



Safety Data Sheet

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This Safety Data Sheet has been prepared in accordance with the REACH Regulation (EC) 1907/2006 and its modifications.

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

1.1. Product identifier

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

Identified uses
Dental Product

Restrictions on Use
For use only by dental professionals

1.3. Details of the supplier of the safety data sheet

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), 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:

Serious Eye Damage/Eye Irritation, Category 2 - Eye Irrit. 2; H319

For full text of H phrases, see Section 16.

2.2. Label elements

CLP REGULATION (EC) No 1272/2008

SIGNAL WORD

WARNING.

Symbols:

GHS07 (Exclamation mark) |

Pictograms



HAZARD STATEMENTS:

H319

Causes serious eye irritation.

PRECAUTIONARY STATEMENTS

Response:

P305 + P351 + P338

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Notes on labelling

Silicosis target organ classification not applied due to the fact that dust exposure is not anticipated during product use

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	EU Inventory	% by Wt	Classification
Tributyl o-acetylcitrate	77-90-7	201-067-0	30 - 40	Substance not classified as hazardous
Sulphonium salt	72140-65-9	276-380-9	25 - 35	Acute Tox. 4, H302; Eye Irrit. 2, H319; Skin Sens. 1B, H317 (Self Classified)
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	68909-20-6	272-697-1	10 - 20	Substance not classified as hazardous
Polyethylene-polypropylene glycol	9003-11-6		5 - 10	Substance not classified as hazardous
Flux calcined diatomaceous earth (68855-54-9) containing cristobalite (unknown or >=10%)	68855-54-9	272-489-0	5 - 10	STOT RE 1, H372 (Self Classified)

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 SDS

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.

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

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. 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

Carbon monoxide.

Carbon dioxide.

Irritant vapours or gases.

Condition

During combustion.

During combustion.

During combustion.

5.3. Advice for fire-fighters

No special protective actions for fire-fighters are anticipated.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Evacuate area. Ventilate the area with fresh air. Refer to other sections of this SDS 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.

6.4. Reference to other sections

Refer to Section 8 and Section 13 for more information

SECTION 7: Handling and storage**7.1. Precautions for safe handling**

Avoid prolonged or repeated skin contact. Do not get in eyes, on skin, or on clothing. Do not eat, drink or smoke when using this product. Wash thoroughly after handling. Avoid release to the environment. Avoid contact with oxidising agents (eg. chlorine, chromic acid etc.)

7.2. Conditions for safe storage including any incompatibilities

Store in a well-ventilated place. Keep container tightly closed. Store away from heat. Store away from acids. Store away from strong bases. Store away from oxidising agents.

7.3. Specific end use(s)

See information in Section 7.1 and 7.2 for handling and storage recommendations. See Section 8 for exposure controls and personal protection recommendations.

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
Quartz	68855-54-9	UK HSC	TWA(respirable):0.1 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 data 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.

Skin/hand protection

See Section 7.1 for additional information on skin protection.

Respiratory protection

Respiratory protection is not required.

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state	Solid.
Specific Physical Form:	Paste
Appearance/Odour	slight characteristic odour, red paste
Odour threshold	No data available.
pH	No data available.
Boiling point/boiling range	Not applicable.
Melting point	No data available.
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.
Vapour pressure	Not applicable.
Relative density	> 1 [Ref Std: WATER=1]
Water solubility	Negligible
Solubility- non-water	No data available.
Partition coefficient: n-octanol/water	No data available.
Evaporation rate	Not applicable.
Vapour density	Not applicable.
Decomposition temperature	No data available.
Viscosity	No data available.
Density	1.1 - 1.4 g/cm ³

9.2. Other information

Percent volatile

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

Strong acids.

Strong bases.

Strong oxidising agents.

10.6 Hazardous decomposition productsSubstance

None known.

Condition

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

This product may have a characteristic odour; however, no adverse health effects are anticipated.

Skin contact

Mild Skin Irritation: Signs/symptoms may include localised redness, swelling, itching, and dryness.

