

Safety Data Sheet

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This Safety Data Sheet has been prepared in accordance with the GHS guidelines & India Hazardous substances (Classification, Labeling & Packaging) Draft Rules 2011.

SECTION 1: Identification

1.1. Product identifier

Astringent Retraction Paste (56943, 6944, 56945)

Product Identification Numbers

UU-0098-0549-8 UU-0134-9324-0

1.2. Recommended use and restrictions on use

Recommended use

Dental Product, Gingival Retraction

Restrictions on use

For use by dental professionals only.

1.3. Supplier's details

Address: KCI Medical India Private Limited, S - 327, Greater Kailash - II, New Delhi, Delhi, 110048, India

Telephone: 1-855-423-6725

E Mail: psops_supportteam@solventum.com

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thereon.

1.4. Emergency telephone number

CHEMTREC 1-800-424-9300 OR 1-703-527-3887, Contract number# 1015211

SECTION 2: Hazard identification

Under MSIHC Rules, information is noted below on flammability, acute toxicity and explosivity relevant to this product. In line with international standards, information on other hazard classes and associated precautionary statements relevant to this product are included as well.

2.1. Classification of the substance or mixture

Acute Toxicity (oral): Category 5. Acute Aquatic Toxicity: Category 3.

2.2. Label elements

Signal Word

Warning

Symbols

Not applicable

Pictograms

Not applicable

HAZARD STATEMENTS:

H303 May be harmful if swallowed.

H402 Harmful to aquatic life.

2.3. Other hazards

Eye damage/irrit. class not applied based on test data in similar mix A similar mixture has been tested for eye damage/irritation and the test results do not meet the criteria for classification. A similar mixture has been tested for skin corrosion/irritation and the test results do not meet the criteria for classification. A similar mixture has been tested for skin sensitization and the test results do not meet the criteria for classification.

SECTION 3: Composition/information on ingredients

This material is a mixture.

Ingredient	CAS Nbr	% by Wt
Mica-group minerals	12001-26-2	60 - 70
Aluminium chloride, hexahydrate	7784-13-6	< 20
Water	7732-18-5	10 - 20
Kaolin	1332-58-7	< 5
POLY(dimethylsiloxane)	63148-62-9	< 5

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation

Remove person to fresh air. If you feel unwell, get medical attention.

Skin contact

No need for first aid is anticipated.

Eye contact

Flush with large amounts of water. Remove contact lenses if easy to do. Continue rinsing. If signs/symptoms persist, get medical attention.

If swallowed

Rinse mouth. If you feel unwell, get medical attention.

4.2. Most important symptoms and effects, both acute and delayed

No critical symptoms or effects. See Section 11.1, information on toxicological effects.

4.3. Indication of any immediate medical attention and special treatment required

Not applicable

SECTION 5: Fire-fighting measures

5.1. Suitable Extinguishing media

In case of fire: Use a fire fighting agent suitable for ordinary combustible material such as water or foam to extinguish.

5.2. Special hazards arising from the substance or mixture

None inherent in this product.

Hazardous Decomposition or By-Products

<u>Substance</u>	Condition
Carbon monoxide.	During combustion.
Carbon dioxide.	During combustion.
Hydrogen Chloride	During combustion.
Oxides of nitrogen.	During combustion.

5.3. Special protective actions for fire-fighters

Wear full protective clothing, including helmet, self-contained, positive pressure or pressure demand breathing apparatus, bunker coat and pants, bands around arms, waist and legs, face mask, and protective covering for exposed areas of the head.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Evacuate area. Ventilate the area with fresh air.

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Collect as much of the spilled material as possible. Place in a closed container approved for transportation by appropriate authorities. Clean up residue. Seal the container. Dispose of collected material as soon as possible in accordance with applicable local/regional/national/international regulations.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid prolonged or repeated skin contact. Do not eat, drink or smoke when using this product. Wash thoroughly after handling. Avoid release to the environment.

