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Safety Data Sheet

2025-02-27 21:37:41.907

Purchase Order #: Customer Number: 925420 0096029960

SDS Coordinator DENTAL HEALTH PRODUCTS INC 2614 N SUGAR BUSH RD NEW FRANKEN, WI 54229-9346 USA

Dear SDS Coordinator

Enclosed is the Safety Data Sheet (SDS)* for the product that your company recently purchased from 3M.

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*An Article Information Sheet (AIS) or Article Information Letter (AIL) may be enclosed in place of an SDS if the product is an article which does not require an SDS under the U.S. OSHA Hazard Communication Standard, 29 CFR 1910.1200.



Safety Data Sheet

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| Document Group: | 29-6283-5 | Version Number: | 3.00 |
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| Issue Date: | 04/07/20 | Supercedes Date: | 02/21/18 |

Product identifier

3M[™] RelyX[™] Luting Plus Automix Cement (3535/3535TK/3535SK)

ID Number(s):

70-2010-8554-8, 70-2010-8555-5, 70-2010-8557-1

7000128981, 7000128982, 7000128984

Recommended use Dental product, Dental luting cement Restrictions on use For use only by dental professionals

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) |

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

This product is a kit or a multipart product which consists of multiple, independently packaged components. A Safety Data Sheet (SDS), Article Information Sheet (AIS), or Article Information Letter (AIL) for each of these components is included. Please do not separate the component documents from this cover page. The document numbers for components of this product are:

29-6280-1, 29-6234-8

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S solventum

Safety Data Sheet

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| Document Group: | 29-6280-1 | Version Number: | 4.00 |
|-----------------|-----------|------------------|----------|
| Issue Date: | 01/21/25 | Supercedes Date: | 06/22/22 |

SECTION 1: Identification

1.1. Product identifier 3MTM RelyXTM Luting Plus Cement Paste B

Product Identification Numbers LE-F100-0969-8

1.2. Recommended use and restrictions on use

Recommended use Dental Product, Luting cement Restrictions on use

For use only by dental professionals

| 1.3. Supplier's details | |
|-------------------------|---|
| MANUFACTURER: | Solventum |
| DIVISION: | Dental Solutions |
| ADDRESS: | Solventum US LLC, 12930 IH 10 West, San Antonio, TX 78249 |
| Telephone: | 1-855-423-6725 |
| | |

1.4. Emergency telephone number +1 703-741-5970; (24/7)

SECTION 2: Hazard identification

2.1. Hazard classification

Serious Eye Damage/Irritation: Category 2A. Respiratory Sensitizer: Category 1. Skin Sensitizer: Category 1.

2.2. Label elements Signal word Danger

Symbols Health Hazard |

Pictograms



Hazard Statements

Causes serious eye irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.

Precautionary Statements

Prevention:

Avoid breathing dust/fume/gas/mist/vapors/spray. In case of inadequate ventilation wear respiratory protection. Wear protective gloves and eye/face protection. Wash thoroughly after handling. Contaminated work clothing must not be allowed out of the workplace.

Response:

IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.

If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

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

If eye irritation persists: Get medical advice/attention.

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.

Disposal:

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

88% 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 Ceramic | 444758-98-9 | 30 - 40 Trade Secret * |
| 2-Hydroxyethyl Methacrylate (HEMA) | 868-77-9 | 10 - 30 Trade Secret * |
| Copolymer Of Acrylic And Itaconic Acids | 25948-33-8 | 10 - 30 Trade Secret * |
| Water | 7732-18-5 | 5 - 15 Trade Secret * |
| Glycerol 1,3 Dimethacrylate | 1830-78-0 | 1 - 5 Trade Secret * |
| Potassium Diphosphate | 7778-77-0 | 1 - 5 Trade Secret * |
| Potassium Persulfate | 7727-21-1 | 1 - 5 Trade Secret * |
| 2,6-Di-Tert-Butyl-P-Cresol (BHT) | 128-37-0 | < 0.5 Trade Secret * |
| Ethylene Dimethacrylate (EGDMA) | 97-90-5 | < 0.5 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:

Immediately flush with large amounts of water. Remove contact lenses if easy to do. Continue rinsing. 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

Allergic respiratory reaction (difficulty breathing, wheezing, cough, and tightness of chest). Allergic skin reaction (redness, swelling, blistering, and itching).

