



Orajel™ 3X Medicated for Denture Pain Gel

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations And According To The Hazardous Products Regulation (February 11, 2015).

Revision Date: 07/04/2021

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Version: 1.1

SECTION 1: IDENTIFICATION

Product Identifier

Product Form: Mixture

Product Name: Orajel™ 3X Medicated for Denture Pain Gel

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 (USA and Canada), 952-853-1925 (Outside USA and Canada);
For Chemical Emergency: ChemTel LLC (800)255-3924 (North America) +1 (813)248-0585 (International)

SECTION 2: HAZARDS IDENTIFICATION

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/CA 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/CA Labeling

Hazard Pictograms (GHS-US/CA) :



GHS07

Signal Word (GHS-US/CA) :

Warning

Hazard Statements (GHS-US/CA) :

H317 - May cause an allergic skin reaction.

H335 - May cause respiratory irritation.

H402 - Harmful to aquatic life.

Precautionary Statements (GHS-US/CA) :

P261 - Avoid breathing vapors, mist, or spray.

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

P272 - Contaminated work clothing should 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 comfortable for breathing.

P312 - Call a POISON CENTER or doctor if you feel unwell.

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

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

P362+P364 - Take off contaminated clothing and wash it 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/CA)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Mixture

Name	Product Identifier	% *	GHS Ingredient Classification
Polyethylene glycol	(CAS-No.) 25322-68-3	65 - 85	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
Zinc chloride	(CAS-No.) 7646-85-7	0.145 - 0.155	Acute Tox. 4 (Oral), H302 Skin Corr. 1B, H314 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 1, H400 Aquatic Chronic 2, H411 Comb. Dust

Full text of H-phrases: see section 16

*Percentages are listed in weight by weight percentage (w/w%) for liquid and solid ingredients. Gas ingredients are listed in volume by volume percentage (v/v%).

The actual concentration of ingredient(s) is withheld as a trade secret in accordance with the Hazardous Products Regulations (HPR) SOR/2015-17 and 29 CFR 1910.1200.

SECTION 4: FIRST AID MEASURES

Description of First-aid Measures

General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

Inhalation: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

Skin Contact: Remove contaminated clothing. Drench affected area with water for at least 15 minutes. Obtain medical attention if irritation develops or persists.

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

Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

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 slight irritation to eyes.

Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: None known.

Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

Extinguishing Media

Suitable Extinguishing Media: Water spray, dry chemical, foam, carbon dioxide.

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Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not considered flammable but may burn at high temperatures.

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.

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).

Other Information: Do not allow run-off from fire fighting to enter drains or water courses.

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: Avoid breathing dust. Do not get in eyes, on skin, or on clothing.

For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective 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.

Ventilate area.

Environmental Precautions

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

Methods and Materials for Containment and Cleaning Up

For Containment: Contain solid spills with appropriate barriers and prevent migration and entry into sewers or streams.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Recover the product by vacuuming, shoveling or sweeping. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

Precautions for Safe Handling

Precautions for Safe Handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid breathing dust. Avoid contact with eyes, skin and clothing.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

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.

Polyethylene glycol (25322-68-3)		
USA AIHA	WEEL TWA (mg/m³)	10 mg/m³ (MW>200-aerosol)

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Zinc chloride (7646-85-7)		
Mexico	OEL TWA (mg/m ³)	1 mg/m ³ (fume)
Mexico	OEL STEL (mg/m ³)	2 mg/m ³ (fume)
USA ACGIH	ACGIH TWA (mg/m ³)	1 mg/m ³ (fume)
USA ACGIH	ACGIH STEL (mg/m ³)	2 mg/m ³ (fume)
USA OSHA	OSHA PEL (TWA) (mg/m ³)	1 mg/m ³ (fume)
USA NIOSH	NIOSH REL (TWA) (mg/m ³)	1 mg/m ³ (fume)
USA NIOSH	NIOSH REL (STEL) (mg/m ³)	2 mg/m ³ (fume)
USA IDLH	US IDLH (mg/m ³)	50 mg/m ³ (fume)
Alberta	OEL STEL (mg/m ³)	2 mg/m ³ (fume)
Alberta	OEL TWA (mg/m ³)	1 mg/m ³ (fume)
British Columbia	OEL STEL (mg/m ³)	2 mg/m ³ (fume)
British Columbia	OEL TWA (mg/m ³)	1 mg/m ³ (fume)
Manitoba	OEL STEL (mg/m ³)	2 mg/m ³ (fume)
Manitoba	OEL TWA (mg/m ³)	1 mg/m ³ (fume)
New Brunswick	OEL STEL (mg/m ³)	2 mg/m ³ (fume)
New Brunswick	OEL TWA (mg/m ³)	1 mg/m ³ (fume)
Newfoundland & Labrador	OEL STEL (mg/m ³)	2 mg/m ³ (fume)
Newfoundland & Labrador	OEL TWA (mg/m ³)	1 mg/m ³ (fume)
Nova Scotia	OEL STEL (mg/m ³)	2 mg/m ³ (fume)
Nova Scotia	OEL TWA (mg/m ³)	1 mg/m ³ (fume)
Nunavut	OEL STEL (mg/m ³)	2 mg/m ³ (fume)
Nunavut	OEL TWA (mg/m ³)	1 mg/m ³ (fume)
Northwest Territories	OEL STEL (mg/m ³)	2 mg/m ³ (fume)
Northwest Territories	OEL TWA (mg/m ³)	1 mg/m ³ (fume)
Ontario	OEL STEL (mg/m ³)	2 mg/m ³ (fume)
Ontario	OEL TWA (mg/m ³)	1 mg/m ³ (fume)
Prince Edward Island	OEL STEL (mg/m ³)	2 mg/m ³ (fume)
Prince Edward Island	OEL TWA (mg/m ³)	1 mg/m ³ (fume)
Québec	VEMP (mg/m ³)	1 mg/m ³ (fume)
Saskatchewan	OEL STEL (mg/m ³)	2 mg/m ³ (fume)
Saskatchewan	OEL TWA (mg/m ³)	1 mg/m ³ (fume)
Yukon	OEL STEL (mg/m ³)	2 mg/m ³ (fume)
Yukon	OEL TWA (mg/m ³)	1 mg/m ³ (fume)

