Safety Information Sheet for Medical Devices

Document group:	29-8225-4	**Version number:**	1.00
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Transportation version number: 1.00 (23/03/2020)

A safety data sheet is not required for this Product. This Safety Information Sheet has been created on a voluntary basis.

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

3M™ Astringent Retraction Paste (56943, 6944, 56945)

Product Identification Numbers

70-2011-3931-1	70-2011-3932-9	70-2011-3933-7	70-2011-4628-2	UU-0098-0548-0
UU-0098-0549-8	UU-0098-0550-6			
7100010071	7100010070	7100010069	7100196314	7100196315
7100196316				

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses

Medical device; refer to Instructions for Use

Restrictions on Use

For use only by dental professionals.

1.3 Details of the supplier of the safety information sheet for medical devices

Address: 3M United Kingdom PLC, 3M Centre, Cain Road, Bracknell, Berkshire, RG12 8HT.
Telephone: +44 (0)1344 858 000
E Mail: tox.uk@mmm.com
Website: www.3M.com/uk

1.4. Emergency telephone number

+44 (0)1344 858 000

SECTION 2: Hazard identification

2.1. Classification of the substance or mixture

CLP REGULATION (EC) No 1272/2008

This product is a medical device as defined in Directive 93/42/EEC (MDD) respectively Regulation (EU) 2017/745

(MDR), which is invasive or used in direct physical contact with the human body, and therefore is exempt from the requirements of classification and labelling according to Regulation (EC) No. 1272/2008 (CLP; Article 1, paragraph 5). Although not required, the classification and label information, as applicable, is provided below.

CLASSIFICATION:
Hazardous to the Aquatic Environment (Chronic), Category 3 - Aquatic Chronic 3; H412

For full text of H phrases, see Section 16.

2.2. Label elements
CLP REGULATION (EC) No 1272/2008

HAZARD STATEMENTS:

H412	Harmful to aquatic life with long lasting effects.

PRECAUTIONARY STATEMENTS

Disposal:

P501	Dispose of contents/container in accordance with applicable local/regional/national/internation regulations.

2.3. Other hazards

For information on hazards and safe use, please consider the corresponding sections of this document.

SECTION 3: Composition/information on ingredients

Ingredient	CAS Nbr	EC No.	% by Wt	Classification
Mica	12001-26-2		60 - 70	Substance with a Community level exposure limit in the workplace
Water	7732-18-5	231-791-2	10 - 20	Substance not classified as hazardous
Aluminum chloride	7784-13-6	7446-70-0	< 20	Skin Irrit. 2, H315; Eye Irrit. 2, H319 Aquatic Chronic 2, H411
Silicon oil	63148-62-9		< 5	Substance not classified as hazardous
Silicate	1332-58-7	310-194-1	< 5	Substance with a Community level exposure limit in the workplace

Please see section 16 for the full text of any H statements referred to in this section

For information on ingredient occupational exposure limits or PBT or vPvB status, see sections 8 and 12 of this SIS

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
Wash with soap and water. If signs/symptoms develop, get medical attention.

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.

SECTION 5: Fire-fighting measures

5.1. 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

Substance	Condition
Carbon monoxide	During combustion.
Carbon dioxide.	During combustion.
Hydrogen Chloride	During combustion.
Oxides of nitrogen.	During combustion.

5.3. Advice 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. For large spill, or spills in confined spaces, provide mechanical ventilation to disperse or exhaust vapours, in accordance with good industrial hygiene practice. Refer to other sections of this SIS for information regarding physical and health hazards, respiratory protection, ventilation, and personal protective equipment.

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.

SECTION 7: Handling and storage

Refer to Instructions for Use (IFU) for more information.

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.

Ingredient	CAS Nbr	Agency	Limit type	Additional comments

DUST, INERT OR NUISANCE	12001-26-2	UK HSC	TWA(as inhalable dust):10 mg/m³;TWA(as respirable dust):4 mg/m³
Mica	12001-26-2	UK HSC	TWA (Inhalable): 10 mg/m³; TWA (respirable): 0.8 mg/m³
DUST, INERT OR NUISANCE	1332-58-7	UK HSC	TWA(as inhalable dust):10 mg/m3
Silicate	1332-58-7	UK HSC	TWA (as respirable dust): 2 mg/m³
Aluminium, soluable salts	7784-13-6	UK HSC	TWA:2 mg/m3

UK HSC : UK Health and Safety Commission
TWA: Time-Weighted-Average
STEL: Short Term Exposure Limit
CEIL: Ceiling

Biological limit values
No biological limit values exist for any of the components listed in Section 3 of this safety information sheet.

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.

Applicable Norms/Standards
Use eye protection conforming to EN 166

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

Appearance	
Physical state	Solid.
Colour	Light Blue
Specific Physical Form:	Paste
Odor	Odourless
pH	3.2 - 4 [*Details:*10% aqueous solution]
Boiling point/boiling range	*Not applicable.*
Melting point	*Not applicable.*
Flammability (solid, gas)	Not classified
Explosive properties	Not classified
Oxidising properties	Not classified

Flash point	Flash point > 93 °C (200 °F)
Autoignition temperature	*No data available.*
Flammable Limits(LEL)	*Not applicable.*
Flammable Limits(UEL)	*Not applicable.*
Relative density	1.8 - 2.2 [*Ref Std:*WATER=1]
Water solubility	Appreciable
Viscosity	*No data available.*
Density	1.8 g/cm3 - 2.2 g/cm3

9.2. Other information

EU Volatile Organic Compounds *No data available.*

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 agree with the EU material classification in Section 2 and/or the ingredient classifications in Section 3 if specific ingredient classifications are mandated by a competent authority. In addition, statements and data presented in Section 11 are based on UN GHS calculation rules and classifications derived from 3M assessments.