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

<u>Substance</u> Carbon monoxide Carbon dioxide <u>Condition</u> During Combustion During Combustion

5.3. Special protective actions 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 vapors, 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

A no-touch technique is recommended. If skin contact occurs, wash skin with soap and water. Acrylates may penetrate commonly-used gloves. If product contacts glove, remove and discard glove, wash hands immediately with soap and water and then re-glove. 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. Wash contaminated clothing before reuse. Do not get in eyes.

7.2. Conditions for safe storage including any incompatibilities

Store away from heat.

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 |
|----------------------------|------------|--------|------------------------------|-------------------------|
| 2,6-Di-Tert-Butyl-P-Cresol | 128-37-0 | ACGIH | TWA(inhalable fraction and | A4: Not class. as human |
| (BHT) | | | vapor):2 mg/m3 | carcin |
| PERSULFATE COMPOUNDS | 7727-21-1 | ACGIH | TWA(as persulfate):0.1 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

| Appearance Physical state Color | Solid Transparent Yellow |
|---------------------------------------|-----------------------------|
| Specific Physical Form: | Paste |

| Odor | Moderate Honey |
|---|--------------------------------|
| Odor threshold | No Data Available |
| рН | No Data Available |
| Melting point | Not Applicable |
| Boiling Point | Not Applicable |
| Flash Point | No flash point |
| Evaporation rate | No Data Available |
| Flammability (solid, gas) | Not Classified |
| Flammable Limits(LEL) | No Data Available |
| Flammable Limits(UEL) | No Data Available |
| Vapor Pressure | No Data Available |
| Vapor Density | No Data Available |
| Density | 1.5 g/cm3 |
| Specific Gravity | 1.5 [<i>Ref Std</i> :WATER=1] |
| Solubility in Water | Negligible |
| Solubility- non-water | No Data Available |
| Partition coefficient: n-octanol/ water | No Data Available |
| Autoignition temperature | No Data Available |
| Decomposition temperature | No Data Available |
| Viscosity | No Data Available |
| Molecular weight | Not Applicable |
| Volatile Organic Compounds | Not Applicable |
| | |

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 Heat

10.5. Incompatible materials None known.

10.6. Hazardous decomposition products

Substance

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.

The information below represents toxicological information associated with the individual components of the uncured

<u>Condition</u>

product. Once properly mixed and/or cured, the product is safe for its intended use.

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:

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

Allergic Respiratory Reaction: Signs/symptoms may include difficulty breathing, wheezing, cough, and tightness of chest.

Skin Contact:

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

Eye Contact:

Severe Eye Irritation: Signs/symptoms may include significant redness, swelling, pain, tearing, cloudy appearance of the cornea, and impaired vision.

Ingestion:

Gastrointestinal Irritation: Signs/symptoms may include abdominal pain, stomach upset, nausea, vomiting and diarrhea.

