



Safety Data Sheet

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Document Group:	16-2592-0	Version Number:	4.03
Issue Date:	04/15/15	Supersedes Date:	09/14/12

Product identifier

3M™ ESPE™ KETAC™ CEM RADIOPAQUE PERMANENT GLASS IONOMER LUTING CEMENT

ID Number(s):

70-2011-0043-8, 70-2011-0046-1, 70-2011-0047-9, 70-2011-0339-0

Recommended use

Dental Product, Dental luting cement

Restrictions on use

For use only by dental professionals

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)

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:

16-2590-4, 26-9894-2

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Document Group:	16-2590-4	Version Number:	7.00
Issue Date:	03/02/15	Supersedes Date:	06/28/13

SECTION 1: Identification

1.1. Product identifier

3M™ ESPE™ KETAC™ CEM RADIOPAQUE POWDER

Product Identification Numbers

LE-F100-1399-4, 70-2011-0044-6, 70-2011-0340-8

1.2. Recommended use and restrictions on use

Recommended use

Dental Product, Luting Cement

Restrictions on use

For use 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

Serious Eye Damage/Irritation: Category 2A.

2.2. Label elements

Signal word

Warning

Symbols

Exclamation mark |

Pictograms**Hazard Statements**

Causes serious eye irritation.

Precautionary Statements**Prevention:**

Wear eye/face protection.
Wash thoroughly after handling.

Response:

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.

2.3. Hazards not otherwise classified

None.

SECTION 3: Composition/information on ingredients

Ingredient	C.A.S. No.	% by Wt
GLASS POWDER	65997-17-3	80 - 90 Trade Secret *
COPOLYMER ACRYLIC ACID-MALEIC ACID	29132-58-9	< 20 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:

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

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.

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

Ventilate the area with fresh air. 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. Seal the container. Dispose of collected material as soon as possible.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid eye contact. Avoid prolonged or repeated skin contact. Avoid breathing dust/fume/gas/mist/vapors/spray. 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.

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
GLASS POWDER	65997-17-3	Manufacturer determined	TWA(as dust):10 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

Respiratory protection is not 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:	Odorless, white powder
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>No Data Available</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	≥ 1 [<i>Ref Std: WATER=1</i>]
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>No Data Available</i>
Percent volatile	<i>No Data Available</i>
VOC Less H2O & Exempt Solvents	<i>No Data Available</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>
Carbon monoxide	Not Specified
Carbon dioxide	Not Specified

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

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.

Skin Contact:

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

Eye Contact:

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

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

Ingestion:

May be harmful if swallowed.

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	Ingestion		No data available; calculated ATE 2,000 - 5,000 mg/kg
GLASS POWDER	Dermal		LD50 estimated to be > 5,000 mg/kg
GLASS POWDER	Ingestion		LD50 estimated to be 2,000 - 5,000 mg/kg
COPOLYMER ACRYLIC ACID-MALEIC ACID	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
COPOLYMER ACRYLIC ACID-MALEIC ACID	Ingestion	Rat	LD50 > 5,000 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
GLASS POWDER	Professional judgement	No significant irritation

Serious Eye Damage/Irritation

Name	Species	Value
GLASS POWDER	Professional judgement	No significant irritation

Skin Sensitization

For the component/components, either no data are currently available or 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
GLASS POWDER	In Vitro	Some positive data exist, but the data are not sufficient for classification

Carcinogenicity

Name	Route	Species	Value
GLASS POWDER	Inhalation	Multiple animal species	Some positive data exist, but the data are not sufficient for classification

Reproductive Toxicity

Reproductive and/or Developmental Effects

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

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
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						Duration
GLASS POWDER	Inhalation	respiratory system	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 - No

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: 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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Document Group:	26-9894-2	Version Number:	3.00
Issue Date:	11/14/14	Supersedes Date:	07/11/12

SECTION 1: Identification

1.1. Product identifier

3M™ ESPE™ KETAC™ CEM RADIOPAQUE LIQUID

Product Identification Numbers

LE-F100-0706-7, 70-2011-0045-3, 70-2011-0341-6

1.2. Recommended use and restrictions on use

Recommended use

Dental Product, Part of a luting material

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

Not classified as hazardous according to OSHA Hazard Communication Standard, 29 CFR 1910.1200.

