Safety Data Sheet

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SECTION 1: Identification

1.1. Product identifier
12115/ 12215 SERIES 3M™ ESPE™ CLINPRO™ 5000 1.1% SODIUM FLUORIDE 5000 ppm F- DENTIFRICE

Product Identification Numbers
70-2010-5655-6, 70-2010-5656-4, 70-2010-7843-6, 70-2010-7846-9, 70-2010-7883-2, 70-2010-7884-0, 70-2010-9848-3, 70-2010-9849-1, 70-2010-9850-9, 70-2014-0086-1, 70-2014-0087-9, 70-2014-0088-7

1.2. Recommended use and restrictions on use

Recommended use
Dental Product, Dental preventative
Restrictions on use
For use only by dental professionals.

1.3. Supplier's details

MANUFACTURER:	3M
DIVISION:	Oral Care Solutions Division
ADDRESS:	3M Center, St. Paul, MN 55144-1000, USA
Telephone:	1-888-3M HELPS (1-888-364-3577)

1.4. Emergency telephone number
1-800-364-3577 or (651) 737-6501 (24 hours)

SECTION 2: Hazard identification

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.

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

2.2. Label elements
Signal word
Danger

Symbols

Health Hazard |

Pictograms

Hazard Statements
Causes damage to organs through prolonged or repeated ingestion exposure:
musculoskeletal system |

Precautionary Statements

Prevention:
Do not eat, drink or smoke when using this product.

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. Hazards not otherwise classified
None.

SECTION 3: Composition/information on ingredients

Ingredient	C.A.S. No.	% by Wt
WATER	7732-18-5	30 - 40 Trade Secret *
NON-CRYSTALLIZING SORBITOL SOLUTION	50-70-4	20 - 30 Trade Secret *
SYNTHETIC AMORPHOUS PRECIPITATED SILICA (CRYSTALLINE-FREE)	112926-00-8	10 - 20 Trade Secret *
GLYCERIN	56-81-5	1 - 10 Trade Secret *
AMORPHOUS SILICA	7631-86-9	5 - 10 Trade Secret *
POLYETHYLENE-POLYPROPYLENE GLYCOL	9003-11-6	1 - 5 Trade Secret *
POLYETHYLENE GLYCOL	25322-68-3	1 - 5 Trade Secret *
SODIUM FLUORIDE	7681-49-4	1 - 2 Trade Secret *
FLAVORINGS	Mixture	< 2 Trade Secret *
MODIFIED TRICALCIUM PHOSPHATE	None	< 2 Trade Secret *
SODIUM LAURYL SULFATE	151-21-3	< 2 Trade Secret *
SODIUM CARBOXYMETHYL CELLULOSE	9004-32-4	< 2 Trade Secret *
SODIUM SACCHARIN	128-44-9	< 2 Trade Secret *
TITANIUM DIOXIDE	13463-67-7	< 2 Trade Secret *

*The specific chemical identity and/or exact percentage (concentration) of this composition 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

Substance	Condition
Carbon monoxide	During Combustion
Carbon dioxide	During Combustion

5.3. Special protective actions 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.

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

General Physical Form:	Solid
Specific Physical Form:	Paste
Odor, Color, Grade:	Opaque paste with vanilla mint, spearmint, or bubble gum flavor
Odor threshold	*No Data Available*
pH	*Not Applicable*
Melting point	*No Data Available*
Boiling Point	*Not Applicable*
Flash Point	No flash point
Evaporation rate	*Not Applicable*
Flammability (solid, gas)	Not Classified
Flammable Limits(LEL)	*Not Applicable*
Flammable Limits(UEL)	*Not Applicable*
Vapor Pressure	*Not Applicable*
Vapor Density	*Not Applicable*
Density	1.04 g/cm3
Specific Gravity	1.04 [*Ref Std:* WATER=1]
Solubility in Water	Appreciable
Solubility- non-water	*No Data Available*
Partition coefficient: n-octanol/ water	*Not Applicable*
Autoignition temperature	*No Data Available*
Decomposition temperature	*No Data Available*
Viscosity	*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 polymerization will not occur.

10.4. Conditions to avoid
None known.

10.5. Incompatible materials
Strong oxidizing agents

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 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 color 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.

Ingredient	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	Professional judgement	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)	Dermal	Rabbit	LD50 > 5,000 mg/kg
SYNTHETIC AMORPHOUS PRECIPITATED SILICA (CRYSTALLINE-FREE)	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 0.691 mg/l
SYNTHETIC AMORPHOUS PRECIPITATED SILICA (CRYSTALLINE-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	Professional judgement	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 LAURYL SULFATE	Inhalation-Dust/Mist		LC50 > 0.975 mg/l
SODIUM SACCHARIN	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
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	Ingestion	Rat	LD50 1,650 mg/kg
SODIUM SACCHARIN	Ingestion	Rat	LD50 14,200 mg/kg
TITANIUM DIOXIDE	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 6.82 mg/l
TITANIUM DIOXIDE	Ingestion	Rat	LD50 > 10,000 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
SYNTHETIC AMORPHOUS PRECIPITATED SILICA (CRYSTALLINE-FREE)	Rabbit	No significant irritation
AMORPHOUS SILICA	Rabbit	No significant irritation
GLYCERIN	Rabbit	No significant irritation
SODIUM FLUORIDE	official classification	Irritant
POLYETHYLENE GLYCOL	Rabbit	Minimal 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)	Rabbit	No significant irritation
AMORPHOUS SILICA	Rabbit	No significant irritation
GLYCERIN	Rabbit	No significant irritation
SODIUM FLUORIDE	official classification	Severe irritant
POLYETHYLENE GLYCOL	Rabbit	Mild irritant
SODIUM LAURYL SULFATE	Rabbit	Corrosive
TITANIUM DIOXIDE	Rabbit	No significant irritation