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 | Inhalation- Dust/Mist(4 hr) | | No data available; calculated ATE >12.5 mg/l |
| Overall product | Ingestion | | No data available; calculated ATE >5,000 mg/kg |
| Silane Treated Ceramic | Dermal | | LD50 estimated to be > 5,000 mg/kg |
| Silane Treated Ceramic | Ingestion | | LD50 estimated to be 2,000 - 5,000 mg/kg |
| Copolymer Of Acrylic And Itaconic Acids | Ingestion | Rat | LD50 > 5,000 mg/kg |
| Copolymer Of Acrylic And Itaconic Acids | Dermal | similar health hazards | LD50 estimated to be > 5,000 mg/kg |
| 2-Hydroxyethyl Methacrylate (HEMA) | Dermal | Rabbit | LD50 > 5,000 mg/kg |
| 2-Hydroxyethyl Methacrylate (HEMA) | Ingestion | Rat | LD50 5,564 mg/kg |
| Glycerol 1,3 Dimethacrylate | Ingestion | Rat | LD50 > 2,000 mg/kg |
| Potassium Diphosphate | Dermal | Rabbit | LD50 > 4,640 mg/kg |
| Potassium Diphosphate | Ingestion | Rat | LD50 > 4,640 mg/kg |
| Potassium Persulfate | Dermal | Rabbit | LD50 > 10,000 mg/kg |
| Potassium Persulfate | Ingestion | Rat | LD50 1,130 mg/kg |
| Potassium Persulfate | Inhalation- Dust/Mist (4 hours) | similar compoun ds | LC50 > 5.1 mg/l |
| Ethylene Dimethacrylate (EGDMA) | Dermal | Professio nal judgeme nt | LD50 estimated to be 2,000 - 5,000 mg/kg |
| Ethylene Dimethacrylate (EGDMA) | Ingestion | Rat | LD50 3,300 mg/kg |
| 2,6-Di-Tert-Butyl-P-Cresol (BHT) | Dermal | Rat | LD50 > 2,000 mg/kg |
| 2,6-Di-Tert-Butyl-P-Cresol (BHT) | Ingestion | Rat | LD50 > 2,930 mg/kg |

ATE = acute toxicity estimate

Skin Corrosion/Irritation

| Name | Species | Value |
|------------------------------------|-----------|---------------------------|
| | | |
| Silane Treated Ceramic | similar | No significant irritation |
| | compoun | |
| | ds | |
| 2-Hydroxyethyl Methacrylate (HEMA) | Rabbit | Minimal irritation |
| Glycerol 1,3 Dimethacrylate | Rabbit | No significant irritation |
| Potassium Diphosphate | Rabbit | No significant irritation |
| Potassium Persulfate | Rabbit | No significant irritation |
| Ethylene Dimethacrylate (EGDMA) | Professio | Mild irritant |
| | nal | |
| | judgeme | |
| | nt | |
| 2,6-Di-Tert-Butyl-P-Cresol (BHT) | Human | Minimal irritation |
| | and | |
| | animal | |

Serious Eye Damage/Irritation

| Name | Species | Value |
|------------------------------------|-----------|---------------------------|
| | | |
| Silane Treated Ceramic | similar | Mild irritant |
| | compoun | |
| | ds | |
| 2-Hydroxyethyl Methacrylate (HEMA) | Rabbit | Moderate irritant |
| Glycerol 1,3 Dimethacrylate | In vitro | Severe irritant |
| | data | |
| Potassium Diphosphate | Rabbit | No significant irritation |
| Potassium Persulfate | Rabbit | No significant irritation |
| Ethylene Dimethacrylate (EGDMA) | Not | Moderate irritant |
| | available | |
| 2,6-Di-Tert-Butyl-P-Cresol (BHT) | Rabbit | Mild irritant |

Skin Sensitization

| Name | Species | Value |
|------------------------------------|---------|----------------|
| Silane Treated Ceramic | similar | Not classified |
| | compoun | |
| | ds | |
| 2-Hydroxyethyl Methacrylate (HEMA) | Human | Sensitizing |
| | and | |
| | animal | |
| Glycerol 1,3 Dimethacrylate | Mouse | Not classified |
| Potassium Diphosphate | similar | Not classified |
| | compoun | |
| | ds | |
| Potassium Persulfate | Mouse | Sensitizing |
| Ethylene Dimethacrylate (EGDMA) | Guinea | Sensitizing |
| | pig | |
| 2,6-Di-Tert-Butyl-P-Cresol (BHT) | Human | Not classified |

Respiratory Sensitization

| Name | Species | Value |
|----------------------|---------|-------------|
| Potassium Persulfate | Human | Sensitizing |

