



Safety Data Sheet

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SECTION 1: Identification

1.1. Product identifier

3M™ ESPE™ DURELON POWDER NORMAL SETTING

Product Identification Numbers

LE-F100-0990-0, 70-2011-0329-1, 70-2011-3601-0

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:	3M ESPE Dental Products
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 exposure:
musculoskeletal system |

Precautionary Statements**Prevention:**

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

Response:

Get medical advice/attention if you feel unwell.

Disposal:

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

2.3. Hazards not otherwise classified

None.

5% of the mixture consists of ingredients of unknown acute inhalation toxicity.

SECTION 3: Composition/information on ingredients

Ingredient	C.A.S. No.	% by Wt
ZINC OXIDE	1314-13-2	85 - 95 Trade Secret *
STANNOUS FLUORIDE	7783-47-3	1 - 10 Trade Secret *
TIN DIOXIDE	18282-10-5	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:

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

Material will not burn.

5.2. Special hazards arising from the substance or mixture

None inherent in this product.

Hazardous Decomposition or By-Products

<u>Substance</u>	<u>Condition</u>
None known.	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. Use wet sweeping compound or water to avoid dusting. Sweep up. 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 breathe dust/fume/gas/mist/vapors/spray. Do not eat, drink or smoke when using this product. Wash thoroughly after handling. Avoid release to the environment. Do not get in eyes.

7.2. Conditions for safe storage including any incompatibilities

No special storage requirements.

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
ZINC OXIDE	1314-13-2	ACGIH	TWA(respirable fraction):2 mg/m3;STEL(respirable fraction):10 mg/m3	
ZINC OXIDE	1314-13-2	OSHA	TWA(as fume):5 mg/m3;TWA(as total dust):15 mg/m3;TWA(respirable fraction):5 mg/m3	
TIN, INORGANIC COMPOUNDS, EXCEPT SnH4	18282-10-5	ACGIH	TWA(as Sn):2 mg/m3	
FLUORIDES	7783-47-3	ACGIH	TWA(as F):2.5 mg/m3	A4: Not class. as human carcin
FLUORIDES	7783-47-3	OSHA	TWA(as dust):2.5 mg/m3;TWA(as F):2.5 mg/m3	
TIN, INORGANIC COMPOUNDS, EXCEPT OXIDES	7783-47-3	OSHA	TWA(as Sn):2 mg/m3	
TIN, INORGANIC COMPOUNDS, EXCEPT SnH4	7783-47-3	ACGIH	TWA(as Sn):2 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:	Powder
Odor, Color, Grade:	Slight characteristic odor, slightly pink in color
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	No flash point
Evaporation rate	<i>Not Applicable</i>
Flammability (solid, gas)	Not Classified
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	4.7 [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>No Data Available</i>
Decomposition temperature	<i>No Data Available</i>
Viscosity	<i>Not Applicable</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.

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:

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:

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

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:

Prolonged or repeated exposure may cause target organ effects:

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.

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
ZINC OXIDE	Dermal		LD50 estimated to be > 5,000 mg/kg
ZINC OXIDE	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 5.7 mg/l
ZINC OXIDE	Ingestion	Rat	LD50 > 5,000 mg/kg
STANNOUS FLUORIDE	Ingestion	Rat	LD50 360 mg/kg
TIN DIOXIDE	Dermal		LD50 estimated to be > 5,000 mg/kg
TIN DIOXIDE	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 2.04 mg/l
TIN DIOXIDE	Ingestion	Rat	LD50 > 2,000 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
ZINC OXIDE	Human and	No significant irritation

STANNOUS FLUORIDE	animal official classifica tion	Irritant
TIN DIOXIDE	In vitro data	No significant irritation

Serious Eye Damage/Irritation

Name	Species	Value
ZINC OXIDE	Rabbit	Mild irritant
STANNOUS FLUORIDE	official classifica tion	Severe irritant
TIN DIOXIDE	Rabbit	No significant irritation

Skin Sensitization

Name	Species	Value
ZINC OXIDE	Guinea pig	Some positive data exist, but the data are not sufficient for classification

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
ZINC OXIDE	In Vitro	Some positive data exist, but the data are not sufficient for classification
ZINC OXIDE	In vivo	Some positive data exist, but the data are not sufficient for classification
STANNOUS FLUORIDE	In vivo	Not mutagenic
STANNOUS FLUORIDE	In Vitro	Some positive data exist, but the data are not sufficient for classification

Carcinogenicity

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

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

Name	Route	Value	Species	Test Result	Exposure Duration
ZINC OXIDE	Ingestion	Some positive reproductive/developmental data exist, but the data are not sufficient for classification	Multiple animal species	NOAEL 125 mg/kg/day	prematuring & during gestation

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

Name	Route	Target Organ(s)	Value	Species	Test Result	Exposure Duration
STANNOUS FLUORIDE	Inhalation	respiratory irritation	Some positive data exist, but the data are not sufficient for classification	Human	NOAEL Not available	occupational exposure

Specific Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test Result	Exposure Duration
ZINC OXIDE	Ingestion	nervous system	Some positive data exist, but the data are not sufficient for classification	Rat	NOAEL 600 mg/kg/day	10 days

ZINC OXIDE	Ingestion	endocrine system hematopoietic system kidney and/or bladder	Some positive data exist, but the data are not sufficient for classification	Other	NOAEL 500 mg/kg/day	6 months
STANNOUS FLUORIDE	Inhalation	bone, teeth, nails, and/or hair	Causes damage to organs through prolonged or repeated exposure	Human	NOAEL Not available	occupational exposure
STANNOUS 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
TIN DIOXIDE	Inhalation	pneumoconiosis	Some positive data exist, but the data are not sufficient for classification	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.

Dispose of waste product in a permitted industrial waste facility. Empty drums/barrels/containers used for transporting and handling hazardous chemicals (chemical substances/mixtures/preparations classified as Hazardous as per applicable regulations) shall be considered, stored, treated & disposed of as hazardous wastes unless otherwise defined by applicable waste regulations. Consult with the respective regulating authorities to determine the available treatment and disposal facilities.

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

Section 313 Toxic Chemicals subject to the reporting requirements of that section and 40 CFR part 372 (EPCRA):

<u>Ingredient</u>	<u>C.A.S. No</u>	<u>% by Wt</u>
ZINC OXIDE (ZINC COMPOUNDS)	1314-13-2	85 - 95

15.2. State Regulations

Contact 3M for more information.

15.3. Chemical Inventories

The components of this material are in compliance with the provisions of Australia National Industrial Chemical Notification and Assessment Scheme (NICNAS). Certain restrictions may apply. Contact the selling division for additional information.

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

The components of this material are in compliance with the China "Measures on Environmental Management of New Chemical Substance". Certain restrictions may apply. Contact the selling division for additional information.

The components of this material are in compliance with the provisions of the Korean Toxic Chemical Control Law. Certain restrictions may apply. Contact the selling division for additional information.

The components of this material are in compliance with the provisions of Japan Chemical Substance Control Law. Certain restrictions may apply. Contact the selling division for additional information.

The components of this material are in compliance with the provisions of Philippines RA 6969 requirements. Certain restrictions may apply. Contact the selling division for additional information.

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: 0 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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