Skin Sensitization

Name	Species	Value
SYNTHETIC AMORPHOUS PRECIPITATED SILICA (CRYSTALLINE-FREE)	Human and animal	Not sensitizing
AMORPHOUS SILICA	Human and animal	Not sensitizing
GLYCERIN	Guinea pig	Not sensitizing
POLYETHYLENE GLYCOL	Guinea pig	Not sensitizing
TITANIUM DIOXIDE	Human and animal	Not sensitizing

Respiratory Sensitization

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

Germ Cell Mutagenicity

Name	Route	Value
SYNTHETIC AMORPHOUS PRECIPITATED SILICA (CRYSTALLINE-FREE)	In Vitro	Not mutagenic
AMORPHOUS SILICA	In Vitro	Not mutagenic
POLYETHYLENE GLYCOL	In Vitro	Not mutagenic

POLYETHYLENE GLYCOL	In vivo	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)	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)	Ingestion	Not toxic to female reproduction	Rat	NOAEL 509 mg/kg/day	1 generation
SYNTHETIC AMORPHOUS PRECIPITATED SILICA (CRYSTALLINE-FREE)	Ingestion	Not toxic to male reproduction	Rat	NOAEL 497 mg/kg/day	1 generation
SYNTHETIC AMORPHOUS PRECIPITATED SILICA (CRYSTALLINE-FREE)	Ingestion	Not toxic to development	Rat	NOAEL 1,350 mg/kg/day	during organogenesis
AMORPHOUS SILICA	Ingestion	Not toxic to female reproduction	Rat	NOAEL 509 mg/kg/day	1 generation
AMORPHOUS SILICA	Ingestion	Not toxic to male reproduction	Rat	NOAEL 497 mg/kg/day	1 generation
AMORPHOUS SILICA	Ingestion	Not toxic to development	Rat	NOAEL 1,350 mg/kg/day	during organogenesis
GLYCERIN	Ingestion	Not toxic to female reproduction	Rat	NOAEL 2,000 mg/kg/day	2 generation
GLYCERIN	Ingestion	Not toxic to male reproduction	Rat	NOAEL 2,000 mg/kg/day	2 generation
GLYCERIN	Ingestion	Not toxic to development	Rat	NOAEL 2,000 mg/kg/day	2 generation
POLYETHYLENE GLYCOL	Ingestion	Not toxic to female reproduction	Rat	NOAEL 1,125 mg/kg/day	during gestation
POLYETHYLENE GLYCOL	Ingestion	Not toxic to male reproduction	Rat	NOAEL 5699 +/- 1341 mg/kg/day	5 days
POLYETHYLENE GLYCOL	Not Specified	Some positive reproductive/developmental data exist, but the data are not sufficient for classification		NOEL N/A	
POLYETHYLENE GLYCOL	Ingestion	Some positive developmental data exist, but the data are not sufficient for classification	Mouse	NOAEL 562 mg/animal/day	during gestation

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	Human	NOAEL Not available	occupational exposure

			classification			
POLYETHYLENE GLYCOL	Inhalation	respiratory irritation	Some positive data exist, but the data are not sufficient for classification	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)	Inhalation	respiratory system | silicosis	All data are negative	Human	NOAEL Not available	occupational exposure
AMORPHOUS SILICA	Inhalation	respiratory system | silicosis	All data are negative	Human	NOAEL Not available	occupational exposure
GLYCERIN	Inhalation	respiratory system	Some positive data exist, but the data are not sufficient for classification	Rat	NOAEL 3.91 mg/l	14 days
GLYCERIN	Inhalation	heart | liver | kidney and/or bladder	All data are negative	Rat	NOAEL 3.91 mg/l	14 days
GLYCERIN	Ingestion	endocrine system | hematopoietic system | liver | kidney and/or bladder	All data are negative	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	environmental exposure
POLYETHYLENE GLYCOL	Inhalation	respiratory system	Some positive data exist, but the data are not sufficient for classification	Rat	NOAEL 1.008 mg/l	2 weeks
POLYETHYLENE GLYCOL	Ingestion	kidney and/or bladder	Some positive data exist, but the data are not sufficient for classification	Rat	NOAEL 5,640 mg/kg/day	13 weeks
POLYETHYLENE GLYCOL	Ingestion	heart | endocrine system | hematopoietic system | liver | nervous system	All data are negative	Rat	NOAEL 5,640 mg/kg/day	13 weeks
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	All data are negative	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

Ecotoxicological information

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

Chemical fate information

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

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.

EPA Hazardous Waste Number (RCRA): Not regulated

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. US Federal Regulations
Contact 3M for more information.

311/312 Hazard Categories:

Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No Immediate Hazard - Yes Delayed Hazard - Yes

15.2. State Regulations
Contact 3M for more information.

15.3. Chemical Inventories
The components of this product are in compliance with the new substance notification requirements of CEPA.

This material contains one or more substances not listed on the TSCA Inventory. Commercial use of this material is regulated by the FDA.

Contact 3M for more information.

15.4. International Regulations
Contact 3M for more information.

This SDS has been prepared to meet the U.S. OSHA Hazard Communication Standard, 29 CFR 1910.1200.

SECTION 16: Other information

NFPA Hazard Classification
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.

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