Germ Cell Mutagenicity

| Name | Route | Value |
|------------------------------------|----------|--|
| | | |
| 2-Hydroxyethyl Methacrylate (HEMA) | In vivo | Not mutagenic |
| 2-Hydroxyethyl Methacrylate (HEMA) | In Vitro | Some positive data exist, but the data are not sufficient for classification |
| Potassium Diphosphate | In Vitro | Not mutagenic |

| Potassium Persulfate | In Vitro | Not mutagenic |
|----------------------------------|----------|--|
| Ethylene Dimethacrylate (EGDMA) | In Vitro | Some positive data exist, but the data are not sufficient for classification |
| 2,6-Di-Tert-Butyl-P-Cresol (BHT) | In Vitro | Not mutagenic |
| 2,6-Di-Tert-Butyl-P-Cresol (BHT) | In vivo | Not mutagenic |

Carcinogenicity

| Name | Route | Species | Value |
|----------------------------------|------------|----------|--|
| Silane Treated Ceramic | Inhalation | similar | Some positive data exist, but the data are not |
| | | compoun | sufficient for classification |
| | | ds | |
| 2,6-Di-Tert-Butyl-P-Cresol (BHT) | Ingestion | Multiple | Some positive data exist, but the data are not |
| | _ | animal | sufficient for classification |
| | | species | |

Reproductive Toxicity

Reproductive and/or Developmental Effects

| Name | Route | Value | Species | Test Result | Exposure Duration |
|------------------------------------|-----------|--|---------|--------------------------|------------------------------------|
| 2-Hydroxyethyl Methacrylate (HEMA) | Ingestion | Not classified for female reproduction | Rat | NOAEL 1,000 mg/kg/day | premating & during gestation |
| 2-Hydroxyethyl Methacrylate (HEMA) | Ingestion | Not classified for male reproduction | Rat | NOAEL 1,000 mg/kg/day | 49 days |
| 2-Hydroxyethyl Methacrylate (HEMA) | Ingestion | Not classified for development | Rat | NOAEL 1,000 mg/kg/day | premating & during gestation |
| Potassium Diphosphate | Ingestion | Not classified for development | Rat | NOAEL 282 mg/kg/day | during organogenesi s |
| 2,6-Di-Tert-Butyl-P-Cresol (BHT) | Ingestion | Not classified for female reproduction | Rat | NOAEL 500 mg/kg/day | 2 generation |
| 2,6-Di-Tert-Butyl-P-Cresol (BHT) | Ingestion | Not classified for male reproduction | Rat | NOAEL 500 mg/kg/day | 2 generation |
| 2,6-Di-Tert-Butyl-P-Cresol (BHT) | Ingestion | Not classified for development | Rat | NOAEL 100 mg/kg/day | 2 generation |

Target Organ(s)

Specific Target Organ Toxicity - single exposure

| Name | Route | Target Organ(s) | Value | Species | Test Result | Exposure |
|--------------------------|------------|------------------------|----------------------------------|------------|-------------|----------|
| | | | | | | Duration |
| Copolymer Of Acrylic And | Ingestion | nervous system | Not classified | Rat | NOAEL | |
| Itaconic Acids | - | - | | | 5,000 mg/kg | |
| Potassium Persulfate | Inhalation | respiratory irritation | May cause respiratory irritation | Human | NOAEL Not | |
| | | | | and | available | |
| | | | | animal | | |
| Ethylene Dimethacrylate | Inhalation | respiratory irritation | May cause respiratory irritation | official | NOAEL Not | |
| (EGDMA) | | | | classifica | available | |
| | | | | tion | | |

Specific Target Organ Toxicity - repeated exposure

| Name | Route | Target Organ(s) | Value | Species | Test Result | Exposure Duration |
|--|------------|---|----------------|--------------------------|-----------------------------|----------------------|
| Silane Treated Ceramic | Inhalation | pulmonary fibrosis | Not classified | similar compoun ds | NOAEL Not available | |
| Copolymer Of Acrylic And Itaconic Acids | Ingestion | endocrine system hematopoietic system liver | Not classified | Rat | NOAEL 200 mg/kg/day | 28 days |
| Copolymer Of Acrylic And Itaconic Acids | Ingestion | heart bone, teeth, nails, and/or hair immune system | Not classified | Rat | NOAEL 2,000 mg/kg/day | 28 days |