Exposure Controls

Appropriate Engineering Controls: 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: 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. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Information on Basic Physical and Chemical Properties

Physical State	: Solid
Appearance	: Blue to blue green translucent smooth 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
Relative Density	: Not available
Specific Gravity	: 1.05 - 1.15
Solubility	: Water: Soluble
Partition Coefficient: N-Octanol/Water	: Not available
Viscosity	: Not available

SECTION 10: STABILITY AND REACTIVITY

Reactivity: Hazardous reactions will not occur under normal conditions.

Chemical Stability: Stable under recommended handling and storage conditions (see section 7).

Possibility of Hazardous Reactions: Hazardous polymerization will not occur.

Conditions to Avoid: Direct sunlight, extremely high or low temperatures, and incompatible materials.

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

Hazardous Decomposition Products: None expected under normal conditions of use.

SECTION 11: TOXICOLOGICAL INFORMATION

Information on Toxicological Effects - Product

Acute Toxicity (Oral): Not classified

Acute Toxicity (Dermal): Not classified

Acute Toxicity (Inhalation): Not classified

LD50 and LC50 Data: Not available

Skin Corrosion/Irritation: Not classified

pH: 4 - 5

Eye Damage/Irritation: Not classified

pH: 4 - 5

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

Germ Cell Mutagenicity: Not classified

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

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

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: None known.

Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data:

Polyethylene glycol (25322-68-3)	
LD50 Oral Rat	22 g/kg
LD50 Dermal Rabbit	> 20 g/kg
Zinc chloride (7646-85-7)	
LD50 Oral Rat	1100 mg/kg
LC50 Inhalation Rat	<= 1975 mg/m ³ (Exposure time: 10 min)
Benzoic acid, 4-amino-, ethyl ester (94-09-7)	
LD50 Oral Rat	3042 mg/kg

SECTION 12: ECOLOGICAL INFORMATION

Toxicity

Ecology - General: Harmful to aquatic life.

Zinc chloride (7646-85-7)	
LC50 Fish 1	727 µg/l
EC50 Daphnia 1	330 µg/l
ErC50 (algae)	0.135 mg/l
NOEC Chronic Algae	0.0325 mg/l
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])

Persistence and Degradability

Orajel™ 3X Medicated for Denture Pain Gel	
Persistence and Degradability	Not established.

Bioaccumulative Potential

Orajel™ 3X Medicated for Denture Pain Gel	
Bioaccumulative Potential	Not established.
Zinc chloride (7646-85-7)	
BCF Fish 1	16000
Benzoic acid, 4-amino-, ethyl ester (94-09-7)	
Log POW	1.86

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, territorial, provincial, and international regulations.

Ecology - Waste Materials: Avoid release to the environment. This material is hazardous to the aquatic environment. Keep out of sewers and waterways.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

In Accordance with DOT Not regulated for transport

In Accordance with IMDG Not regulated for transport

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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

Orajel™ 3X Medicated for Denture Pain Gel	
SARA Section 311/312 Hazard Classes	Health hazard - Specific target organ toxicity (single or repeated exposure) Health hazard - Respiratory or skin sensitization
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 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 CICR (Turkish Inventory and Control of Chemicals) Listed on the TCSI (Taiwan Chemical Substance Inventory)	
EPA TSCA Regulatory Flag	XU - XU - indicates a substance exempt from reporting under the Chemical Data Reporting Rule, (40 CFR 711).
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 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 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) Listed on the TCSI (Taiwan Chemical Substance Inventory)	
CERCLA RQ	1000 lb
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 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	

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Listed on INSQ (Mexican National Inventory of Chemical Substances)
Listed on the TCSI (Taiwan Chemical Substance Inventory)

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

Polyethylene glycol (25322-68-3)

Listed on the Canadian DSL (Domestic Substances List)

Zinc chloride (7646-85-7)

Listed on the Canadian DSL (Domestic Substances List)

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

Listed on the Canadian DSL (Domestic Substances List)

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

Date of Preparation or Latest Revision : 07/04/2021

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200 and Canada's Hazardous Products Regulations (HPR) SOR/2015-17.
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 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 1	Hazardous to the aquatic environment - Acute Hazard Category 1
Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Aquatic Chronic 2	Hazardous to the aquatic environment - Chronic Hazard Category 2
Comb. Dust	Combustible Dust
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Skin Corr. 1B	Skin corrosion/irritation Category 1B
Skin Sens. 1	Skin sensitization, Category 1
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H302	Harmful if swallowed
H314	Causes severe skin burns and eye damage
H317	May cause an allergic skin reaction
H318	Causes serious eye damage
H335	May cause respiratory irritation
H400	Very toxic to aquatic life
H402	Harmful to aquatic life
H411	Toxic to aquatic life with long lasting effects

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.

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