

<u>Safety Data Sheet Cover-Sheet</u> – This page provides additional New Zealand specific information for this product, and must be read in conjunction with the Safety Data Sheet (SDS) attached.

| Product Name: | ESPE™ RelyX™ Veneer Try-In Paste |
|-----------------------|---|
| Manufacturer: | 3M |
| SDS Expiry: | 14 July 2024 |
| Supplier Details: | Henry Schein New Zealand 23 William Pickering Drive, Albany PO Box 101 140, North Shore, Auckland 0745 Ph. 0800 808 855 www.henryschein.co.nz |
| Emergency Contacts: | Poisons/Hazardous Chemical Info Centre – 0800POISON/0800764766 (24 Hours) Phone 111 for Fire, Ambulance or Police |
| HSNO Class/Category: | Non Hazardous |
| HSNO Group Standard: | Non Hazardous |
| Statements/Pictograms | : As per attached Safety Data Sheet (SDS) |
| Date Prepared: | This coversheet was prepared on 17 April 2020 |

This SDS coversheet has been produced by Henry Schein NZ and has been prepared in accordance with NZ EPA advice on making overseas SDS compliant to HSNO Act. The above information is based on the present state of our knowledge of the product at the time of publication. It is given in good faith, no warranty is implied with respect to the quality or the specifications of the product. Users must satisfy that the product is entirely suitable for their purpose. The SDS and this coversheet may be revised from time to time, please ensure you have a current copy.





Safety Data Sheet

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| Document group: | 16-1922-0 | Version number: | 4.00 |
|-----------------|------------|------------------|------------|
| Issue Date: | 14/07/2019 | Supersedes date: | 16/10/2014 |

This Safety Data Sheet has been prepared in accordance with the New Zealand, Hazardous Substances (Safety Data Sheets) Notice 2017.

SECTION 1: Identification

1.1. Product identifier 3MTM ESPETM RelyXTM Veneer Try-In Paste

Product Identification Numbers 70-2010-3192-2

1.2. Recommended use and restrictions on use

Recommended use Dental Product, Veneer try-in paste

Restrictions on use For use by dental professionals only.

1.3. Supplier's details

| Address: | 3M New Zealand Ltd, 94 Apollo Drive, Rosedale 0632, Auckland |
|------------|--|
| Telephone: | (09) 477 4040 |
| E Mail: | innovation@nz.mmm.com |
| Website: | 3m.co.nz |

1.4. Emergency telephone number

24 hr Medical Emergency, National Poisons Centre, 0800 764 766 (0800 POISON)

SECTION 2: Hazard identification

Not classified as hazardous in accordance with the relevant criteria of the HSNO Act 1996, the Hazardous Substances (Classification) Notice 2017 and Hazardous Substances (Minimum Degrees of Hazard) Notice 2017. Refer to Section 14 of this Safety Data Sheet for product Dangerous Goods Classification.

2.1. Classification of the substance or mixture

| GHS | HSNO |
|------------------------------|------------------------------|
| Not classified as hazardous. | Not classified as hazardous. |

2.2. Label elements

SIGNAL WORD

Not applicable.

Symbols:

Not applicable.

SECTION 3: Composition/information on ingredients

| Ingredient | CAS Nbr | % by Weight |
|---|------------|-------------|
| Poly(oxy-1,2-ethanediyl),alpha-hydro-omega-hydroxy-ethane-1,2-diol, | 25322-68-3 | 80 - 95 |
| ethoxylated | | |
| Ceramic powder | 66402-68-4 | 5 - 15 |
| Titanium oxide | 13463-67-7 | < 1 |

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

| <u>Substa</u> | ince | | |
|---------------|-------------|--|--|
| Carbon | n monoxide. | | |
| Carbon | n 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.

5.4. Hazchem code: Not applicable.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

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. Observe precautions from other sections.

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. Dispose of collected material as soon as possible in accordance with applicable local/regional/national/international regulations.

SECTION 7: Handling and storage

Refer to Section 15 - Controls for more information

7.1. Precautions for safe handling

Avoid prolonged or repeated skin contact. Do not eat, drink or smoke when using this product. Wash thoroughly after handling.

7.2. Conditions for safe storage including any incompatibilities

No special storage requirements.