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.

Eye 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 ATE2,000 - 5,000 mg/kg
Mica	Dermal		LD50 estimated to be > 5,000 mg/kg
Mica	Ingestion		LD50 estimated to be 2,000 - 5,000 mg/kg
Silicate	Dermal		LD50 estimated to be > 5,000 mg/kg
Silicate	Ingestion	Human	LD50 > 15,000 mg/kg
Silicon oil	Dermal	Rabbit	LD50 > 19,400 mg/kg
Silicon oil	Ingestion	Rat	LD50 > 17,000 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Overall product	Rabbit	No significant irritation
Silicate	Professional judgement	No significant irritation
Silicon oil	Rabbit	No significant irritation

Serious Eye Damage/Irritation

Name	Species	Value
Overall product	Rabbit	No significant irritation
Silicate	Professional judgement	No significant irritation
Silicon oil	Rabbit	No significant irritation

Skin Sensitisation

Name	Species	Value
Overall product	Guinea pig	Not classified

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

Germ Cell Mutagenicity
For the component/components, either no data is currently available or the data is not sufficient for classification.

Carcinogenicity

Name	Route	Species	Value
Silicate	Inhalation	Multiple animal species	Not carcinogenic

Reproductive Toxicity

Reproductive and/or Developmental Effects
For the component/components, either no data is currently available or the data is not sufficient for classification.

Target Organ(s)

Specific Target Organ Toxicity - single exposure
For the component/components, either no data is currently available or the data is not sufficient for classification.

Specific Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Mica	Inhalation	pneumoconiosis	Causes damage to organs through prolonged or repeated exposure	Human	NOAEL Not available	occupational exposure
Silicate	Inhalation	pneumoconiosis	Causes damage to organs through prolonged or repeated exposure	Human	NOAEL NA	occupational exposure
Silicate	Inhalation	pulmonary fibrosis	Not classified	Rat	NOAEL Not available	

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

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

The product was evaluated by a toxicologist to be safe for its intended use.

SECTION 12: Ecological information

The information below may not agree with the EU material classification in Section 2 and/or the ingredient classifications in Section 3 if specific ingredient classifications are mandated by a competent authority. In addition, statements and data presented in Section 12 are based on UN GHS calculation rules and classifications derived from 3M assessments.

12.1. Toxicity

No product test data available.

Material	CAS #	Organism	Type	Exposure	Test endpoint	Test result
Mica	12001-26-2		Data not available or insufficient for classification			
Aluminum chloride	7784-13-6	Green Algae	Estimated	72 hours	EC50	19.7 mg/l
Aluminum chloride	7784-13-6	Rainbow trout	Estimated	96 hours	LC50	5.1 mg/l
Aluminum chloride	7784-13-6	Water flea	Estimated	48 hours	EC50	2.72 mg/l
Silicate	1332-58-7	Water flea	Experimental	48 hours	LC50	>1,100 mg/l
Silicon oil	63148-62-9		Data not available or insufficient for classification			

12.2. Persistence and degradability

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Mica	12001-26-2	Data not availbl-insufficient			N/A	
Aluminum chloride	7784-13-6	Data not availbl-insufficient			N/A	

Silicate	1332-58-7	Data not availbl-insufficient			N/A	
Silicon oil	63148-62-9	Data not availbl-insufficient			N/A	

12.3 : Bioaccumulative potential

Material	Cas No.	Test type	Duration	Study Type	Test result	Protocol
Mica	12001-26-2	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Aluminum chloride	7784-13-6	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Silicate	1332-58-7	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Silicon oil	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. Results of the PBT and vPvB assessment

This material does not contain any substances that are assessed to be a PBT or vPvB

12.6. Other adverse effects
No information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods
Dispose of contents/ container in accordance with the local/regional/national/international regulations.

Refer to Instructions for Use (IFU) for more information.

EU waste code (product as sold)
180106* Chemicals consisting of or containing dangerous substances.

EU waste code (product container after use)
180107 Chemicals other than those mentioned in 18 01 06

SECTION 14: Transportation information

70-2011-3931-1, 70-2011-3932-9, 70-2011-3933-7, 70-2011-4628-2,
UU-0098-0548-0, UU-0098-0549-8, UU-0098-0550-6

Not hazardous for transportation

SECTION 15: Regulatory information

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

Global inventory status
Contact the manufacturer for more information

SECTION 16: Other information

List of relevant H statements

H315 Causes skin irritation.

H319	Causes serious eye irritation.
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

Revision information:
Revision information not available

The product to which this Safety Information Sheet applies is classified as a medical device according to the EU Medical Device Regulation EU 2017/745. _x000D_
Medical devices which are invasive or used in direct physical contact with the human body are exempt from the requirements of classification and labelling according to Regulation (EC) No. 1272/2008 (CLP; Article 1, paragraph 5)._x000D_
The EU Medical Device Regulation does not foresee the use of Safety Data sheets for medical devices which are invasive or used in direct physical contact with the human body, as the safe use of the product is described through the Instructions for Use and /or the labelling for the product. Nevertheless, the 3M Safety Information Sheet is provided as a further service to customers to provide additional toxicology and chemical information on the product. In case of further questions, please contact your 3M representative listed on the Safety Information Sheet.

3M United Kingdom Safety Information Sheets are available at www.3M.com/uk