7.2. Conditions for safe storage including any incompatibilities

Store away from heat.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limits

If a component is disclosed in section 3 but does not appear in the table below, an occupational exposure limit is not available for the component.

for the component.				
Ingredient	CAS Nbr	Agency	Limit type	Additional comments
Mica-group minerals	12001-26-2	ACGIH	TWA(respirable fraction):0.1	
			mg/m3	
Kaolin	1332-58-7	ACGIH	TWA(respirable fraction):2	A4: Not class. as human
			mg/m3	carcin

ACGIH: American Conference of Governmental Industrial Hygienists

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AIHA: American Industrial Hygiene Association

CMRG: Chemical Manufacturer's Recommended Guidelines

TWA: Time-Weighted-Average STEL: Short Term Exposure Limit

CEIL: Ceiling

8.2. Exposure controls

8.2.1. Engineering controls

Use in a well-ventilated area.

8.2.2. Personal protective equipment (PPE)

Eye/face protection

Select and use eye/face protection to prevent contact based on the results of an exposure assessment. The following eye/face protection(s) are recommended:
Safety glasses with side shields.

Skin/hand protection

See Section 7.1 for additional information on skin protection.

Respiratory protection

None required.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Solid.	
Specific Physical Form:	Paste	
Color	Light Blue	
Odor	Odourless	
Odour threshold	No data available.	
рН	3.2 - 4 [Details: 10% aqueous solution]	
Melting point/Freezing point: NA	Not applicable.	
Boiling point/Initial boiling point/Boiling range	Not applicable.	
Flash point	Flash point > 93 °C (200 °F)	
Evaporation rate	No data available.	
Flammability	Not applicable.	
Flammable Limits(LEL)	Not applicable.	
Flammable Limits(UEL)	Not applicable.	
Vapour pressure	No data available.	
Relative Vapor Density	No data available.	
Density	1.8 g/cm3 - 2.2 g/cm3	
Relative density	1.8 - 2.2 [<i>Ref Std</i> :WATER=1]	
Water solubility	Appreciable	
Solubility- non-water	No data available.	
Partition coefficient: n-octanol/water	No data available.	
Autoignition temperature	No data available.	
Decomposition temperature	No data available.	
Kinematic Viscosity	No data available.	
Volatile organic compounds (VOC)	No data available.	
Percent volatile	No data available.	

VOC less H2O & exempt solvents	No data available.
Molecular weight	Not applicable.

Particle Characteristics	Not applicable.
Turticle Characteristics	rot applicate.

SECTION 10: Stability and reactivity

10.1 Reactivity

This material may be reactive with certain agents under certain conditions - see the remaining headings in this section

10.2 Chemical stability

Stable.

10.3 Possibility of hazardous reactions

Hazardous polymerisation will not occur.

10.4 Conditions to avoid

Heat.

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products

Substance

Condition

None known.

Refer to section 5.2 for hazardous decomposition products during combustion.

SECTION 11: Toxicological information

The information below may not be consistent with the material classification in Section 2 if specific ingredient classifications are mandated by a competent authority. In addition, toxicological data on ingredients may not be reflected in the material classification and/or the signs and symptoms of exposure, because an ingredient may be present below the threshold for labelling, an ingredient may not be available for exposure, or the data may not be relevant to the material as a whole.

11.1 Information on Toxicological effects

Signs and Symptoms of Exposure

Based on test data and/or information on the components, this material may produce the following health effects:

Inhalation

No known health effects.

Skin contact

Contact with the skin during product use is not expected to result in significant irritation.

Eve contact

Contact with the eyes during product use is not expected to result in significant irritation.

Ingestion

May be harmful if swallowed.

Gastrointestinal irritation: Signs/symptoms may include abdominal pain, stomach upset, nausea, vomiting and diarrhoea.

Toxicological Data

If a component is disclosed in section 3 but does not appear in a table below, either no data are available for that endpoint or the data are not sufficient for classification.

