



Orajel™ Mouth Sore Gel

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations
Revision Date: 01/14/2016 Date of Issue: 01/14/2016

Version: 1.0

SECTION 1: IDENTIFICATION

Product Identifier

Product Form: Mixture

Product Name: Orajel™ Mouth Sore Gel

Product Code: MSDS-7115

Intended Use of the Product

Oral analgesic

Name, Address, and Telephone of the Responsible Party

Company

Church & Dwight

500 Charles Ewing Blvd

Ewing Township, NJ 08628

T 1-800-524-1328

www.churchdwight.com

Emergency Telephone Number

Emergency Number : For Medical Emergency: 1-888-234-1828, For Chemical Emergency: 1-800-424-9300 (CHEMTREC)

SECTION 2: HAZARDS IDENTIFICATION

The consumer variant of this product is labeled in accordance with regulations administered by the Consumer Product Safety Commission (CPSC) and the Food and Drug Administration (FDA). The use pattern and exposure in the workplace are generally not consistent with those experienced by consumers. The requirements of the Occupational Safety and Health Administration applicable to this SDS differ from the labeling requirements of the CPSC and FDA, and as a result, this SDS may contain additional health hazard information not pertinent to consumer use and not found on the product label.

Classification of the Substance or Mixture

GHS-US classification

Skin Sens. 1 H317

STOT SE 3 H335

Aquatic Acute 3 H402

Full text of hazard classes and H-statements : see section 16

Label Elements

GHS-US Labeling

Hazard Pictograms (GHS-US) :



Signal Word (GHS-US)

: Warning

Hazard Statements (GHS-US)

: H317 - May cause an allergic skin reaction.

H335 - May cause respiratory irritation.

H402 - Harmful to aquatic life.

Precautionary Statements (GHS-US)

: P261 - Avoid breathing vapors, mist, or spray.

P271 - Use only outdoors or in a well-ventilated area.

P272 - Contaminated work clothing must not be allowed out of the workplace.

P273 - Avoid release to the environment.

P280 - Wear protective gloves, protective clothing, and eye protection.

P302+P352 - If on skin: Wash with plenty of water.

P304+P340 - If inhaled: Remove person to fresh air and keep at rest in a position

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comfortable for breathing.

P312 - Call a poison center or doctor if you feel unwell.

P321 - Specific treatment (see section 4 on this SDS).

P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.

P363 - Wash contaminated clothing before reuse.

P403+P233 - Store in a well-ventilated place. Keep container tightly closed.

P405 - Store locked up.

P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

Unknown Acute Toxicity (GHS-US) Not available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Mixture

Name	Product Identifier	% (w/w)	GHS-US classification
Polyethylene glycol	(CAS No) 25322-68-3	60 - 100	STOT SE 3, H335
Benzoic acid, 4-amino-, ethyl ester	(CAS No) 94-09-7	10 - 30	Skin Sens. 1, H317 Aquatic Acute 3, H402
Oils, peppermint	(CAS No) 8006-90-4	0.1 - 1	Flam. Liq. 4, H227 Skin Irrit. 2, H315 Eye Irrit. 2A, H319 Skin Sens. 1, H317 Aquatic Acute 2, H401 Aquatic Chronic 2, H411
Zinc chloride	(CAS No) 7646-85-7	0.1 - 0.5	Combustible Dust Acute Tox. 4 (Oral), H302 Skin Corr. 1B, H314 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Full text of H-phrases: see section 16

A range of concentration as prescribed by the Controlled Products Regulations has been used where necessary, due to varying composition.

SECTION 4: FIRST AID MEASURES

Description of First Aid Measures

General: Never give anything by mouth to an unconscious person. If exposed or concerned: Get medical advice/attention.

Inhalation: When symptoms occur: go into open air and ventilate suspected area. Remove to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER/doctor/physician if you feel unwell.

Skin Contact: Remove contaminated clothing and shoes. Flush with plenty of water for at least 15 minutes. Seek medical advice if irritation develops or persists. Wash contaminated clothing before reuse.