7.3. Certified handler

Not required

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limits

If a component is disclosed in section 3 but does not appear in the table below, an occupational exposure limit is not available for the component.

| Ingredient | CAS Nbr | Agency | Limit type | Additional comments |
|--|-------------------|--------------------|--------------------------|------------------------------------|
| Titanium oxide | 13463-67-7 | ACGIH | TWA:10 mg/m ³ | A4: Not class. as human carcinogin |
| Titanium oxide | 13463-67-7 | New Zealand WES | TWA(8 hours):10 mg/m3 | |
| Poly(oxy-1,2-ethanediyl),alpha- | 25322-68-3 | AIHA | TWA(as aerosol):10 mg/m3 | |
| hydro-omega-hydroxy-ethane-1,2- | - | | | |
| diol, ethoxylated | | | | |
| ACGIH : American Conference of Governme | nental Industrial | Hygienists | | |
| AIHA : American Industrial Hygiene Asso | | | | |
| CMRG : Chemical Manufacturer's Recomm | | | | |
| New Zealand WES : New Zealand Workpla | ace Exposure Sta | ndards. | | |
| TWA: Time-Weighted-Average | | | | |
| STEL: Short Term Exposure Limit | | | | |
| ppm: parts per million | | | | |
| mg/m ³ : milligrams per cubic metre | | | | |
| 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.

Refer AS/NZS 1336 - Recommended practices for occupational eye protection and for performance specifications AS/NZS 1337, Parts 1 - 6 - Personal eye-protection.

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 | | |
| Appearance/Odour | Characteristic odour, various shades | | |
| Odour threshold | No data available. | | |
| рН | Not applicable. | | |
| Melting point/Freezing point | No data available. | | |
| Boiling point/Initial boiling point/Boiling range | Not applicable. | | |
| Flash point | Not applicable. | | |
| Evaporation rate | Not applicable. | | |
| Flammability (solid, gas) | Not classified | | |
| Flammable Limits(LEL) | Not applicable. | | |
| Flammable Limits(UEL) | Not applicable. | | |
| Vapour pressure | Not applicable. | | |
| Vapour density | Not applicable. | | |
| Density | 1.3 g/cm3 | | |
| Relative density | 1.3 [<i>Ref Std</i> :WATER=1] | | |
| Water solubility | 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. | | |
| Molecular weight | No data available. | | |
| Percent volatile | Not applicable. | | |
| | | | |

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 polymerisation will not occur.

10.4 Conditions to avoid None known.

10.5 Incompatible materials None known.

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

11.1 Information on Toxicological effects

Signs and Symptoms of Exposure

Based on test data and/or information on the components, this material may produce the following health effects:

Inhalation

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

Skin contact

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

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 diarrhoea.

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.

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

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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 |
| Poly(oxy-1,2-ethanediyl),alpha-hydro-omega-hydroxy-ethane- 1,2-diol, ethoxylated | Dermal | Rabbit | LD50 > 20,000 mg/kg |
| Poly(oxy-1,2-ethanediyl),alpha-hydro-omega-hydroxy-ethane- 1,2-diol, ethoxylated | Ingestion | Rat | LD50 32,770 mg/kg |
| Ceramic powder | Dermal | | LD50 estimated to be > 5,000 mg/kg |
| Ceramic powder | Ingestion | | LD50 estimated to be 2,000 - 5,000 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 |

ATE = acute toxicity estimate

Skin Corrosion/Irritation

| Name | | Value |
|---|--------|---------------------------|
| | | |
| Poly(oxy-1,2-ethanediyl),alpha-hydro-omega-hydroxy-ethane-1,2-diol, ethoxylated | Rabbit | Minimal irritation |
| Ceramic powder | Rabbit | No significant irritation |
| Titanium oxide | Rabbit | No significant irritation |

Serious Eye Damage/Irritation

| Name | Species | Value |
|---|---------|---------------------------|
| Poly(oxy-1,2-ethanediyl),alpha-hydro-omega-hydroxy-ethane-1,2-diol, ethoxylated | Rabbit | Mild irritant |
| Ceramic powder | Rabbit | Mild irritant |
| Titanium oxide | Rabbit | No significant irritation |

Skin Sensitisation

| Name | Species | Value |
|---|---------|----------------|
| | | |
| Poly(oxy-1,2-ethanediyl),alpha-hydro-omega-hydroxy-ethane-1,2-diol, | Guinea | Not classified |
| ethoxylated | pig | |
| Titanium oxide | Human | Not classified |
| | and | |
| | animal | |

Respiratory Sensitisation

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

Germ Cell Mutagenicity

| Name | Route | Value |
|---|----------|--|
| Poly(oxy-1,2-ethanediyl),alpha-hydro-omega-hydroxy-ethane-1,2-diol, ethoxylated | In Vitro | Not mutagenic |
| Poly(oxy-1,2-ethanediyl),alpha-hydro-omega-hydroxy-ethane-1,2-diol, ethoxylated | In vivo | Not mutagenic |
| Ceramic powder | In Vitro | Some positive data exist, but the data are not sufficient for classification |
| Titanium oxide | In Vitro | Not mutagenic |
| Titanium oxide | In vivo | Not mutagenic |