| | | muscles nervous system eyes kidney and/or bladder respiratory system vascular system | | | | |
|-------------------------------------|-----------|---|--|--------------------------|------------------------------|--------------|
| Potassium Diphosphate | Ingestion | kidney and/or bladder | Some positive data exist, but the data are not sufficient for classification | similar compoun ds | NOAEL 322.88 mg/kg/day | 90 days |
| 2,6-Di-Tert-Butyl-P-Cresol (BHT) | Ingestion | liver | Some positive data exist, but the data are not sufficient for classification | Rat | NOAEL 250 mg/kg/day | 28 days |
| 2,6-Di-Tert-Butyl-P-Cresol (BHT) | Ingestion | kidney and/or bladder | Not classified | Rat | NOAEL 500 mg/kg/day | 2 generation |
| 2,6-Di-Tert-Butyl-P-Cresol (BHT) | Ingestion | blood | Not classified | Rat | LOAEL 420 mg/kg/day | 40 days |
| 2,6-Di-Tert-Butyl-P-Cresol (BHT) | Ingestion | endocrine system | Not classified | Rat | NOAEL 25 mg/kg/day | 2 generation |
| 2,6-Di-Tert-Butyl-P-Cresol (BHT) | Ingestion | heart | Not classified | Mouse | NOAEL 3,480 mg/kg/day | 10 weeks |

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.

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 14: Transport Information

Please contact the emergency numbers listed on the first page of the SDS for Transportation Information for this material.

SECTION 15: Regulatory information

15.1. US Federal Regulations

Contact manufacturer for more information

EPCRA 311/312 Hazard Classifications:

| Physical Hazards | |
|-----------------------------------|--|
| Not applicable | |
| Health Hazards | |
| Respiratory or Skin Sensitization | |

Serious eye damage or eye irritation

15.2. State Regulations

Contact manufacturer 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 manufacturer for more information

15.4. International Regulations

Contact manufacturer 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: 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: | 29-6280-1 | Version Number: | 4.00 |
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| Issue Date: | 01/21/25 | Supercedes Date: | 06/22/22 |

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| Document Group: | 29-6234-8 | Version Number: | 2.03 |
|-----------------|-----------|------------------|----------|
| Issue Date: | 04/22/21 | Supercedes Date: | 04/03/20 |

SECTION 1: Identification

1.1. Product identifier 3MTM RelyXTM Luting Plus Cement Paste A

Product Identification Numbers LE-F100-0969-1

1.2. Recommended use and restrictions on use

Recommended use Dental Product, Luting cement Restrictions on use For use only by dental professionals

| 1.3. Supplier's details | | |
|-------------------------|----------------------------|-----------------|
| MANUFACTURER: | 3M | |
| DIVISION: | Oral Care Solutions Divisi | ion |
| 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

Skin Sensitizer: Category 1.

2.2. Label elements Signal word Warning

Symbols Exclamation mark |





Hazard Statements May cause an allergic skin reaction.

Precautionary Statements

Prevention:

Wear protective gloves. 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.

Disposal:

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

72% of the mixture consists of ingredients of unknown acute oral toxicity.

SECTION 3: Composition/information on ingredients

| Ingredient | C.A.S. No. | % by Wt |
|------------------------------------|------------|------------------------|
| Silane Treated Glass | None | 70 - 80 Trade Secret * |
| Water | 7732-18-5 | 10 - 20 Trade Secret * |
| 2-Hydroxyethyl Methacrylate (HEMA) | 868-77-9 | < 10 Trade Secret * |
| Silane Treated Silica | 68909-20-6 | < 2 Trade Secret * |
| 4-(Dimethylamino)-Benzeneethanol | 50438-75-0 | < 1 Trade Secret * |
| Allylthiourea | 109-57-9 | < 0.5 Trade Secret * |
| Titanium Oxide | 13463-67-7 | < 0.5 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

Allergic skin reaction (redness, swelling, blistering, and itching).