Eye Contact: Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do so. Continue rinsing. Obtain medical attention if irritation persists.

Ingestion: Rinse mouth. Do not induce vomiting. Get medical advice and attention if you feel unwell.

Most Important Symptoms and Effects Both Acute and Delayed

General: May cause respiratory irritation. Skin sensitization.

Inhalation: Irritation of the respiratory tract and the other mucous membranes.

Skin Contact: May cause an allergic skin reaction.

Eye Contact: May cause eye irritation.

Ingestion: Ingestion in large amounts is likely to be harmful or have adverse effects.

Chronic Symptoms: None expected under normal conditions of use.

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Indication of Any Immediate Medical Attention and Special Treatment Needed

If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

Extinguishing Media

Suitable Extinguishing Media: Use extinguishing media appropriate for surrounding fire.

Unsuitable Extinguishing Media: For surrounding fire. Use of heavy stream of water may spread fire.

Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not flammable.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire. Under fire conditions, hazardous fumes will be present.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Carbon oxides (CO, CO₂).

Reference to Other Sections

Refer to section 9 for flammability properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Do not get in eyes, on skin, or on clothing. Do not breathe vapor, mist or spray. Spilled material may present a slipping hazard.

For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protection equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit.

Environmental Precautions

Prevent entry to sewers and public waters. Avoid release to the environment.

Methods and Material for Containment and Cleaning Up

For Containment: Contain and collect as any solid.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely.

Reference to Other Sections

See Section 8, Exposure Controls and Personal Protection. See Section 13, Disposal Considerations.

SECTION 7: HANDLING AND STORAGE

Precautions for Safe Handling

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking, or smoking and again when leaving work.

Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Store in a dry, cool and well-ventilated place. Keep container tightly closed.

Incompatible Materials: Strong acids. Strong bases. Strong oxidizers.

Specific End Use(s)

Oral analgesic.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Control Parameters

For substances listed in section 3 that are not listed here, there are no established Exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), OSHA (PEL), Canadian provincial governments, or the Mexican government

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Polyethylene glycol (25322-68-3)		
USA AIHA	WEEL TWA (mg/m³)	10 mg/m³ (MW>200, aerosol)
Zinc chloride (7646-85-7)		
Mexico	OEL TWA (mg/m³)	1 mg/m³ (fume)
Mexico	OEL STEL (mg/m³)	2 mg/m³ (fume)
USA ACGIH	ACGIH TWA (mg/m³)	1 mg/m³ (fume)
USA ACGIH	ACGIH STEL (mg/m³)	2 mg/m³ (fume)
USA OSHA	OSHA PEL (TWA) (mg/m³)	1 mg/m³ (fume)
USA NIOSH	NIOSH REL (TWA) (mg/m³)	1 mg/m³ (fume)
USA NIOSH	NIOSH REL (STEL) (mg/m³)	2 mg/m³ (fume)
USA IDLH	US IDLH (mg/m³)	50 mg/m³ (fume)
Alberta	OEL STEL (mg/m³)	2 mg/m³ (fume)
Alberta	OEL TWA (mg/m³)	1 mg/m³ (fume)
British Columbia	OEL STEL (mg/m³)	2 mg/m³ (fume)
British Columbia	OEL TWA (mg/m³)	1 mg/m³ (fume)
Manitoba	OEL STEL (mg/m³)	2 mg/m³ (fume)
Manitoba	OEL TWA (mg/m³)	1 mg/m³ (fume)
New Brunswick	OEL STEL (mg/m³)	2 mg/m³ (fume)
New Brunswick	OEL TWA (mg/m³)	1 mg/m³ (fume)
Newfoundland & Labrador	OEL STEL (mg/m³)	2 mg/m³ (fume)
Newfoundland & Labrador	OEL TWA (mg/m³)	1 mg/m³ (fume)
Nova Scotia	OEL STEL (mg/m³)	2 mg/m³ (fume)
Nova Scotia	OEL TWA (mg/m³)	1 mg/m³ (fume)
Nunavut	OEL STEL (mg/m³)	2 mg/m³ (fume)
Nunavut	OEL TWA (mg/m³)	1 mg/m³ (fume)
Northwest Territories	OEL STEL (mg/m³)	2 mg/m³ (fume)
Northwest Territories	OEL TWA (mg/m³)	1 mg/m³ (fume)
Ontario	OEL STEL (mg/m³)	2 mg/m³ (fume)
Ontario	OEL TWA (mg/m³)	1 mg/m³ (fume)
Prince Edward Island	OEL STEL (mg/m³)	2 mg/m³ (fume)
Prince Edward Island	OEL TWA (mg/m³)	1 mg/m³ (fume)
Québec	VEMP (mg/m³)	1 mg/m³ (fume)
Saskatchewan	OEL STEL (mg/m³)	2 mg/m³ (fume)
Saskatchewan	OEL TWA (mg/m³)	1 mg/m³ (fume)
Yukon	OEL STEL (mg/m³)	2 mg/m³ (fume)
Yukon	OEL TWA (mg/m³)	1 mg/m³ (fume)

