

Safety Data Sheet

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 Document Group:
 37-9340-3
 Version Number:
 3.01

 Issue Date:
 11/26/18
 Supercedes Date:
 10/29/18

SECTION 1: Identification

1.1. Product identifier

3MTM XEROSTOMIA RELIEF SPRAY

Product Identification Numbers

70-2014-0663-7, 70-2014-0664-5, 70-2014-0688-4 7100176557, 7100171601, 7100175294

1.2. Recommended use and restrictions on use

Recommended use

Dental Product, For relief from xerostomia (dry mouth)

Restrictions on use

Prescription-only medical device

1.3. 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)

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.

SECTION 3: Composition/information on ingredients

Ingredient	C.A.S. No.	% by Wt
OXIDIZED CORN OIL	223705-62-2	> 80 Trade Secret *
(+/-)-P-MENTHA-1,8-DIENE	7705-14-8	<= 5 Trade Secret *
D-CARVONE	2244-16-8	< 1 Trade Secret *
L-CARVONE	6485-40-1	< 1 Trade Secret *
PROPYLENE GLYCOL	57-55-6	< 1 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:

No need for first aid is anticipated.

Skin Contact:

Wash with soap and water. If signs/symptoms develop, get medical attention.

Eve 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

SubstanceConditionCarbon monoxideDuring CombustionCarbon dioxideDuring 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

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. Collect as much of the spilled material as possible. Place in a closed container approved for transportation by appropriate authorities. Clean up residue with an appropriate solvent selected by a qualified and authorized person. Ventilate the area with fresh air. Read and follow safety precautions on the solvent label and SDS. Seal the container. Dispose of collected material as soon as possible in accordance with applicable local/regional/national/international regulations.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Do not eat, drink or smoke when using this product. Wash thoroughly after handling. Avoid release to the environment.

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
PROPYLENE GLYCOL	57-55-6	AIHA	TWA(as aerosol):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

No engineering controls required.

8.2.2. Personal protective equipment (PPE)

Eye/face protection

None required.

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Skin/hand protection

No protective gloves required.

Respiratory protection

None required.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

General Physical Form: Liquid

Odor, Color, Grade: Yellow liquid with orange, grapefruit, and mint odor

Odor thresholdNo Data AvailablepHNo Data AvailableMelting pointNo Data AvailableBoiling PointNo Data Available

Flash Point 121 °C

Evaporation rateNo Data AvailableEvaporation rateNo Data AvailableFlammability (solid, gas)Not ApplicableFlammable Limits(LEL)No Data AvailableVapor PressureNo Data AvailableVapor DensityNo Data Available

Density 0.9 g/ml

Specific Gravity 0.9 [Ref Std:WATER=1]

Solubility in Water Negligible

Solubility- non-waterNo Data AvailablePartition coefficient: n-octanol/ waterNo Data AvailableAutoignition temperatureNot ApplicableDecomposition temperatureNo Data AvailableViscosityNo 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

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:

No known health effects.

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	Inhalation- Dust/Mist(4 hr)		No data available; calculated ATE >12.5 mg/l
Overall product	Ingestion	Rat	LD50 > 5,000 mg/kg
Overall product	Dermal	similar health hazards	LD50 NA mg/kg
(+/-)-P-MENTHA-1,8-DIENE	Inhalation- Vapor (4 hours)	Mouse	LC50 > 3.14 mg/l
(+/-)-P-MENTHA-1,8-DIENE	Dermal	Rabbit	LD50 > 5,000 mg/kg
(+/-)-P-MENTHA-1,8-DIENE	Ingestion	Rat	LD50 4,400 mg/kg
PROPYLENE GLYCOL	Dermal	Rabbit	LD50 20,800 mg/kg
PROPYLENE GLYCOL	Ingestion	Rat	LD50 22,000 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

3MTM	VEBUSTOMIA	RELIEF SPRAY
31V1~~	ALKUSTUMIA	NELIEF SENAI

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Name	Species	Value
(+/-)-P-MENTHA-1,8-DIENE	Rabbit	Mild irritant
PROPYLENE GLYCOL	Rabbit	No significant irritation