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

<u>Substance</u> Carbon monoxide Carbon dioxide <u>Condition</u> During Combustion During Combustion

5.3. Special protective actions 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 vapors, 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

A no-touch technique is recommended. If skin contact occurs, wash skin with soap and water. Acrylates may penetrate commonly-used gloves. If product contacts glove, remove and discard glove, wash hands immediately with soap and water and then re-glove. 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. Wash contaminated clothing before reuse. Do not get in eyes.

7.2. Conditions for safe storage including any incompatibilities

Store away from heat.

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 Oxide | 13463-67-7 | ACGIH | TWA:10 mg/m3 | A4: Not class. as human |
| | | | | carcin |
| Titanium Oxide | 13463-67-7 | OSHA | TWA(as total dust):15 mg/m3 | |
| SILICA, AMORPHOUS | 68909-20-6 | OSHA | TWA:20 millions of | |
| | | | particles/cu. ft.;TWA | |
| | | | concentration:0.8 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

| Appearance | |
|---------------------------|---------------------|
| Physical state | Solid |
| Color | Off-White, Yellow |
| Specific Physical Form: | Paste |
| Ödor | Characteristic Odor |
| Odor threshold | No Data Available |
| рН | No Data Available |
| Melting point | No Data Available |
| Boiling Point | No Data Available |
| Flash Point | No flash point |
| Evaporation rate | No Data Available |
| Flammability (solid, gas) | Not Classified |
| Flammable Limits(LEL) | No Data Available |
| | |

| Flammable Limits(UEL) | No Data Available |
|---|--------------------------------|
| Vapor Pressure | No Data Available |
| Vapor Density | No Data Available |
| Density | 1.5 g/cm3 |
| Specific Gravity | 1.5 [<i>Ref Std</i> :WATER=1] |
| Solubility in Water | Negligible |
| Solubility- non-water | No Data Available |
| Partition coefficient: n-octanol/ water | No Data Available |
| Autoignition temperature | No Data Available |
| Decomposition temperature | No Data Available |
| Viscosity | No Data Available |
| Molecular weight | Not Applicable |
| Volatile Organic Compounds | No Data Available |

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 Heat

10.5. Incompatible materials None known.

10.6. Hazardous decomposition products Substance

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. The information below represents toxicological information associated with the individual components of the uncured product. Once properly mixed and/or cured, the product is safe for its intended use.

11.1. Information on Toxicological effects

Signs and Symptoms of Exposure

Condition

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 odor; however, no adverse health effects are anticipated.

Skin Contact:

Contact with the skin during product use is not expected to result in significant irritation. Allergic Skin Reaction (non-photo induced): Signs/symptoms may include redness, swelling, blistering, and itching.

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.

Additional Health Effects:

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 Oxide | 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 | Ingestion | | No data available; calculated ATE >5,000 mg/kg |
| 2-Hydroxyethyl Methacrylate (HEMA) | Dermal | Rabbit | LD50 > 5,000 mg/kg |
| 2-Hydroxyethyl Methacrylate (HEMA) | Ingestion | Rat | LD50 5,564 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 |
| Titanium Oxide | Dermal | Rabbit | LD50 > 10,000 mg/kg |
| Titanium Oxide | Inhalation- Dust/Mist (4 hours) | Rat | LC50 > 6.82 mg/l |
| Titanium Oxide | Ingestion | Rat | LD50 > 10,000 mg/kg |
| Allylthiourea | Ingestion | Rat | LD50 200 mg/kg |

ATE = acute toxicity estimate

Skin Corrosion/Irritation

| Name | Species | Value |
|------------------------------------|-----------|---------------------------|
| | | |
| 2-Hydroxyethyl Methacrylate (HEMA) | Rabbit | Minimal irritation |
| Silane Treated Silica | Rabbit | No significant irritation |
| Titanium Oxide | Rabbit | No significant irritation |
| Allylthiourea | Professio | Minimal irritation |
| | nal | |
| | judgeme | |
| | nt | |