Exposure Controls

Appropriate Engineering Controls: For occupational/workplace settings: Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal Protective Equipment: For occupational/workplace settings and bulk quantities: Gloves. Protective clothing. Protective goggles.



Materials for Protective Clothing: For occupational/workplace settings: Chemically resistant materials and fabrics.

Hand Protection: For occupational/workplace settings: Wear protective gloves.

Eye Protection: For occupational/workplace settings: Chemical safety goggles.

Skin and Body Protection: For occupational/workplace settings: Wear suitable protective clothing.

Respiratory Protection: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Information on Basic Physical and Chemical Properties

Physical State	: Liquid
Appearance	: White gel
Odor	: Peppermint
Odor Threshold	: Not available
pH	: Not available
Evaporation Rate	: Not available
Melting Point	: 31 - 33 °C (87.8 - 91.4 °F)
Freezing Point	: Not available
Boiling Point	: Not available
Flash Point	: Not available
Auto-ignition Temperature	: Not available
Decomposition Temperature	: Not available
Flammability (solid, gas)	: Not available
Lower Flammable Limit	: Not available
Upper Flammable Limit	: Not available
Vapor Pressure	: Not available
Relative Vapor Density at 20 °C	: Not available
Relative Density	: Not available
Specific Gravity	: Not available
Solubility	: Not available
Partition Coefficient: N-Octanol/Water	: Not available
Viscosity	: Not available
Explosion Data – Sensitivity to Mechanical Impact	: Not expected to present an explosion hazard due to mechanical impact.
Explosion Data – Sensitivity to Static Discharge	: Not expected to present an explosion hazard due to static discharge.

SECTION 10: STABILITY AND REACTIVITY

Reactivity: Hazardous reactions will not occur under normal conditions.

Chemical Stability: The product is stable at normal handling and storage conditions.

Possibility of Hazardous Reactions: Hazardous polymerization will not occur.

Conditions to Avoid: Extremely high or low temperatures. Incompatible materials.

Incompatible Materials: Strong acids. Strong bases. Strong oxidizers.

Hazardous Decomposition Products: Thermal decomposition generates: Carbon oxides (CO, CO₂).

SECTION 11: TOXICOLOGICAL INFORMATION

Information on Toxicological Effects - Product

Acute Toxicity: Not classified

LD50 and LC50 Data: Not available

Skin Corrosion/Irritation: Not classified

Serious Eye Damage/Irritation: Not classified

Respiratory or Skin Sensitization: May cause an allergic skin reaction.

Germ Cell Mutagenicity: Not classified

Teratogenicity: Not available

Carcinogenicity: Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Reproductive Toxicity: Not classified

Specific Target Organ Toxicity (Single Exposure): May cause respiratory irritation.