2.2. Label elements

Signal word

Not applicable.

Symbols

Not applicable.

Pictograms

Not applicable.

2.3. Hazards not otherwise classified

None.

SECTION 3: Composition/information on ingredients

Ingredient	C.A.S. No.	% by Wt
WATER	7732-18-5	80 - 90 Trade Secret *
TARTARIC ACID	87-69-4	< 20 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. Use a fire fighting agent suitable for the surrounding fire.

5.2. Special hazards arising from the substance or mixture

None inherent in this product.

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

Ventilate the area with fresh air. Observe precautions from other sections.

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Contain spill. Working from around the edges of the spill inward, cover with bentonite, vermiculite, or commercially available inorganic absorbent material. Mix in sufficient absorbent until it appears dry. Remember, adding an absorbent material does not remove a physical, health, or environmental hazard. Collect as much of the spilled material as possible. Place in a closed container approved for transportation by appropriate authorities. Clean up residue with water. 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. Avoid breathing dust/fume/gas/mist/vapors/spray. Do not eat, drink or smoke when using this product. Wash thoroughly after handling.

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

No occupational exposure limit values exist for any of the components listed in Section 3 of this SDS.

8.2. Exposure controls

8.2.1. Engineering controls

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

Respiratory protection is not required.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

General Physical Form:	Liquid
Specific Physical Form:	Liquid
Odor, Color, Grade:	slight characteristic odor, colorless liquid
Odor threshold	<i>No Data Available</i>
pH	<i>No Data Available</i>
Melting point	Approximately 0 °C
Boiling Point	Approximately 100 °C
Flash Point	No flash point
Evaporation rate	<=1.0 [<i>Ref Std: BUOAC=1</i>]
Flammability (solid, gas)	Not Applicable
Flammable Limits(LEL)	<i>Not Applicable</i>
Flammable Limits(UEL)	<i>Not Applicable</i>
Vapor Pressure	16 mmHg [<i>Ref Std: AIR=1</i>]
Vapor Density	<=1.0 [<i>Ref Std: AIR=1</i>]
Specific Gravity	>=1.0 [<i>Ref Std: WATER=1</i>]
Solubility in Water	Complete
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>No Data Available</i>
Volatile Organic Compounds	<i>No Data Available</i>
Percent volatile	<i>No Data Available</i>
VOC Less H2O & Exempt Solvents	<i>No Data Available</i>

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.

Condition

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.

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 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	Ingestion		No data available; calculated ATE > 5,000 mg/kg
TARTARIC ACID	Ingestion	Mouse	LD50 4,360 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Overall product	Rabbit	Minimal irritation

Serious Eye Damage/Irritation

Name	Species	Value
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Skin Sensitization

Name	Species	Value
------	---------	-------

Respiratory Sensitization

Name	Species	Value
------	---------	-------

Germ Cell Mutagenicity

Name	Route	Value
------	-------	-------

Carcinogenicity

Name	Route	Species	Value
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Reproductive Toxicity**Reproductive and/or Developmental Effects**

Name	Route	Value	Species	Test Result	Exposure Duration
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Target Organ(s)**Specific Target Organ Toxicity - single exposure**

Name	Route	Target Organ(s)	Value	Species	Test Result	Exposure Duration
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Specific Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test Result	Exposure Duration
------	-------	-----------------	-------	---------	-------------	-------------------

Aspiration Hazard

Name	Value
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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 and clean product containers may be disposed as non-hazardous waste. Consult your specific regulations and service providers to determine available options and requirements.

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 - No

15.2. State Regulations

Contact 3M for more information.

15.3. Chemical Inventories

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

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.

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

Contact 3M for more information.

15.4. International Regulations

Contact 3M for more information.

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

SECTION 16: Other information

NFPA Hazard Classification

Health: 1 **Flammability:** 1 **Instability:** 0 **Special Hazards:** None

National Fire Protection Association (NFPA) hazard ratings are designed for use by emergency response personnel to address the hazards that are presented by short-term, acute exposure to a material under conditions of fire, spill, or similar emergencies. Hazard ratings are primarily based on the inherent physical and toxic properties of the material but also include the toxic properties of combustion or decomposition products that are known to be generated in significant quantities.

Document Group:	26-9894-2	Version Number:	3.00
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