Eye contact

Moderate eye irritation: Signs/symptoms may include redness, swelling, pain, tearing, and blurred or hazy vision.

Ingestion

Gastrointestinal irritation: Signs/symptoms may include abdominal pain, stomach upset, nausea, vomiting and diarrhoea. May cause additional health effects (see below).

Additional Health Effects:

Single exposure may cause target organ effects:

Central nervous system (CNS) depression: Signs/symptoms may include headache, dizziness, drowsiness, incoordination, nausea, slowed reaction time, slurred speech, giddiness, and unconsciousness.

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	Dermal		No data available; calculated ATE >5,000 mg/kg
Overall product	Ingestion		No data available; calculated ATE >5,000 mg/kg
Sulphonium salt	Dermal	Rat	LD50 > 2,000 mg/kg
Sulphonium salt	Ingestion	Rat	LD50 300-2000 mg/kg
Tributyl o-acetylcitrate	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
Tributyl o-acetylcitrate	Ingestion	Rat	LD50 > 25,000 mg/kg
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Dermal	Rabbit	LD50 > 5,000 mg/kg
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 0.691 mg/l
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Ingestion	Rat	LD50 > 5,110 mg/kg

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Flux calcined diatomaceous earth (68855-54-9) containing cristobalite (unknown or >=10%)	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
Flux calcined diatomaceous earth (68855-54-9) containing cristobalite (unknown or >=10%)	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 2.7 mg/l
Flux calcined diatomaceous earth (68855-54-9) containing cristobalite (unknown or >=10%)	Ingestion	Rat	LD50 > 2,000 mg/kg
Polyethylene-polypropylene glycol	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
Polyethylene-polypropylene glycol	Ingestion	Rat	LD50 5,700 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Sulphonium salt	Rabbit	Mild irritant
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Rabbit	No significant irritation
Flux calcined diatomaceous earth (68855-54-9) containing cristobalite (unknown or >=10%)	In vitro data	No significant irritation

Serious Eye Damage/Irritation

Name	Species	Value
Sulphonium salt	similar health hazards	Moderate irritant
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Rabbit	No significant irritation
Flux calcined diatomaceous earth (68855-54-9) containing cristobalite (unknown or >=10%)	Rabbit	Mild irritant

Skin Sensitisation

Name	Species	Value
Sulphonium salt	Mouse	Sensitising
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Human and animal	Not sensitising
Flux calcined diatomaceous earth (68855-54-9) containing cristobalite (unknown or >=10%)	Mouse	Not sensitising

Respiratory Sensitisation

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

Germ Cell Mutagenicity

Name	Route	Value
Sulphonium salt	In Vitro	Not mutagenic
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	In Vitro	Not mutagenic
Flux calcined diatomaceous earth (68855-54-9) containing cristobalite (unknown or >=10%)	In Vitro	Some positive data exist, but the data are not sufficient for classification

Carcinogenicity

Name	Route	Species	Value
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Not specified.	Mouse	Some positive data exist, but the data are not sufficient for classification
Flux calcined diatomaceous earth (68855-54-9) containing cristobalite (unknown or >=10%)	Inhalation	Human and animal	Carcinogenic.

3M ESPE PERMADYNE CATALYST**Reproductive Toxicity****Reproductive and/or Developmental Effects**

Name	Route	Value	Species	Test result	Exposure Duration
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Ingestion	Not toxic to female reproduction	Rat	NOAEL 509 mg/kg/day	1 generation
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Ingestion	Not toxic to male reproduction	Rat	NOAEL 497 mg/kg/day	1 generation
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Ingestion	Not toxic to development	Rat	NOAEL 1,350 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
Sulphonium salt	Ingestion	central nervous system depression	May cause drowsiness or dizziness	Rat	LOAEL 2,000 mg/kg	
Sulphonium salt	Ingestion	respiratory system	Some positive data exist, but the data are not sufficient for classification	Rat	NOAEL 300 mg/kg	

Specific Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Inhalation	respiratory system silicosis	All data are negative	Human	NOAEL Not available	occupational exposure
Flux calcined diatomaceous earth (68855-54-9) containing cristobalite (unknown or >=10%)	Inhalation	silicosis	Causes damage to organs through prolonged or repeated exposure	Human	NOAEL Not available	occupational exposure
Flux calcined diatomaceous earth (68855-54-9) containing cristobalite (unknown or >=10%)	Ingestion	hematopoietic system eyes kidney and/or bladder	All data are negative	Rat	NOAEL 3,738 mg/kg/day	90 days

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 SDS for additional toxicological information on this material and/or its components.

