



Safety Data Sheet

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Document Group:	16-3924-4	Version Number:	11.01
Issue Date:	12/29/17	Supersedes Date:	10/07/16

SECTION 1: Identification

1.1. Product identifier

3M™ ESPE™ SINFONY OPAQUER POWDER

Product Identification Numbers

70-2011-0715-1, 70-2011-0716-9, 70-2011-0717-7, 70-2011-0718-5, 70-2011-0719-3, 70-2011-0720-1, 70-2011-0721-9, 70-2011-0722-7, 70-2011-0723-5, 70-2011-0724-3, 70-2011-0725-0, 70-2011-0726-8, 70-2011-0727-6, 70-2011-0728-4, 70-2011-0729-2, 70-2011-0730-0, 70-2011-0731-8, 70-2011-0732-6, 70-2011-0733-4, 70-2011-0734-2, 70-2011-0735-9

1.2. Recommended use and restrictions on use

Recommended use

Dental Product, Restorative

Restrictions on use

For use only by dental professionals

1.3. Supplier's details

MANUFACTURER:	3M
DIVISION:	Oral Care Solutions Division

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

Organic Peroxide: Type D.
Skin Sensitizer: Category 1B.
Carcinogenicity: Category 2.

2.2. Label elements

Signal word

Danger

Symbols

Flame | Exclamation mark | Health Hazard |

Pictograms**Hazard Statements**

Heating may cause a fire.

May cause an allergic skin reaction.

Suspected of causing cancer.

Precautionary Statements**Prevention:**

Obtain special instructions before use.

Do not handle until all safety precautions have been read and understood.

Keep away from heat/sparks/open flames/hot surfaces. - No smoking.

Keep away from clothing and other combustible materials.

Keep only in original container.

Avoid breathing dust/fume/gas/mist/vapors/spray.

Wear protective gloves and eye/face protection.

Contaminated work clothing must not be allowed out of the workplace.

Response:

IF ON SKIN: Wash with plenty of soap and water.

If skin irritation or rash occurs: Get medical advice/attention.

Wash contaminated clothing before reuse.

IF exposed or concerned: Get medical advice/attention.

Storage:

Protect from sunlight.

Store at temperatures not exceeding 5C/40F. Keep cool.

Store away from other materials.

Disposal:

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

4% of the mixture consists of ingredients of unknown acute oral toxicity.

4% of the mixture consists of ingredients of unknown acute dermal toxicity.

10% of the mixture consists of ingredients of unknown acute inhalation toxicity.

SECTION 3: Composition/information on ingredients

Ingredient	C.A.S. No.	% by Wt
SILANE TREATED QUARTZ	100402-78-6	40 - 50 Trade Secret *
CALCIUM FLUORIDE	7789-75-5	15 - 30 Trade Secret *
TITANIUM DIOXIDE	13463-67-7	15 - 30 Trade Secret *

ISOBUTYLMALONYL-N,N'- DICYCLOHEXYLSULFAMIDE	117204-17-8	1 - 5 Trade Secret *
LAUROYL PEROXIDE	105-74-8	1 - 5 Trade Secret *
SILANE TREATED SILICA	68909-20-6	< 2 Trade Secret *
C.I. PIGMENT YELLOW 42	51274-00-1	< 1.5 Trade Secret *
IRON HYDROXIDE OXIDE	20344-49-4	< 1.5 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:

Immediately wash with soap and water. Remove contaminated clothing and wash before reuse. 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

Closed containers exposed to heat from fire may build pressure and explode.

Hazardous Decomposition or By-Products

Substance

Carbon monoxide
Carbon dioxide

Condition

During Combustion
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. Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Use only non-sparking tools. Ventilate the area with fresh air. For large spill, or spills in confined spaces, provide mechanical ventilation to disperse or exhaust vapors, in accordance with good industrial hygiene practice. Warning! A motor could be an ignition source and could cause flammable gases or vapors in the spill area to burn or explode. 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 using non-sparking tools. 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

Do not handle until all safety precautions have been read and understood. Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Avoid breathing dust/fume/gas/mist/vapors/spray. Do not eat, drink or smoke when using this product. Wash thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace. Avoid release to the environment. Wash contaminated clothing before reuse. Do not get in eyes. Use personal protective equipment (gloves, respirators, etc.) as required. A no-touch technique is recommended. If skin contact occurs, wash skin with soap and water. If product contacts glove, remove and discard glove, wash hands immediately with soap and water and then re-glove.

7.2. Conditions for safe storage including any incompatibilities

Protect from sunlight. Store at temperatures not exceeding 5C/40F. Keep cool. Keep only in original container. Store away from other materials. Keep/store away from clothing and other combustible materials.

