	None	Not Regulated	None	None	None
IATA/ICAO	None	Not Regulated	None	None	None

**14.6 Special Precautions for User:** Not applicable.

**14.7 Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code:** Not applicable - product is transported only in packaged form.

#### 15. REGULATORY INFORMATION

15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture:

#### **U.S. Federal Regulations**

Comprehensive Environmental Response and Liability Act of 1980 (CERCLA): This product is not subject to CERCLA reporting requirements. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations.

Toxic Substances Control Act (TSCA): All of the components of this product are listed on the TSCA inventory.

Clean Water Act (CWA): This material is not regulated under the Clean Water Act.

Clean Air Act (CAA): This material is not regulated under the Clean Air Act.

Superfund Amendments and Reauthorization Act (SARA) Title III Information:

SARA Section 311/312 (40 CFR 370) Hazard Categories: See OSHA Hazard Classification in Section 2.

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372): None.

#### **State Regulations**

**California:** This product contains the following substances known to the state of California to cause cancer and/or reproductive toxicity: None known.

#### **International Regulations**

**Canadian Environmental Protection Act:** All of the components in this product are listed on the Domestic Substance List (DSL).

**Australian Inventory of Chemical Substances:** All of the components in this product are listed on the AICS for Australia.

**China Inventory of Existing Chemicals and Chemical Substances:** All of the components in this product are listed on the IECSC for China.

Korean Existing Chemicals List: All of the components in this product are listed on the KECL for Korea.

**Philippine Inventory of Chemicals and Chemical Substances:** All of the components in this product are listed on the PICCS.

15.2 Chemical Safety Assessment: None required.

#### 16. OTHER INFORMATION

HMIS Hazard Rating:

Health –1 Flammability – 0 Physical Hazard– 0

Full text of Classification abbreviations used in Section 2 and 3: None

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Eye Irrit Cat 2 Eye Irritant Category 2 H319 Causes serious eye irritation

Supersedes: 13 August 2014 Date Updated: 20 November 2017

Revision Summary: Comprehensive review, new format.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, ECHA REACH Registration Website,

Country websites for occupational exposure limits.

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