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.

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Material	CAS Nbr	Organism	Type	Exposure	Test endpoint	Test result
Polyethylene-polypropylene glycol	9003-11-6	Inland Silverside	Experimental	96 hours	LC50	650 mg/l
Polyethylene-polypropylene glycol	9003-11-6	Atlantic Salmon	Experimental	96 hours	LC50	>1,000 mg/l
Tributyl o-acetylcitrate	77-90-7	Water flea	Experimental	48 hours	EC50	7.82 mg/l
Sulphonium salt	72140-65-9		Data not available or insufficient for classification			
Silanameine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	68909-20-6	Algae	Estimated	72 hours	EC50	>100 mg/l
Flux calcined diatomaceous earth (68855-54-9) containing cristobalite (unknown or >=10%)	68855-54-9		Data not available or insufficient for classification			

12.2. Persistence and degradability

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Polyethylene-polypropylene glycol	9003-11-6	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Flux calcined diatomaceous earth (68855-54-9) containing cristobalite (unknown or >=10%)	68855-54-9	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Sulphonium salt	72140-65-9	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Silanameine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	68909-20-6	Data not available or insufficient for classification	N/A	N/A	N/A	N/A

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Tributyl o-acetyl citrate	77-90-7	Experimental Biodegradation	28 days	BOD	48 % weight	Other methods
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12.3 : Bioaccumulative potential

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Sulphonium salt	72140-65-9	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	68909-20-6	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Flux calcined diatomaceous earth (68855-54-9) containing cristobalite (unknown or >=10%)	68855-54-9	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Polyethylene-polypropylene glycol	9003-11-6	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Tributyl o-acetyl citrate	77-90-7	Estimated Bioconcentration		Bioaccumulation factor	5.1	Estimated: Bioconcentration factor

12.4. Mobility in soil

Please contact manufacturer for more details

12.5. Results of the PBT and vPvB assessment

No information available at this time, contact manufacturer for more details

12.6. Other adverse effects

No information available.

SECTION 13: Disposal considerations**13.1 Waste treatment methods**

See Section 11.1 Information on toxicological effects

Dispose of completely cured (or polymerised) material in a permitted industrial waste facility. As a disposal alternative, incinerate uncured product in a permitted waste incineration facility. If no other disposal options are available, waste product that has been completely cured or polymerised may be placed in a landfill properly designed for industrial waste.

The coding of a waste stream is based on the application of the product by the consumer. Since this is out of the control of 3M, no waste code(s) for products after use will be provided. Please refer to the European Waste Code (EWC - 2000/532/EC and amendments) to assign the correct waste code to your waste stream. Ensure national and/or regional regulations are

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complied with and always use a licensed waste contractor.

EU waste code (product as sold)

180106*

Chemicals consisting of or containing dangerous substances.

SECTION 14: Transportation information

ADR/IMDG/IATA: Not restricted for transport.

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.

15.2. Chemical Safety Assessment

Not applicable

SECTION 16: Other information

List of relevant H statements

H302	Harmful if swallowed.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H372	Causes damage to organs through prolonged or repeated exposure.

Revision information:

Section 3: Composition/ Information of ingredients table information was modified.
Section 11: Acute Toxicity table information was modified.
Section 11: Skin Sensitization Table information was modified.
Section 11: Target Organs - Single Table information was modified.
Section 12: Component ecotoxicity information was modified.
Section 14: Transportation classification information was modified.
Two-column table displaying the unique list of H Codes and statements (std phrases) for all components of the given material.
information was modified.

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3M United Kingdom MSDSs are available at www.3M.com/uk