Serious Eye Damage/Irritation

| Name | Species | Value |
|------------------------------------|-----------|---------------------------|
| | | |
| 2-Hydroxyethyl Methacrylate (HEMA) | Rabbit | Moderate irritant |
| Silane Treated Silica | Rabbit | No significant irritation |
| Titanium Oxide | Rabbit | No significant irritation |
| Allylthiourea | Professio | Mild irritant |
| | nal | |
| | judgeme | |
| | nt | |

Skin Sensitization

| Name | Species | Value |
|------------------------------------|-----------|----------------|
| 2-Hydroxyethyl Methacrylate (HEMA) | Human | Sensitizing |
| | and | |
| | animal | |
| Silane Treated Silica | Human | Not classified |
| | and | |
| | animal | |
| Titanium Oxide | Human | Not classified |
| | and | |
| | animal | |
| Allylthiourea | Professio | Sensitizing |
| | nal | |
| | judgeme | |
| | nt | |

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 |
|------------------------------------|----------|--|
| | | |
| 2-Hydroxyethyl Methacrylate (HEMA) | In vivo | Not mutagenic |
| 2-Hydroxyethyl Methacrylate (HEMA) | In Vitro | Some positive data exist, but the data are not sufficient for classification |
| Silane Treated Silica | In Vitro | Not mutagenic |
| Titanium Oxide | In Vitro | Not mutagenic |
| Titanium Oxide | In vivo | Not mutagenic |
| Allylthiourea | In Vitro | Not mutagenic |

Carcinogenicity

| Name | Route | Species | Value |
|-----------------------|------------|----------|--|
| Silane Treated Silica | Not | Mouse | Some positive data exist, but the data are not |
| | Specified | | sufficient for classification |
| Titanium Oxide | Ingestion | Multiple | Not carcinogenic |
| | _ | animal | |
| | | species | |
| Titanium Oxide | Inhalation | Rat | Carcinogenic |
| Allylthiourea | Ingestion | Rat | 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 |
| 2-Hydroxyethyl Methacrylate (HEMA) | Ingestion | Not classified for female reproduction | Rat | NOAEL 1,000 | premating & |
| | C | Ĩ | | mg/kg/day | during |
| | | | | | gestation |
| 2-Hydroxyethyl Methacrylate (HEMA) | Ingestion | Not classified for male reproduction | Rat | NOAEL 1,000 | 49 days |
| | _ | | | mg/kg/day | |
| 2-Hydroxyethyl Methacrylate (HEMA) | Ingestion | Not classified for development | Rat | NOAEL 1,000 | premating & |
| | | | | mg/kg/day | during |

| | | | | | gestation |
|-----------------------|-----------|--|-----|-------------|--------------|
| Silane Treated Silica | Ingestion | Not classified for female reproduction | Rat | NOAEL 509 | 1 generation |
| | | | | mg/kg/day | |
| Silane Treated Silica | Ingestion | Not classified for male reproduction | Rat | NOAEL 497 | 1 generation |
| | | | | mg/kg/day | |
| Silane Treated Silica | Ingestion | Not classified for development | Rat | NOAEL 1,350 | during |
| | | | | mg/kg/day | organogenesi |
| | | | | | S |

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 Silica | Inhalation | respiratory system silicosis | Not classified | Human | NOAEL Not available | occupational exposure |
| Titanium Oxide | Inhalation | respiratory system | Some positive data exist, but the data are not sufficient for classification | Rat | LOAEL 0.01 mg/l | 2 years |
| Titanium Oxide | Inhalation | pulmonary fibrosis | Not classified | Human | NOAEL Not available | occupational exposure |
| Allylthiourea | Ingestion | endocrine system | Not classified | Rat | NOAEL 23 mg/kg/day | 15 months |

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.

Dispose of completely cured (or polymerized) 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 polymerized may be placed in a landfill properly designed for industrial waste.

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.

EPCRA 311/312 Hazard Classifications:

Physical Hazards Not applicable

Health Hazards

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: 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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|-----------------|-----------|------------------|----------|
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