



Orajel™ 2X Toothache & Gum Medicated Gel (NA GHS 2015)

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).

Date of Issue: 05/17/2022

Version: 1.0

SECTION 1: IDENTIFICATION

Product Identifier

Product Form: Mixture

Product Name: Orajel™ 2X Toothache & Gum Medicated Gel (NA GHS 2015)

Product Code: 42015192

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

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/CA Classification

Skin Irrit. 2 H315

Eye Irrit. 2A H319

Skin Sens. 1 H317

STOT SE 3 H335

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) :

H315 - Causes skin irritation.

H317 - May cause an allergic skin reaction.

H319 - Causes serious eye irritation.

H335 - May cause respiratory irritation.

Precautionary Statements (GHS-US/CA) : P261 - Avoid breathing vapors, mist, or spray.

P264 - Wash hands, forearms, and other exposed areas thoroughly after handling.

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

P272 - Contaminated work clothing should 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 comfortable for

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breathing.

P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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.

P337+P313 - If eye irritation persists: 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 additional information 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 Irrit. 2, H315 Eye Irrit. 2A, H319 Skin Sens. 1, H317 STOT SE 3, H335 Aquatic Acute 3, H402 Aquatic Chronic 3, H412 Comb. Dust

Full text of H-statements: 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. Wash affected area with soap and water for at least 15 minutes. Obtain medical attention if irritation/rash develops or persists.

Eye Contact: Immediately rinse 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. Causes skin irritation. Causes serious eye irritation.

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

Skin Contact: May cause an allergic skin reaction. Redness, pain, swelling, itching, burning, dryness, and dermatitis.

Eye Contact: Contact causes severe irritation with redness and swelling of the conjunctiva.

Ingestion: Ingestion of large quantities may have adverse effects.

Chronic Symptoms: May cause an allergic skin reaction.

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.

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SECTION 5: FIRE-FIGHTING MEASURES

Extinguishing Media

Suitable Extinguishing Media: Water spray, fog, carbon dioxide (CO₂), alcohol-resistant foam, or dry chemical.

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). Sodium oxides. Nitrogen oxides. Smoke.

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. Avoid all contact with skin, eyes, or 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.

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

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. Store locked up/in a secure area.

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), or Canadian provincial governments.

Polyethylene glycol (25322-68-3)

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USA AIHA	WEEL TWA	10 mg/m ³ (molecular weight>200-aerosol)
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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. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Other Information: When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Information on Basic Physical and Chemical Properties

Physical State	: Solid
Appearance	: Pale yellow to light tan translucent smooth ointment
Odor	: Mentholated Odor
Odor Threshold	: No data available
pH	: 4 – 5
Evaporation Rate	: No data available
Melting Point	: No data available
Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: No data available
Lower Flammable Limit	: No data available
Upper Flammable Limit	: No data available
Vapor Pressure	: No data available
Relative Vapor Density at 20°C	: No data available
Relative Density	: 1.05 – 1.15 (Water=1)
Specific Gravity	: No data available
Solubility	: No data available
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: No data 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.

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Incompatible Materials:

Strong acids, strong bases, strong oxidizers.

Hazardous Decomposition Products:

Not expected to decompose under ambient conditions.

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:

No additional information available

Skin Corrosion/Irritation: Causes skin irritation.

pH: 4 – 5

Eye Damage/Irritation: Causes serious eye irritation.

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.

Symptoms/Injuries After Skin Contact: May cause an allergic skin reaction. Redness, pain, swelling, itching, burning, dryness, and dermatitis.

Symptoms/Injuries After Eye Contact: Contact causes severe irritation with redness and swelling of the conjunctiva.

Symptoms/Injuries After Ingestion: Ingestion of large quantities may have adverse effects.

Chronic Symptoms: May cause an allergic skin reaction.

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
Benzoic acid, 4-amino-, ethyl ester (94-09-7)	
LD50 Oral Rat	3042 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])

Persistence and Degradability

Orajel™ 2X Toothache & Gum Medicated Gel	
Persistence and Degradability	Not established.

Bioaccumulative Potential

Orajel™ 2X Toothache & Gum Medicated Gel	
Bioaccumulative Potential	Not established.
Benzoic acid, 4-amino-, ethyl ester (94-09-7)	
Log POW	1.86

Mobility in Soil

No additional information available

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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.

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

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™ 2X Toothache & Gum Medicated Gel	
SARA Section 311/312 Hazard Classes	Health hazard - Specific target organ toxicity (single or repeated exposure) Health hazard - Respiratory or skin sensitization Health hazard - Skin corrosion or Irritation Health hazard - Serious eye damage or eye irritation
Polyethylene glycol (25322-68-3)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active Listed on the Canadian DSL (Domestic Substances List) Listed on the EU NLP (No Longer Polymers) inventory Listed introduction on Australian Industrial Chemicals Introduction Scheme (AICIS Inventory) Listed on PICCS (Philippines Inventory of Chemicals and Chemical Substances) Listed on the Japanese ENCS (Existing & New Chemical Substances) inventory Listed on KECL/KECI (Korean Existing Chemicals Inventory) Listed on IECSC (Inventory of Existing Chemical Substances Produced or Imported in China) Listed on NZIoC (New Zealand Inventory of Chemicals) Listed on the Japanese ISHL (Industrial Safety and Health Law) Listed on the TCSI (Taiwan Chemical Substance Inventory) Listed on the NCI (Vietnam - National Chemicals Inventory)	
EPA TSCA Regulatory Flag	XU - XU - indicates a substance exempt from reporting under the Chemical Data Reporting Rule, (40 CFR 711).
Benzoic acid, 4-amino-, ethyl ester (94-09-7)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active Listed on the Canadian DSL (Domestic Substances List) Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances) Listed on PICCS (Philippines Inventory of Chemicals and Chemical Substances) Listed on the Japanese ENCS (Existing & New Chemical Substances) inventory Listed on KECL/KECI (Korean Existing Chemicals Inventory) Listed on IECSC (Inventory of Existing Chemical Substances Produced or Imported in China) Listed on NZIoC (New Zealand Inventory of Chemicals) Listed on the Japanese ISHL (Industrial Safety and Health Law) Listed on INSQ (Mexican National Inventory of Chemical Substances) Listed on the TCSI (Taiwan Chemical Substance Inventory)	

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Listed on the NCI (Vietnam - National Chemicals Inventory)

US State Regulations

Neither this product nor its chemical components appear on any US state lists, or its chemical components are not required to be disclosed

Canadian Regulations

Polyethylene glycol (25322-68-3)

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)

1,2,3-Propanetriol (56-81-5)

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 : 05/17/2022

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200. This product is labeled in accordance with regulations administered by the Consumer Product Safety Commission (CPSC) 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
Aquatic Chronic 3	Hazardous to the aquatic environment - Chronic Hazard Category 3
Comb. Dust	Combustible Dust
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, Respiratory tract irritation
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
H412	Harmful to aquatic life with long lasting effects

This Product Safety Data Sheet is offered solely for your information, consideration and investigation. Church & Dwight Co., Inc. provides no warranties; either expressed or implied, and assumes no responsibility for the accuracy or completeness of data contained herein. Church & Dwight Co., Inc. urges persons receiving this information to make their own determination as to the information suitability for their particular application.

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