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: May cause respiratory irritation

Symptoms/Injuries After Skin Contact: May cause an allergic skin reaction

Symptoms/Injuries After Eye Contact: May cause eye irritation

Symptoms/Injuries After Ingestion: Ingestion in large amounts is likely to be harmful or have adverse effects

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Chronic Symptoms: None expected under normal conditions of use

Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data:

Polyethylene glycol (25322-68-3)	
LD50 Oral Rat	47000 mg/kg
LD50 Dermal Rabbit	> 20 ml/kg
Oils, peppermint (8006-90-4)	
LD50 Oral Rat	2426 mg/kg
Zinc chloride (7646-85-7)	
LD50 Oral Rat	1100 mg/kg

SECTION 12: ECOLOGICAL INFORMATION

Toxicity

Ecology - General: Harmful to aquatic life.

Benzoic acid, 4-amino-, ethyl ester (94-09-7)	
LC50 Fish 1	34.6 - 36.1 mg/l (Exposure time: 96 h - Species: Pimephales promelas [flow-through])
LC50 Fish 2	24.9 - 26.9 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
Zinc chloride (7646-85-7)	
LC50 Fish 1	727 µg/l
EC50 Daphnia 1	330 µg/l

Persistence and Degradability

Not available

Bioaccumulative Potential

Benzoic acid, 4-amino-, ethyl ester (94-09-7)	
Log POW	1.86
Zinc chloride (7646-85-7)	
BCF Fish 1	16000

Mobility in Soil

Not available

Other Adverse Effects

Other Information: Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, and international regulations

SECTION 14: TRANSPORT INFORMATION

In Accordance with DOT Not regulated for transport

In Accordance with IMDG Not regulated for transport

In Accordance with IATA Not regulated for transport

In Accordance with TDG Not regulated for transport

SECTION 15: REGULATORY INFORMATION

US Federal and International Regulations

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SARA Section 311/312 Hazard Classes	Immediate (acute) health hazard
Benzoic acid, 4-amino-, ethyl ester (94-09-7)	
Listed on the AICS (Australian Inventory of Chemical Substances)	
Listed on the Canadian DSL (Domestic Substances List)	
Listed on IECSC (Inventory of Existing Chemical Substances Produced or Imported in China)	
Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)	
Listed on the Japanese ENCS (Existing & New Chemical Substances) inventory	
Listed on the Korean ECL (Existing Chemicals List)	

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Listed on NZIoC (New Zealand Inventory of Chemicals) Listed on PICCS (Philippines Inventory of Chemicals and Chemical Substances) Listed on the United States TSCA (Toxic Substances Control Act) inventory Listed on INSQ (Mexican national Inventory of Chemical Substances)	
Polyethylene glycol (25322-68-3)	
Listed on the EU NLP (No Longer Polymers) inventory Listed on the AICS (Australian Inventory of Chemical Substances) Listed on the Canadian DSL (Domestic Substances List) Listed on IECSC (Inventory of Existing Chemical Substances Produced or Imported in China) Listed on the Japanese ENCS (Existing & New Chemical Substances) inventory Listed on the Korean ECL (Existing Chemicals List) Listed on NZIoC (New Zealand Inventory of Chemicals) Listed on PICCS (Philippines Inventory of Chemicals and Chemical Substances) Listed on the United States TSCA (Toxic Substances Control Act) inventory Listed on CICR (Turkish Inventory and Control of Chemicals)	
Oils, peppermint (8006-90-4)	
Listed on the AICS (Australian Inventory of Chemical Substances) Listed on the Canadian DSL (Domestic Substances List) Listed on IECSC (Inventory of Existing Chemical Substances Produced or Imported in China) Listed on the Japanese ISHL (Industrial Safety and Health Law) Listed on the Korean ECL (Existing Chemicals List) Listed on NZIoC (New Zealand Inventory of Chemicals) Listed on PICCS (Philippines Inventory of Chemicals and Chemical Substances) Listed on the United States TSCA (Toxic Substances Control Act) inventory Listed on INSQ (Mexican national Inventory of Chemical Substances)	
Zinc chloride (7646-85-7)	
Listed on the AICS (Australian Inventory of Chemical Substances) Listed on the Canadian DSL (Domestic Substances List) Listed on IECSC (Inventory of Existing Chemical Substances Produced or Imported in China) Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances) Listed on the Japanese ENCS (Existing & New Chemical Substances) inventory Listed on the Korean ECL (Existing Chemicals List) Listed on NZIoC (New Zealand Inventory of Chemicals) Listed on PICCS (Philippines Inventory of Chemicals and Chemical Substances) Listed on the United States TSCA (Toxic Substances Control Act) inventory Japanese Poisonous and Deleterious Substances Control Law Japanese Pollutant Release and Transfer Register Law (PRTR Law) Listed on the Canadian IDL (Ingredient Disclosure List) Listed on INSQ (Mexican national Inventory of Chemical Substances) Listed on CICR (Turkish Inventory and Control of Chemicals)	
US State Regulations	
Zinc chloride (7646-85-7)	
U.S. - Massachusetts - Right To Know List U.S. - New Jersey - Right to Know Hazardous Substance List U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List U.S. - Pennsylvania - RTK (Right to Know) List	
Canadian Regulations	
Orajel™ Mouth Sore Gel	
WHMIS Classification	Class D Division 2 Subdivision B - Toxic material causing other toxic effects

