

Safety Data Sheet

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Document group:25-7311-1Version number:1.00Issue Date:2020/06/12Supercedes Date:Initial Issue

This Safety Data Sheet has been prepared in accordance with the Canadian Hazardous Products Regulations.

SECTION 1: Identification

1.1. Product identifier

3MTM ClinproTM 5000 1.1% Sodium Fluoride Anti-Cavity ToothPaste (12115, 12214, 12215)

1.2. Recommended use and restrictions on use

Intended Use

Dental Product

Specific Use

Dental preventative

Restrictions on use

For use only by dental professionals.

1.3. Supplier's details

Company: 3M Canada Company

Division: Oral Care Solutions Division

Address: 1840 Oxford Street East, Post Office Box 5757, London, Ontario N6A 4T1

Telephone: (800) 364-3577 **Website:** www.3M.ca

1.4. Emergency telephone number

Medical Emergency Telephone: (519) 451-2500, Ext. 2222; Transportation Emergency Telephone (CANUTEC): (613) 996-6666

SECTION 2: Hazard identification

This product is exempt from hazard classification according to Canadian Hazardous Products Regulations for the following reason(s):

Cosmetic, device, drug or food as defined in section 2 of the Food and Drugs Act;

2.1. Classification of the substance or mixture

Specific Target Organ Toxicity (repeated exposure): Category 1.

2.2. Label elements

Signal word

3MTM ClinproTM 5000 1.1% Sodium Fluoride Anti-Cavity ToothPaste (12115, 12214, 12215)

Danger

Symbols

Health Hazard

Pictograms



Hazard statements

Causes damage to organs through prolonged or repeated exposure: musculoskeletal system

Precautionary statements

Prevention:

Do not breathe dust/fume/gas/mist/vapours/spray. Do not eat, drink or smoke when using this product. Wash exposed skin thoroughly after handling.

Response:

Get medical advice/attention if you feel unwell.

Disposal:

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

2.3. Other hazards

None known.

SECTION 3: Composition/information on ingredients

This material is a mixture.

Ingredient	C.A.S. No.	% by Wt	Common Name
Water	7732-18-5	30 - 40 Trade Secret *	Water
Non-Crystallizing Sorbitol Solution	50-70-4	20 - 30 Trade Secret *	D-Glucitol
Synthetic Amorphous Precipitated Silica (Crystalline- Free) FREE)	112926-00-8	10 - 20 Trade Secret *	Silica gel, pptd., crystfree
Amorphous Silica	7631-86-9	5 - 10 Trade Secret *	Silica
Glycerin	56-81-5	1 - 10 Trade Secret *	1,2,3-Propanetriol
Polyethylene Glycol	25322-68-3	1 - 5 Trade Secret *	Poly(oxy-1,2-ethanediyl), .alpha hydroomegahydroxy-
Polyethylene-Polypropylene Glycol	9003-11-6	1 - 5 Trade Secret *	Oxirane, methyl-, polymer with oxirane
Flavourings	Mixture	< 2 Trade Secret *	Not Applicable
Modified Tricalcium Phosphate	None	< 2 Trade Secret *	Not Applicable
Sodium Carboxymethyl Cellulose	9004-32-4	< 2 Trade Secret *	Cellulose, carboxymethyl ether, sodium salt
Sodium Fluoride	7681-49-4	1 - 2 Trade Secret *	Sodium fluoride (NaF)
Sodium Lauryl Sulfate	151-21-3	< 2 Trade Secret *	Sulfuric acid monododecyl ester sodium

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			salt
Sodium Saccharin	128-44-9	< 2 Trade Secret *	1,2-Benzisothiazol-3(2H)-one, 1,1-dioxide,
			sodium salt
Titanium Dioxide	13463-67-7	< 2 Trade Secret *	Titanium oxide (TiO2)

^{*}The actual concentration of this ingredient has been withheld as a trade secret.

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. 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

SubstanceConditionCarbon monoxideDuring CombustionCarbon dioxideDuring Combustion

5.3. Special protective actions for fire-fighters

Wear full protective equipment (Bunker Gear) and a self-contained breathing apparatus (SCBA).

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 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 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. Avoid release to the environment. Avoid contact with oxidizing agents (eg. chlorine, chromic acid etc.) Do not get in eyes.

7.2. Conditions for safe storage including any incompatibilities

Store away from oxidizing agents.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

No occupational exposure limit values exist for any of the components listed in Section 3 of this SDS.