Acute Toxicity

Name	Route	Species	Value
Overall product	Ingestion		No data available; calculated ATE >2,000 - =5,000
			mg/kg
Mica-group minerals	Dermal		LD50 estimated to be > 5,000 mg/kg
Mica-group minerals	Ingestion		LD50 estimated to be 2,000 - 5,000 mg/kg
Aluminium chloride, hexahydrate	Ingestion	Rat	LD50 6,247 mg/kg
Kaolin	Dermal		LD50 estimated to be > 5,000 mg/kg
Kaolin	Ingestion	Human	LD50 > 15,000 mg/kg
POLY(dimethylsiloxane)	Dermal	Multiple	LD50 > 2,000 mg/kg
		animal	
		species	
POLY(dimethylsiloxane)	Ingestion	Rat	LD50 > 5,000 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Overall product	Rabbit	No significant irritation
Aluminium chloride, hexahydrate	In vitro	Corrosive
	data	
Kaolin	Professio	No significant irritation
	nal	
	judgemen	
	t	
POLY(dimethylsiloxane)	Human	No significant irritation
	and	
	animal	

Serious Eye Damage/Irritation

Name	Species	Value
	D 11.4	N · · · · · · · · · · · · · · ·
Overall product	Rabbit	No significant irritation
Aluminium chloride, hexahydrate	similar	Corrosive
	health	
	hazards	
Kaolin	Professio	No significant irritation
	nal	
	judgemen	
	t	
POLY(dimethylsiloxane)	Rabbit	No significant irritation

Sensitization:

Skin Sensitisation

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Name	Species	Value	
Overall product	Guinea pig	Not classified	
POLY(dimethylsiloxane)	Human and animal	Not classified	

Respiratory Sensitisation

For the component/components, either no data are currently available or the data are not sufficient for classification.

Germ Cell Mutagenicity

Name	Route	Value
Aluminium chloride, hexahydrate	In Vitro	Not mutagenic
POLY(dimethylsiloxane)	In Vitro	Not mutagenic
POLY(dimethylsiloxane)	In vivo	Not mutagenic

Carcinogenicity

Name	Route	Species	Value
Kaolin	Inhalation	Multiple	Not carcinogenic
		animal	
		species	
POLY(dimethylsiloxane)	Dermal	Mouse	Not carcinogenic
POLY(dimethylsiloxane)	Ingestion	Mouse	Not carcinogenic

Reproductive Toxicity

Reproductive and/or Developmental Effects

Name	Route	Value	Species	Test result	Exposure Duration
POLY(dimethylsiloxane)	Ingestion	Not classified for development	Rat	NOAEL 3,800 mg/kg/day	during organogenesis
POLY(dimethylsiloxane)	Dermal	Not classified for development	Rabbit	NOAEL 1,000 mg/kg/day	during organogenesis

Target Organ(s)

Specific Target Organ Toxicity - single exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Aluminium chloride,	Inhalation	respiratory irritation	May cause respiratory irritation	similar	NOAEL Not	
hexahydrate				health	available	
				hazards		

Specific Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration	
Mica-group minerals	Inhalation	pneumoconiosis	Causes damage to organs through prolonged or repeated exposure	Human	NOAEL Not available	occupational exposure	
Aluminium chloride, hexahydrate	Inhalation	hematopoietic system respiratory system heart skin endocrine system gastrointestinal tract bone, teeth, nails, and/or hair liver immune system muscles nervous system eyes kidney and/or bladder vascular system	Not classified	Rat	NOAEL 0.002 mg/l	90 days	
Kaolin	Inhalation	pneumoconiosis	Causes damage to organs through prolonged or repeated exposure	Human	NOAEL NA	occupational exposure	
Kaolin	Inhalation	pulmonary fibrosis	Not classified	Rat	NOAEL Not available		
POLY(dimethylsiloxane)	Ingestion	eyes	Not classified	Rat	NOAEL 10%	90 days	
POLY(dimethylsiloxane)	Ingestion	respiratory system	Not classified	Rat	NOAEL 1%	90 days	
POLY(dimethylsiloxane)	Ingestion	gastrointestinal tract	Not classified	Multiple animal species	NOAEL 10%	90 days	
POLY(dimethylsiloxane)	Ingestion	hematopoietic	Not classified	Rat	NOAEL 10%	90 days	

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		system				
POLY(dimethylsiloxane)	Ingestion	heart liver kidney and/or bladder	Not classified	Rat	NOAEL 1%	90 days
		vascular system				

Aspiration Hazard

For the component/components, either no data are currently available or the data are not sufficient for classification.