Carcinogenicity

| Name | Route | Species | Value |
|--|-----------|---------|------------------|
| Poly(oxy-1,2-ethanediyl),alpha-hydro-omega-hydroxy-ethane-1,2- | Ingestion | Rat | Not carcinogenic |

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| diol, ethoxylated | | | |
|-------------------|------------|-------------------------------|--|
| Ceramic powder | Inhalation | Multiple animal species | Some positive data exist, but the data are not sufficient for classification |
| Titanium oxide | Ingestion | Multiple animal species | Not carcinogenic |
| Titanium oxide | Inhalation | Rat | Carcinogenic. |

Reproductive Toxicity

Reproductive and/or Developmental Effects

| Name | Route | Value | Species | Test result | Exposure Duration |
|--|-------------------|---|---------|------------------------------------|----------------------|
| Poly(oxy-1,2-ethanediyl),alpha-hydro- omega-hydroxy-ethane-1,2-diol, ethoxylated | Ingestion | Not classified for female reproduction | Rat | NOAEL 1,125 mg/kg/day | during gestation |
| Poly(oxy-1,2-ethanediyl),alpha-hydro- omega-hydroxy-ethane-1,2-diol, ethoxylated | Ingestion | Not classified for male reproduction | Rat | NOAEL 5699 +/-1341 mg/kg/day | 5 days |
| Poly(oxy-1,2-ethanediyl),alpha-hydro- omega-hydroxy-ethane-1,2-diol, ethoxylated | Not specified. | Not classified for reproduction and/or development | | NOEL N/A | |
| Poly(oxy-1,2-ethanediyl),alpha-hydro- omega-hydroxy-ethane-1,2-diol, ethoxylated | Ingestion | Not classified for development | Mouse | NOAEL 562 mg/animal/da y | during gestation |

Target Organ(s)

Specific Target Organ Toxicity - single exposure

| Name | Route | Target Organ(s) | Value | Species | Test result | Exposure Duration |
|---|------------|------------------------|----------------|---------|---------------------|----------------------|
| Poly(oxy-1,2- ethanediyl),alpha-hydro- omega-hydroxy-ethane- 1,2-diol, ethoxylated | Inhalation | respiratory irritation | Not classified | Rat | NOAEL 1.008 mg/l | 2 weeks |

Specific Target Organ Toxicity - repeated exposure

| Name | Route | Target Organ(s) | Value | Species | Test result | Exposure Duration |
|---|------------|---|--|-------------------------------|-----------------------------|--------------------------|
| Poly(oxy-1,2- ethanediyl),alpha-hydro- omega-hydroxy-ethane- 1,2-diol, ethoxylated | Inhalation | respiratory system | Not classified | Rat | NOAEL 1.008 mg/l | 2 weeks |
| Poly(oxy-1,2- ethanediyl),alpha-hydro- omega-hydroxy-ethane- 1,2-diol, ethoxylated | Ingestion | kidney and/or bladder heart endocrine system hematopoietic system liver nervous system | Not classified | Rat | NOAEL 5,640 mg/kg/day | 13 weeks |
| Ceramic powder | Inhalation | pulmonary fibrosis | Not classified | Multiple animal species | NOAEL not available | |
| Ceramic powder | Inhalation | respiratory system | 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 |

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

The information below may not be consistent with the material classification in Section 2 if specific ingredient classifications are mandated by a competent authority. Additional information leading to material classification in Section 2 is available upon request. In addition, environmental fate and effects data on ingredients may not be reflected in this section because an ingredient is present below the threshold for labelling, an ingredient is not expected to be available for exposure, or the data is considered not relevant to the material as a whole.

12.1. Toxicity

No product test data available.

| Material | CAS Number | Organism | Туре | Exposure | Test endpoint | Test result |
|------------------|------------|------------|------------------|----------|---------------|--------------|
| Poly(oxy-1,2- | 25322-68-3 | Atlantic | Experimental | 96 hours | LC50 | >1,000 mg/l |
| ethanediyl),alp | | Salmon | | | | |
| ha-hydro- | | | | | | |
| omega- | | | | | | |
| hydroxy- | | | | | | |
| ethane-1,2-diol, | | | | | | |
| ethoxylated | | | | | | |
| Ceramic | 66402-68-4 | | Data not | | | |
| powder | | | available or | | | |
| | | | insufficient for | | | |
| | | | classification | | | |
| Titanium oxide | 13463-67-7 | Diatom | Experimental | 72 hours | EC50 | >10,000 mg/l |
| Titanium oxide | 13463-67-7 | Fathead | Experimental | 96 hours | LC50 | >100 mg/l |
| | | minnow | | | | |
| Titanium oxide | 13463-67-7 | Water flea | Experimental | 48 hours | EC50 | >100 mg/l |
| Titanium oxide | 13463-67-7 | Diatom | Experimental | 72 hours | NOEC | 5,600 mg/l |