8.2. Exposure controls

8.2.1. Engineering controls

No engineering controls required.

8.2.2. Personal protective equipment (PPE)

Eye/face protection

None required.

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

Colour White

Odour Minty, Bubble gum **Odour threshold** No Data Available pН Not Applicable Melting point/Freezing point No Data Available **Boiling point** Not Applicable **Flash Point** No flash point Not Applicable **Evaporation rate** Not Classified Flammability (solid, gas) Flammable Limits(LEL) Not Applicable Flammable Limits(UEL) Not Applicable

Vapour PressureNot ApplicableVapour DensityNot ApplicableDensity1.04 g/cm3

Relative density 1.04 [*Ref Std*:WATER=1]

Water solubilityAppreciableSolubility- non-waterNo Data AvailablePartition coefficient: n-octanol/ waterNot ApplicableAutoignition temperatureNo Data AvailableDecomposition temperatureNo Data AvailableViscosityNo 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 polymerization will not occur.

10.4. Conditions to avoid

None known.

10.5. Incompatible materials

Strong oxidizing agents

10.6. Hazardous decomposition products

<u>Substance</u> <u>Condition</u>

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 labeling, an ingredient may not be available for exposure, or the data may not be relevant to the material as a whole.

This document has been prepared in accordance with the U.S. OSHA Hazard Communication Standard, which requires the inclusion of all known hazards of the product or ingredients regardless of the potential risk. The risks of the hazards communicated in this document may vary depending on the potential for exposure.

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:

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

Eye Contact:

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

Ingestion:

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

Additional Health Effects:

Prolonged or repeated exposure may cause target organ effects:

Exposures needed to cause the following health effect(s) are not expected during normal, intended use:

Hard Tissue Effects: Signs/symptoms may include colour changes in the teeth and nails; changes in development of bone, teeth or nails; weakening of the bones; and/or hair loss.

Carcinogenicity:

Exposures needed to cause the following health effect(s) are not expected during normal, intended use:

Contains a chemical or chemicals which can cause cancer.

<u>Ingredient</u>	CAS No.	Class Description	Regulation
Titanium Dioxide	13463-67-7	Grp. 2B: Possible human carc.	International Agency for Research on Cancer

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
Non-Crystallizing Sorbitol Solution	Dermal	Professio nal judgeme nt	LD50 estimated to be > 5,000 mg/kg
Non-Crystallizing Sorbitol Solution	Ingestion	Rat	LD50 15,900 mg/kg
Synthetic Amorphous Precipitated Silica (Crystalline-Free) FREE)	Dermal	Rabbit	LD50 > 5,000 mg/kg
Synthetic Amorphous Precipitated Silica (Crystalline-Free) FREE)	Inhalation- Dust/Mist (4 hours)	Rat	LC50 > 0.691 mg/l
Synthetic Amorphous Precipitated Silica (Crystalline-Free) FREE)	Ingestion	Rat	LD50 > 5,110 mg/kg
Amorphous Silica	Dermal	Rabbit	LD50 > 5,000 mg/kg
Amorphous Silica	Inhalation- Dust/Mist (4 hours)	Rat	LC50 > 0.691 mg/l
Amorphous Silica	Ingestion	Rat	LD50 > 5,110 mg/kg
Glycerin	Dermal	Rabbit	LD50 estimated to be > 5,000 mg/kg
Glycerin	Ingestion	Rat	LD50 > 5,000 mg/kg
Polyethylene-Polypropylene Glycol	Dermal	Professio nal judgeme nt	LD50 estimated to be > 5,000 mg/kg
Polyethylene-Polypropylene Glycol	Ingestion	Rat	LD50 5,700 mg/kg
Sodium Fluoride	Dermal	Rat	LD50 > 2,000 mg/kg
Sodium Fluoride	Inhalation- Dust/Mist	Rat	LC50 1 mg/l
Sodium Fluoride	Ingestion	Rat	LD50 148.5 mg/kg
Sodium Saccharin	Dermal	Professio	LD50 estimated to be > 5,000 mg/kg

