



Orajel™ Maximum Strength Gel - (NA GHS 2015 - EN)

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations
Revision Date: 05/30/2022 Date of issue: 11/10/2015 Supersedes Date: 07/06/2021

Version: 1.2

SECTION 1: IDENTIFICATION

Product Identifier

Product Form: Mixture

Product Name: Orajel™ Maximum Strength Gel - (NA GHS 2015 - EN)

Product Code: MSDS-7895

Intended Use of the Product

Oral care.

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 :For Medical Emergency: 1-888-234-1828 (USA and Canada), 952-853-1925 (Outside USA and Canada)

Emergency Number :For Chemical Emergency: ChemTel LLC (800)255-3924 (North America) +1 (813)248-0585 (International)

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

Full text of H-phrases: 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.

Precautionary Statements (GHS-US) :

P261 - Avoid breathing vapors, mist, or spray.

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

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 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.

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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 those with 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
Sorbic acid	(CAS No) 110-44-1	0.1 - 1	Combustible Dust Skin Irrit. 2, H315 Eye Irrit. 2A, H319 STOT SE 3, H335

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

Full text of H-phrases: see section 16

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.

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.

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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 care.

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), NIOSH (REL), OSHA (PEL), Canadian provincial governments, or the Mexican government

Polyethylene glycol (25322-68-3)

USA AIHA

WEEL TWA (mg/m³)

10 mg/m³ (MW>200, aerosol)

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.

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



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

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

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

Skin and Body Protection: For occupational/workplace settings: Wash contaminated clothing before reuse.

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

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Information on Basic Physical and Chemical Properties

Physical State	: Solid
Appearance	: Soft white gel
Odor	: Eucalyptus mint
Odor Threshold	: Not available
pH	: 4 - 5
Evaporation Rate	: Not available
Melting Point	: Not available
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
Specific Gravity	: 1.05-1.15
Solubility	: Soluble in water.
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

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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

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
Benzoic acid, 4-amino-, ethyl ester (94-09-7)	
LD50 Oral Rat	3042 mg/kg
Sorbic acid (110-44-1)	
LD50 Oral Rat	3200 mg/kg

SECTION 12: ECOLOGICAL INFORMATION

Toxicity

Ecology - General: Not classified.

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])
Sorbic acid (110-44-1)	
EC50 Daphnia 1	353.54 mg/l (Exposure time: 48 h - Species: Daphnia magna)

Persistence and Degradability

Orajel™ Maximum Strength Gel	
Persistence and Degradability	Not established.

Bioaccumulative Potential

Orajel™ Maximum Strength Gel	
Bioaccumulative Potential	Not established.
Benzoic acid, 4-amino-, ethyl ester (94-09-7)	
Log POW	1.86
Sorbic acid (110-44-1)	
Log POW	1.38 (at 20 °C)

Mobility in Soil: Not available

Other Adverse Effects

Other Information: Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

Sewage Disposal Recommendations: Do not empty into drains; dispose of this material and its container in a safe way.

Waste Disposal Recommendations: Dispose of waste material in accordance with all local, regional, national, provincial, territorial and international regulations.

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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

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 Turkish inventory of chemical

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)
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)

Sorbic acid (110-44-1)

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
Listed on the Canadian IDL (Ingredient Disclosure List)
Listed on INSQ (Mexican national Inventory of Chemical Substances)
Listed on Turkish inventory of chemical

EPA TSCA Regulatory Flag

T - T - indicates a substance that is the subject of a Section 4 test rule under TSCA.

US State Regulations

No additional information available.

Canadian Regulations

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WHMIS Classification

Uncontrolled product according to WHMIS classification criteria

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Polyethylene glycol (25322-68-3)	
Listed on the Canadian DSL (Domestic Substances List)	
WHMIS Classification	Uncontrolled product according to WHMIS classification criteria
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
Sorbic acid (110-44-1)	
Listed on the Canadian DSL (Domestic Substances List)	
Listed on the Canadian IDL (Ingredient Disclosure List)	
IDL Concentration 1 %	
WHMIS Classification	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 : 05/30/2022

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:

Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Skin Irrit. 2	Skin corrosion/irritation Category 2
Skin Sens. 1	Skin sensitization Category 1
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H319	Causes serious eye irritation
H335	May cause respiratory irritation
H402	Harmful to aquatic life

Party Responsible for the Preparation of This Document

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This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

Church&Dwight NA GHS SDS