Please contact the address or phone number listed on the first page of the SDS for additional toxicological information on this material and/or its components.

SECTION 12: Ecological information

The information below may not be consistent with the material classification in Section 2 if specific ingredient classifications are mandated by a competent authority. Additional information leading to material classification in Section 2 is available upon request. In addition, environmental fate and effects data on ingredients may not be reflected in this section because an ingredient is present below the threshold for labelling, an ingredient is not expected to be available for exposure, or the data is considered not relevant to the material as a whole.

12.1. Toxicity

Acute aquatic hazard:

GHS Acute 3: Harmful to aquatic life.

Chronic aquatic hazard:

Not chronically toxic to aquatic life by GHS criteria.

No product test data available.

Material	CAS Nbr	Organism	Type	Exposure	Test endpoint	Test result
Mica-group minerals	12001-26-2	N/A	Data not available or insufficient for classification	N/A	N/A	N/A
Aluminium chloride, hexahydrate	7784-13-6	Green algae	Estimated	72 hours	ErC50	9.4 mg/l
Aluminium chloride, hexahydrate	7784-13-6	Rainbow trout	Experimental	96 hours	LC50	66 mg/l
Aluminium chloride, hexahydrate	7784-13-6	Water flea	Experimental	48 hours	LC50	49.4 mg/l
Aluminium chloride, hexahydrate	7784-13-6	Redworm	Estimated	14 days	LC50	2,830 mg/kg (Dry Weight)
Aluminium chloride, hexahydrate	7784-13-6	Activated sludge	Experimental	180 minutes	EC10	>1,000 mg/l
Kaolin	1332-58-7	Water flea	Experimental	48 hours	LC50	>1,100 mg/l
POLY(dimethylsilo xane)	63148-62-9	N/A	Data not available or insufficient for classification	N/A	N/A	N/A

12.2. Persistence and degradability

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Mica-group	12001-26-2	Data not	N/A	N/A	N/A	N/A

minerals		available- insufficient				
Aluminium chloride, hexahydrate	7784-13-6	Data not available- insufficient	N/A	N/A	N/A	N/A
Kaolin	1332-58-7	Data not available- insufficient	N/A	N/A	N/A	N/A
POLY(dimethylsilo xane)	63148-62-9	Data not available- insufficient	N/A	N/A	N/A	N/A

12.3: Bioaccumulative potential

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Mica-group minerals	12001-26-2	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Aluminium chloride, hexahydrate	7784-13-6	Analogous Compound BCF - Fish		Bioaccumulation factor	232	
Kaolin	1332-58-7	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
POLY(dimethylsilo xane)	63148-62-9	Data not available or insufficient for classification	N/A	N/A	N/A	N/A

12.4. Mobility in soil

Please contact manufacturer for more details

12.5 Other Adverse effects

No information available.

SECTION 13: Disposal considerations

13.1. Disposal methods

Dispose of contents/ container in accordance with the local/regional/national/international regulations.

Dispose of waste product in a permitted industrial waste facility. As a disposal alternative, incinerate in a permitted waste incineration facility. Combustion products will include halogen acid (HCl/HF/HBr). Facility must be capable of handling halogenated materials.

SECTION 14: Transport Information

Not hazardous for transportation.

Air Transport (IATA)Regulations

UN No Not applicable

Proper Shipping Name Not applicable **Hazard Classs/Division** Not applicable

Subsidiary Risk Not applicable **Packing Group:** Not applicable

Marine Transport (IMDG) UN No Not applicable

Proper Shipping Name Not applicable **Hazard Classs/Division** Not applicable

Subsidiary Risk Not applicable **Packing Group:** Not applicable

Environmental Hazards: Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Global inventory status

Contact 3M for more information. The components of this product are in compliance with the new substance notification requirements of CEPA.