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		nal judgeme nt	
Polyethylene Glycol	Dermal	Rabbit	LD50 > 20,000 mg/kg
Sodium Carboxymethyl Cellulose	Dermal	Rabbit	LD50 > 2,000 mg/kg
Sodium Lauryl Sulfate	Dermal	Rabbit	LD50 580 mg/kg
Titanium Dioxide	Dermal	Rabbit	LD50 > 10,000 mg/kg
Polyethylene Glycol	Ingestion	Rat	LD50 32,770 mg/kg
Sodium Carboxymethyl Cellulose	Ingestion	Rat	LD50 > 27,000 mg/kg
Sodium Lauryl Sulfate	Inhalation-	Rat	LC50 > 0.975 mg/l
	Dust/Mist		
	(4 hours)		
Sodium Lauryl Sulfate	Ingestion	Rat	LD50 1,650 mg/kg
Sodium Saccharin	Ingestion	Rat	LD50 14,200 mg/kg
Titanium Dioxide	Inhalation-	Rat	LC50 > 6.82 mg/l
	Dust/Mist		
	(4 hours)		
Titanium Dioxide	Ingestion	Rat	LD50 > 10,000 mg/kg

 \overline{ATE} = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Synthetic Amorphous Precipitated Silica (Crystalline-Free) FREE)	Rabbit	No significant irritation
Amorphous Silica	Rabbit	No significant irritation
Glycerin	Rabbit	No significant irritation
Sodium Fluoride	official	Irritant
	classifica	
	tion	
Polyethylene Glycol	Rabbit	Minimal irritation
Sodium Carboxymethyl Cellulose	Human	No significant irritation
Sodium Lauryl Sulfate	Rabbit	Irritant
Titanium Dioxide	Rabbit	No significant irritation

Serious Eye Damage/Irritation

Name	Species	Value	
Synthetic Amorphous Precipitated Silica (Crystalline-Free) FREE)	Rabbit	No significant irritation	
Amorphous Silica	Rabbit	No significant irritation	
Glycerin	Rabbit	No significant irritation	
Sodium Fluoride	official	Severe irritant	
	classifica		
	tion		
Polyethylene Glycol	Rabbit	Mild irritant	
Sodium Carboxymethyl Cellulose	Rabbit	No significant irritation	
Sodium Lauryl Sulfate	Rabbit	Corrosive	
Titanium Dioxide	Rabbit	No significant irritation	

Skin Sensitization

Name	Species	Value
Synthetic Amorphous Precipitated Silica (Crystalline-Free) FREE)	Human	Not classified
	and	
	animal	
Amorphous Silica	Human	Not classified
	and	
	animal	
Glycerin	Guinea	Not classified
	pig	
Polyethylene Glycol	Guinea	Not classified
	pig	
Sodium Carboxymethyl Cellulose	Human	Not classified
Titanium Dioxide	Human	Not classified
	and	
	animal	

Respiratory Sensitization

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

Germ Cell Mutagenicity

Germ een riumgemeng					
Name	Route	Value			
Synthetic Amorphous Precipitated Silica (Crystalline-Free) FREE)	In Vitro	Not mutagenic			
Amorphous Silica	In Vitro	Not mutagenic			
Polyethylene Glycol	In Vitro	Not mutagenic			
Polyethylene Glycol	In vivo	Not mutagenic			
Sodium Carboxymethyl Cellulose	In Vitro	Not mutagenic			
Titanium Dioxide	In Vitro	Not mutagenic			
Titanium Dioxide	In vivo	Not mutagenic			

Carcinogenicity

Name	Route	Species	Value
Synthetic Amorphous Precipitated Silica (Crystalline-Free) FREE)	Not Specified	Mouse	Some positive data exist, but the data are not sufficient for classification
Amorphous Silica	Not Specified	Mouse	Some positive data exist, but the data are not sufficient for classification
Glycerin	Ingestion	Mouse	Some positive data exist, but the data are not sufficient for classification
Polyethylene Glycol	Ingestion	Rat	Not carcinogenic
Titanium Dioxide	Ingestion	Multiple animal species	Not carcinogenic
Titanium Dioxide	Inhalation	Rat	Carcinogenic