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Benzoic acid, 4-amino-, ethyl ester (94-09-7)

Listed on the Canadian DSL (Domestic Substances List)

WHMIS Classification Class D Division 2 Subdivision B - Toxic material causing other toxic effects

Oils, peppermint (8006-90-4)

Listed on the Canadian DSL (Domestic Substances List)

WHMIS Classification Class B Division 3 - Combustible Liquid
Class D Division 2 Subdivision B - Toxic material causing other toxic effects

Zinc chloride (7646-85-7)

Listed on the Canadian DSL (Domestic Substances List)

Listed on the Canadian IDL (Ingredient Disclosure List)

IDL Concentration 1 %

WHMIS Classification Class E - Corrosive Material
Class D Division 2 Subdivision B - Toxic material causing other toxic effects

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the SDS contains all of the information required by CPR.

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Revision Date : 01/14/2016

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200. The consumer variant of this product is labeled in accordance with regulations administered by the Consumer Product Safety Commission (CPSC) and the Food and Drug Administration (FDA). The use pattern and exposure in the workplace are generally not consistent with those experienced by consumers. The requirements of the Occupational Safety and Health Administration applicable to this SDS differ from the labeling requirements of the CPSC and FDA, and as a result, this SDS may contain additional health hazard information not pertinent to consumer use and not found on the product label.

GHS Full Text Phrases:

Acute Tox. 4 (Inhalation)	Acute toxicity (inhalation) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 1	Hazardous to the aquatic environment - Acute Hazard Category 1
Aquatic Acute 2	Hazardous to the aquatic environment - Acute Hazard Category 2
Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Aquatic Chronic 1	Hazardous to the aquatic environment - Chronic Hazard Category 1
Aquatic Chronic 2	Hazardous to the aquatic environment - Chronic Hazard Category 2
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Flam. Liq. 2	Flammable liquids Category 2
Flam. Liq. 4	Flammable liquids Category 4
Skin Corr. 1B	Skin corrosion/irritation Category 1B
Skin Irrit. 2	Skin corrosion/irritation Category 2
Skin Sens. 1	Skin sensitization Category 1
STOT RE 2	Specific target organ toxicity (repeated exposure) Category 2
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H225	Highly flammable liquid and vapor
H227	Combustible liquid

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H302	Harmful if swallowed
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H318	Causes serious eye damage
H319	Causes serious eye irritation
H332	Harmful if inhaled
H335	May cause respiratory irritation
H336	May cause drowsiness or dizziness
H373	May cause damage to organs through prolonged or repeated exposure
H400	Very toxic to aquatic life
H401	Toxic to aquatic life
H402	Harmful to aquatic life
H410	Very toxic to aquatic life with long lasting effects
H411	Toxic to aquatic life with long lasting effects

Party Responsible for the Preparation of This Document

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