Applicable Environmental, Health and Safety Regulations

The Manufacture, Storage and Import of Hazardous Chemical Rules, 1989

The Bio Medical Waste (Management & Handling) Rules, 1998

Hazardous Chemicals (Classification, Packaging and Labelling Draft Rules), 2011

The following ingredients are listed as hazardous on Part II of Schedule I of the India Manufacture, Storage and Import of Hazardous Chemicals (MSIHC) rules

None.

The following ingredients are classified as hazardous based on the criteria listed under Part I of Schedule I of the India Manufacture, Storage and Import of Hazardous Chemicals (MSIHC) rules:

The product is classified as Non-Hazardous as per MSIHC Rules, 1989.

SECTION 16: Other information

NFPA Hazard Classification

Health: 0 Flammability: 1 Instability: 0 Special Hazards: None

National Fire Protection Association (NFPA) hazard ratings are designed for use by emergency response personnel to address the hazards that are presented by short-term, acute exposure to a material under conditions of fire, spill, or similar emergencies. Hazard ratings are primarily based on the inherent physical and toxic properties of the material but also include the toxic properties of combustion or decomposition products that are known to be generated in significant quantities.

Revision information:

Section 1: Address information was modified.

Company Telephone information was modified.

Section 1: E-mail address information was modified.

Section 1: Emergency telephone information was modified.

Section 1: Product identification numbers information was modified.

Section 1: Product name information was modified

Section 02: GHS Pictogram Not Applicable information was added.

Section 02: GHS Symbol Text - Not applicable information was added.

Section 2: Hazard - Other information was modified.

Label: GHS Classification information was modified.

Label: GHS Environmental Hazard Statements information was modified.

Label: GHS Precautionary - Disposal information was deleted.

Label: Signal Word information was modified.

Section 2: Ingredient table information was modified.

Section 4: First aid for skin contact information information was modified.

Section 04: Information on toxicological effects information was deleted.

Section 6: Accidental release personal information information was modified.

Section 8: Occupational exposure limit table information was modified.

Section 9: Flammability (solid, gas) information information was deleted.

Section 09: Flammability information information was added.

- Section 09: Kinematic Viscosity information information was added.
- Section 09: Particle Characteristics N/A information was added.
- Section 09: Percent Volatile information was added.
- Section 9: Property description for optional properties information was added.
- Section 9: Property description for optional properties information was deleted.
- Section 09: Vapor Density Value information was added.
- Section 9: Vapour density value information was deleted.
- Section 9: Viscosity information information was deleted.
- Section 09: VOC Less H2O & Exempt Solvents information was added.
- Section 09: Volatile Organic Compounds information was added.
- Section 11: Acute Toxicity table information was modified.
- Section 11: Carcinogenicity Table information was modified.
- Section 11: Germ Cell Mutagenicity Table information was added.
- Section 11: Germ Cell Mutagenicity text information was deleted.
- Section 11: Reproductive and/or Developmental Effects text information was added.
- Section 11: Reproductive Toxicity Table information was added.
- Section 11: Serious Eye Damage/Irritation Table information was modified.
- Section 11: Skin Corrosion/Irritation Table information was modified.
- Section 11: Skin Sensitization Table information was modified.
- Section 11: Specific Target Organ Toxicity single exposure text information was deleted.
- Section 11: Target Organs Repeated Table information was modified.
- Section 11: Target Organs Single Table information was added.
- Section 12: Chronic aquatic hazard information information was modified.
- Section 12: Component ecotoxicity information information was modified.
- Section 12: Persistence and Degradability information information was modified.
- Section 12:Bioccumulative potential information information was modified.
- Section 13: Standard Phrase Category Waste GHS information was modified.
- Section 16: Web address information was modified.

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