12.2. Persistence and degradability

| Material | CAS Number | Test type | Duration | Study Type | Test result | Protocol |
|------------------|------------|----------------|----------|------------|-------------|------------------|
| Poly(oxy-1,2- | 25322-68-3 | Experimental | 28 days | BOD | 53 % | OECD 301C - MITI |
| ethanediyl),alp | | Biodegradation | - | | BOD/ThBOD | test (I) |
| ha-hydro- | | | | | | |
| omega- | | | | | | |
| hydroxy- | | | | | | |
| ethane-1,2-diol, | | | | | | |
| ethoxylated | | | | | | |
| Ceramic | 66402-68-4 | Data not | | | N/A | |
| powder | | availbl- | | | | |
| | | insufficient | | | | |
| Titanium oxide | 13463-67-7 | Data not | | | N/A | |
| | | availbl- | | | | |
| | | insufficient | | | | |

12.3 : Bioaccumulative potential

| Material | CAS Number | Test type | Duration | Study Type | Test result | Protocol |
|---------------|------------|-----------|----------|----------------|-------------|------------|
| Poly(oxy-1,2- | 25322-68-3 | Estimated | | Bioaccumulatio | 2.3 | Estimated: |

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| ethanediyl),alp | | Bioconcentrati | | n factor | | Bioconcentration factor |
|------------------|------------|------------------|---------|----------------|-----|-------------------------|
| ha-hydro- | | on | | | | |
| omega- | | | | | | |
| hydroxy- | | | | | | |
| ethane-1,2-diol, | | | | | | |
| ethoxylated | | | | | | |
| Ceramic | 66402-68-4 | Data not | N/A | N/A | N/A | N/A |
| powder | | available or | | | | |
| - | | insufficient for | | | | |
| | | classification | | | | |
| Titanium oxide | 13463-67-7 | Experimental | 42 days | Bioaccumulatio | 9.6 | Other methods |
| | | BCF-Carp | - | n factor | | |

12.4. Mobility in soil

Please contact manufacturer for more details

12.5 Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1. Disposal methods

In accordance with the Hazardous Substances (Disposal) Notice 2017 and the relevant criteria of the HSNO Act 1996.

Incinerate in a permitted waste incineration facility. As a disposal alternative, utilize an acceptable permitted waste disposal facility. If no other disposal options are available, waste product may be placed in a landfill properly designed for industrial waste.

Packaging (that may or may not contain any residual substance) may be lawfully disposed of by householders or other consumers through public or commercial waste collection services.

SECTION 14: Transport Information

New Zealand Land Transport Rule: Dangerous Goods - Road/Rail Transport

UN No.: Not applicable. Proper Shipping Name: Not applicable. Class/Division: Not applicable. Sub Risk: Not applicable. Packing Group: Not applicable.

Hazchem Code: Not applicable. IERG: Not applicable.

International Air Transport Association (IATA) - Air Transport UN No.: Not applicable. Proper Shipping Name: Not applicable. Class/Division: Not applicable. Sub Risk: Not applicable. Packing Group: Not applicable.

International Maritime Dangerous Goods Code (IMDG) - Marine Transport UN No.: Not applicable. Proper Shipping Name: Not applicable. Class/Division: Not applicable.

Sub Risk: Not applicable. Packing Group: Not applicable. Marine Pollutant: Not applicable.

SECTION 15: Regulatory information

HSNO Approval numberNot applicableGroup standard nameNot applicableHSNO Hazard classificationRefer to Section 2: Hazard identification

NZ Inventory of Chemicals (NZIoC) Status

All applicable chemical ingredients in this material are in compliance with NZIoC listing requirements.

Controls in accordance with the Health and Safety at Work (Hazardous Substances) Regulations 2017

| Certified handler | Not required |
|---------------------------------|--------------|
| Location Compliance Certificate | Not required |
| Hazardous atmosphere zone | Not required |
| Fire extinguishers | Not required |
| Emergency response plan | Not required |
| Secondary containment | Not required |
| Tracking | Not required |
| Warning signage | Not required |

SECTION 16: Other information

Revision information:

Complete document review.

| Document group: | 16-1922-0 | Version number: | 4.00 |
|-----------------|------------|------------------|------------|
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Key to abbreviations and acronyms

GHS means the Globally Harmonised System of Classification and Labelling of Chemicals, 5th revised edition 2013 **HSNO** means Hazardous Substances and New Organisms Act 1996

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