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	C.A.S. No.	Agency	Limit type	Additional Comments
TITANIUM DIOXIDE	13463-67-7	ACGIH	TWA:10 mg/m3	A4: Not class. as human carcin
TITANIUM DIOXIDE	13463-67-7	OSHA	TWA(as total dust):15 mg/m3	
FLUORIDES	7789-75-5	ACGIH	TWA(as F):2.5 mg/m3	A4: Not class. as human carcin
FLUORIDES	7789-75-5	OSHA	TWA(as dust):2.5 mg/m3;TWA(as F):2.5 mg/m3	

ACGIH : American Conference of Governmental Industrial Hygienists
 AIHA : American Industrial Hygiene Association
 CMRG : Chemical Manufacturer's Recommended Guidelines
 OSHA : United States Department of Labor - Occupational Safety and Health Administration
 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

General Physical Form:	Solid
Specific Physical Form:	Fine Powder (less than 10 microns)
Odor, Color, Grade:	Various colors, characteristic odor
Odor threshold	<i>No Data Available</i>
pH	<i>Not Applicable</i>
Melting point	<i>No Data Available</i>
Boiling Point	<i>Not Applicable</i>
Flash Point	Flash point > 93 °C (200 °F)
Evaporation rate	<i>Not Applicable</i>
Flammability (solid, gas)	Organic Peroxide: Type D.
Flammable Limits(LEL)	<i>Not Applicable</i>
Flammable Limits(UEL)	<i>Not Applicable</i>
Vapor Pressure	<i>Not Applicable</i>
Vapor Density	<i>Not Applicable</i>
Density	<i>No Data Available</i>
Specific Gravity	0.95 - 1.05 [Ref Std:WATER=1]
Solubility in Water	Nil
Solubility- non-water	<i>No Data Available</i>
Partition coefficient: n-octanol/ water	<i>No Data Available</i>
Autoignition temperature	<i>Not Applicable</i>
Decomposition temperature	<i>No Data Available</i>
Viscosity	<i>Not Applicable</i>
Molecular weight	<i>No Data Available</i>
Volatile Organic Compounds	<i>Not Applicable</i>
Percent volatile	<i>Not Applicable</i>
VOC Less H2O & Exempt Solvents	<i>Not Applicable</i>

SECTION 10: Stability and reactivity

10.1. Reactivity

This material is considered to be non reactive under normal use conditions.

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

None known.

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.

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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:

May be harmful if inhaled. Respiratory Tract Irritation: Signs/symptoms may include cough, sneezing, nasal discharge, headache, hoarseness, and nose and throat pain.

May cause additional health effects (see below).

Skin Contact:

Mechanical Skin irritation: Signs/symptoms may include abrasion, redness, pain, and itching.

Allergic Skin Reaction (non-photo induced): Signs/symptoms may include redness, swelling, blistering, and itching.

Eye Contact:

Mechanical eye irritation: Signs/symptoms may include pain, redness, tearing and corneal abrasion.

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:

May accumulate in the body.

Carcinogenicity:

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	Inhalation-Dust/Mist(4 hr)		No data available; calculated ATE5 - 12.5 mg/l
Overall product	Ingestion		No data available; calculated ATE >5,000 mg/kg
SILANE TREATED QUARTZ	Dermal	Rabbit	LD50 > 5,000 mg/kg
SILANE TREATED QUARTZ	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 0.691 mg/l
SILANE TREATED QUARTZ	Ingestion	Rat	LD50 > 5,110 mg/kg
CALCIUM FLUORIDE	Dermal	Professional judgement	LD50 estimated to be 2,000 - 5,000 mg/kg
TITANIUM DIOXIDE	Dermal	Rabbit	LD50 > 10,000 mg/kg
CALCIUM FLUORIDE	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 5.07 mg/l
CALCIUM FLUORIDE	Ingestion	Rat	LD50 > 2,000 mg/kg
TITANIUM DIOXIDE	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 6.82 mg/l
TITANIUM DIOXIDE	Ingestion	Rat	LD50 > 10,000 mg/kg
LAUROYL PEROXIDE	Dermal		estimated to be > 5,000 mg/kg
LAUROYL PEROXIDE	Inhalation-Dust/Mist		estimated to be > 12.5 mg/l
LAUROYL PEROXIDE	Ingestion		estimated to be > 5,000 mg/kg
ISOBUTYLMALONYL-N,N'-DICYCLOHEXYLSULFAMIDE	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
ISOBUTYLMALONYL-N,N'-DICYCLOHEXYLSULFAMIDE	Ingestion	Rat	LD50 > 2,000 mg/kg
C.I. PIGMENT YELLOW 42	Dermal		LD50 estimated to be > 5,000 mg/kg
IRON HYDROXIDE OXIDE	Dermal		LD50 estimated to be > 5,000 mg/kg
C.I. PIGMENT YELLOW 42	Ingestion	Rat	LD50 > 10,000 mg/kg
IRON HYDROXIDE OXIDE	Ingestion	Rat	LD50 > 10,000 mg/kg
SILANE TREATED SILICA	Dermal	Rabbit	LD50 > 5,000 mg/kg
SILANE TREATED SILICA	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 0.691 mg/l
SILANE TREATED SILICA	Ingestion	Rat	LD50 > 5,110 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
SILANE TREATED QUARTZ	Rabbit	No significant irritation