Reproductive Toxicity

Reproductive and/or Developmental Effects

Name	Route	Value	Species	Test result	Exposure Duration
Synthetic Amorphous Precipitated Silica (Crystalline-Free) FREE)	Ingestion	Not classified for female reproduction	Rat	NOAEL 509 mg/kg/day	1 generation
Synthetic Amorphous Precipitated Silica (Crystalline-Free) FREE)	Ingestion	Not classified for male reproduction	Rat	NOAEL 497 mg/kg/day	1 generation
Synthetic Amorphous Precipitated Silica (Crystalline-Free) FREE)	Ingestion	Not classified for development	Rat	NOAEL 1,350 mg/kg/day	during organogenesi s
Amorphous Silica	Ingestion	Not classified for female reproduction	Rat	NOAEL 509 mg/kg/day	1 generation
Amorphous Silica	Ingestion	Not classified for male reproduction	Rat	NOAEL 497 mg/kg/day	1 generation
Amorphous Silica	Ingestion	Not classified for development	Rat	NOAEL 1,350 mg/kg/day	during organogenesi s
Glycerin	Ingestion	Not classified for female reproduction	Rat	NOAEL 2,000 mg/kg/day	2 generation
Glycerin	Ingestion	Not classified for male reproduction	Rat	NOAEL 2,000 mg/kg/day	2 generation
Glycerin	Ingestion	Not classified for development	Rat	NOAEL 2,000 mg/kg/day	2 generation
Polyethylene Glycol	Ingestion	Not classified for female reproduction	Rat	NOAEL 1,125 mg/kg/day	during gestation
Polyethylene Glycol	Ingestion	Not classified for male reproduction	Rat	NOAEL 5699 +/- 1341 mg/kg/day	5 days
Polyethylene Glycol	Not Specified	Not classified for reproduction and/or development		NOEL N/A	
Polyethylene Glycol	Ingestion	Not classified for development	Mouse	NOAEL 562 mg/animal/da y	during gestation

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Sodium Carboxymethyl Cellulose	Ingestion	Not classified for female reproduction	Rat	NOAEL 1	3 generation
				g/kg in	
				the diet	
Sodium Carboxymethyl Cellulose	Ingestion	Not classified for male reproduction	Rat	NOAEL 1	3 generation
		_		g/kg in	
				the diet	

Target Organ(s)

Specific Target Organ Toxicity - single exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Sodium Fluoride	Inhalation	respiratory irritation	Some positive data exist, but the data are not sufficient for classification	Human	NOAEL Not available	occupational exposure
Polyethylene Glycol	Inhalation	respiratory irritation	Not classified	Rat	NOAEL 1.008 mg/l	2 weeks
Sodium Lauryl Sulfate	Inhalation	respiratory irritation	May cause respiratory irritation	similar health hazards	NOAEL Not available	

Specific Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Synthetic Amorphous Precipitated Silica (Crystalline-Free) FREE)	Inhalation	respiratory system silicosis	Not classified	Human	NOAEL Not available	occupational exposure
Amorphous Silica	Inhalation	respiratory system silicosis	Not classified	Human	NOAEL Not available	occupational exposure
Glycerin	Inhalation	respiratory system heart liver kidney and/or bladder	Not classified	Rat	NOAEL 3.91 mg/l	14 days
Glycerin	Ingestion	endocrine system hematopoietic system liver kidney and/or bladder	Not classified	Rat	NOAEL 10,000 mg/kg/day	2 years
Sodium Fluoride	Inhalation	bone, teeth, nails, and/or hair	Causes damage to organs through prolonged or repeated exposure	Human	NOAEL Not available	occupational exposure
Sodium Fluoride	Ingestion	bone, teeth, nails, and/or hair	Causes damage to organs through prolonged or repeated exposure	Human	NOAEL 0.33 mg/kg/day	environmenta l exposure
Polyethylene Glycol	Inhalation	respiratory system	Not classified	Rat	NOAEL 1.008 mg/l	2 weeks
Polyethylene Glycol	Ingestion	kidney and/or bladder heart endocrine system hematopoietic system liver nervous system	Not classified	Rat	NOAEL 5,640 mg/kg/day	13 weeks
Sodium Carboxymethyl Cellulose	Ingestion	blood kidney and/or bladder	Not classified	Rat	NOAEL 1 g/kg in the diet	25 months
Titanium Dioxide	Inhalation	respiratory system	Some positive data exist, but the data are not sufficient for classification	Rat	LOAEL 0.01 mg/l	2 years
Titanium Dioxide	Inhalation	pulmonary fibrosis	Not classified	Human	NOAEL Not available	occupational exposure

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

No data available.

SECTION 13: Disposal considerations

13.1. Disposal methods

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

Incinerate in a permitted waste incineration facility. As a disposal alternative, utilize an acceptable permitted waste disposal facility.

SECTION 14: Transport Information

For Transport Information, please visit http://3M.com/Transportinfo or call 1-800-364-3577 or 651-737-6501

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.

SECTION 16: Other information

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.

Health: 1 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.

Document group:	25-7311-1	Version number:	1.00
Issue Date:	2020/06/12	Supercedes Date:	Initial Issue

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3M Canada SDSs are available at www.3M.ca	

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