Serious Eye Damage/Irritation

Name	Species	Value
Overall product	Rabbit	No significant irritation
(+/-)-P-MENTHA-1,8-DIENE	Rabbit	Mild irritant
PROPYLENE GLYCOL	Rabbit	No significant irritation

Skin Sensitization

Name	Species	Value
Overall product	Guinea	Not classified
	pig	
(+/-)-P-MENTHA-1,8-DIENE	Mouse	Sensitizing
PROPYLENE GLYCOL	Human	Not classified

Respiratory Sensitization

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

Germ Cell Mutagenicity

Name	Route	Value
(+/-)-P-MENTHA-1,8-DIENE	In Vitro	Not mutagenic
(+/-)-P-MENTHA-1,8-DIENE	In vivo	Not mutagenic
PROPYLENE GLYCOL	In Vitro	Not mutagenic
PROPYLENE GLYCOL	In vivo	Not mutagenic

Carcinogenicity

Name	Route	Species	Value
(+/-)-P-MENTHA-1,8-DIENE	Ingestion	Rat	Some positive data exist, but the data are not
			sufficient for classification
PROPYLENE GLYCOL	Dermal	Mouse	Not carcinogenic
PROPYLENE GLYCOL	Ingestion	Multiple	Not carcinogenic
		animal	
		species	

Reproductive Toxicity

Reproductive and/or Developmental Effects

Name	Route	Value	Species	Test Result	Exposure Duration
(+/-)-P-MENTHA-1,8-DIENE	Ingestion	Not classified for female reproduction	Rat	NOAEL 750 mg/kg/day	premating & during gestation
(+/-)-P-MENTHA-1,8-DIENE	Ingestion	Not classified for development	Multiple animal species	NOAEL 591 mg/kg/day	during organogenesi s
PROPYLENE GLYCOL	Ingestion	Not classified for female reproduction	Mouse	NOAEL 10,100 mg/kg/day	2 generation
PROPYLENE GLYCOL	Ingestion	Not classified for male reproduction	Mouse	NOAEL 10,100 mg/kg/day	2 generation
PROPYLENE GLYCOL	Ingestion	Not classified for development	Multiple animal species	NOAEL 1,230 mg/kg/day	during organogenesi s

Target Organ(s)

Specific Target Organ Toxicity - single exposure

Name	Route	Target Organ(s)	Value	Species	Test Result	Exposure
Name	Koute	Target Organ(s)	value	Species	1 est Result	Duration
(+/-)-P-MENTHA-1,8- DIENE	Ingestion	nervous system	Not classified		NOAEL Not available	Duration
PROPYLENE GLYCOL	Ingestion	central nervous system depression	Not classified	Human and animal	NOAEL Not available	

Specific Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test Result	Exposure Duration
(+/-)-P-MENTHA-1,8- DIENE	Ingestion	kidney and/or bladder	Not classified	Rat	LOAEL 75 mg/kg/day	103 weeks
(+/-)-P-MENTHA-1,8- DIENE	Ingestion	liver	Not classified	Mouse	NOAEL 1,000 mg/kg/day	103 weeks
(+/-)-P-MENTHA-1,8- DIENE	Ingestion	heart endocrine system bone, teeth, nails, and/or hair hematopoietic system immune system muscles nervous system respiratory system	Not classified	Rat	NOAEL 600 mg/kg/day	103 weeks
PROPYLENE GLYCOL	Ingestion	hematopoietic system	Not classified	Multiple animal species	NOAEL 1,370 mg/kg/day	117 days
PROPYLENE GLYCOL	Ingestion	kidney and/or bladder	Not classified	Dog	NOAEL 5,000 mg/kg/day	104 weeks

Aspiration Hazard

	F	
N	ame	Value
(+	+/-)-P-MENTHA-1,8-DIENE	Aspiration hazard

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.

Prior to disposal, consult all applicable authorities and regulations to insure proper classification. 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.

EPCRA 311/312 Hazard Classifications:

Physical Hazards

Not applicable

Health Hazards

Not applicable

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.

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: 0 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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 37-9340-3
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