TITANIUM DIOXIDE	Rabbit	No significant irritation
ISOBUTYLMALONYL-N,N'-DICYCLOHEXYLSULFAMIDE	Rabbit	No significant irritation
C.I. PIGMENT YELLOW 42	Rabbit	No significant irritation
IRON HYDROXIDE OXIDE	Rabbit	No significant irritation
SILANE TREATED SILICA	Rabbit	No significant irritation

Serious Eye Damage/Irritation

Name	Species	Value
SILANE TREATED QUARTZ	Rabbit	No significant irritation
TITANIUM DIOXIDE	Rabbit	No significant irritation
ISOBUTYLMALONYL-N,N'-DICYCLOHEXYLSULFAMIDE	Rabbit	No significant irritation
C.I. PIGMENT YELLOW 42	Rabbit	No significant irritation
IRON HYDROXIDE OXIDE	Rabbit	No significant irritation
SILANE TREATED SILICA	Rabbit	No significant irritation

Skin Sensitization

Name	Species	Value
SILANE TREATED QUARTZ	Human and animal	Not classified
TITANIUM DIOXIDE	Human and animal	Not classified
ISOBUTYLMALONYL-N,N'-DICYCLOHEXYLSULFAMIDE	Guinea pig	Not classified
LAUROYL PEROXIDE	Guinea pig	Sensitizing
C.I. PIGMENT YELLOW 42	Human and animal	Not classified
IRON HYDROXIDE OXIDE	Human and animal	Not classified
SILANE TREATED SILICA	Human and animal	Not classified

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
SILANE TREATED QUARTZ	In Vitro	Not mutagenic
TITANIUM DIOXIDE	In Vitro	Not mutagenic
TITANIUM DIOXIDE	In vivo	Not mutagenic
ISOBUTYLMALONYL-N,N'-DICYCLOHEXYLSULFAMIDE	In Vitro	Not mutagenic
SILANE TREATED SILICA	In Vitro	Not mutagenic

Carcinogenicity

Name	Route	Species	Value
SILANE TREATED QUARTZ	Not Specified		Some positive data exist, but the data are not sufficient for classification
TITANIUM DIOXIDE	Ingestion	Multiple animal species	Not carcinogenic
TITANIUM DIOXIDE	Inhalation	Rat	Carcinogenic
C.I. PIGMENT YELLOW 42	Inhalation	Rat	Not carcinogenic
IRON HYDROXIDE OXIDE	Inhalation	Rat	Not carcinogenic
SILANE TREATED SILICA	Not Specified	Mouse	Some positive data exist, but the data are not sufficient for classification

Reproductive Toxicity**Reproductive and/or Developmental Effects**

Name	Route	Value	Species	Test Result	Exposure Duration
SILANE TREATED QUARTZ	Ingestion	Not classified for female reproduction	Rat	NOAEL 509 mg/kg/day	1 generation
SILANE TREATED QUARTZ	Ingestion	Not classified for male reproduction	Rat	NOAEL 497 mg/kg/day	1 generation
SILANE TREATED QUARTZ	Ingestion	Not classified for development	Rat	NOAEL 1,350 mg/kg/day	during organogenesis
SILANE TREATED SILICA	Ingestion	Not classified for female reproduction	Rat	NOAEL 509 mg/kg/day	1 generation
SILANE TREATED SILICA	Ingestion	Not classified for male reproduction	Rat	NOAEL 497 mg/kg/day	1 generation
SILANE TREATED SILICA	Ingestion	Not classified for development	Rat	NOAEL 1,350 mg/kg/day	during organogenesis

Target Organ(s)**Specific Target Organ Toxicity - single exposure**

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

Specific Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test Result	Exposure Duration
SILANE TREATED QUARTZ	Inhalation	respiratory system silicosis	Not classified	Human	NOAEL Not available	occupational exposure
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
C.I. PIGMENT YELLOW 42	Inhalation	respiratory system liver kidney and/or bladder	Not classified	Rat	NOAEL 0.2 mg/l	14 days
IRON HYDROXIDE OXIDE	Inhalation	respiratory system liver kidney and/or bladder	Not classified	Rat	NOAEL 0.2 mg/l	14 days
SILANE TREATED SILICA	Inhalation	respiratory system silicosis	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.

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.

EPA Hazardous Waste Number (RCRA): Not regulated

SECTION 15: Regulatory information

15.1. US Federal Regulations

Contact 3M for more information.

EPCRA 311/312 Hazard Classifications:

Physical Hazards

Organic peroxide

Health Hazards

Carcinogenicity

Respiratory or Skin Sensitization

15.2. State Regulations

Contact 3M for more information.

15.3. Chemical Inventories

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: 2 **Flammability:** 1 **Instability:** 1 **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: 16-3924-4 **Version Number:** 11.01
Issue Date: 12/29/17 **Supersedes Date:** 10/07/16

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