



# Orajel™ Medicated Daytime & Nighttime Teething Gels - (NA GHS 2015 - EN)

## 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).  
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## SECTION 1: IDENTIFICATION

### Product Identifier

**Product Form:** Mixture

**Product Name:** Orajel™ Medicated Daytime & Nighttime Teething Gels - (NA GHS 2015 - EN)

**Product Code:** 40002654; 40002657

**Synonyms:** Orajel™ Medicated Teething Gel, Orajel™ Medicated Nighttime Teething Gel

### Intended Use of the Product

Teething Pain Medication.

### 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](http://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

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

### Label Elements

#### **GHS-US/CA Labeling**

#### **Hazard Pictograms (GHS-US/CA)**



#### **Signal Word (GHS-US/CA)**

: Warning

#### **Hazard Statements (GHS-US/CA)**

: H317 - May cause an allergic skin reaction.

#### **Precautionary Statements (GHS-US/CA)**

: P261 - Avoid breathing vapors, mist, or spray.  
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.  
P321 - Specific treatment (see section 4 on this SDS).  
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.  
P362+P364 - Take off contaminated clothing and wash it before reuse.  
P501 - Dispose of contents/container in accordance with local, regional, national, territorial, provincial, and international regulations.

### Other Hazards

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

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### Unknown Acute Toxicity (GHS-US/CA)

No data available

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### Mixture

Name	Product Identifier	% *	GHS Ingredient Classification
Benzoic acid, 4-amino-, ethyl ester	(CAS No) 94-09-7	7.5 - 10	Skin Sens. 1, H317 Aquatic Acute 3, H402
Polyethylene glycol	(CAS No) 25322-68-3	5.085 - 5.297	STOT SE 3, H335
White mineral oil, petroleum	(CAS No) 8042-47-5	2.75 - 3.75	Asp. Tox. 1, H304

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%).

## 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:** Skin sensitization.

**Inhalation:** Prolonged exposure may cause irritation.

**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 expected under normal conditions of use.

### 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.

**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, CO<sub>2</sub>). Nitrogen oxides.

### 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 (vapor, mist, spray). Do not get in eyes, on skin, or on clothing.

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### 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:** Ventilate area. 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.

### Methods and Materials for Containment and Cleaning Up

**For Containment:** Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

**Methods for Cleaning Up:** Clean up spills immediately and dispose of waste safely. 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 prolonged contact with eyes, skin and clothing. Avoid breathing vapors, mist, spray.

**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)

Teething Pain Medication.

## 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.

White mineral oil, petroleum (8042-47-5)		
USA ACGIH	ACGIH TWA (mg/m <sup>3</sup> )	5 mg/m <sup>3</sup> (mist)
Polyethylene glycol (25322-68-3)		
USA AIHA	WEEL TWA (mg/m <sup>3</sup> )	10 mg/m <sup>3</sup> (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.

**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.

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**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.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### Information on Basic Physical and Chemical Properties

Physical State	: Liquid
Appearance	: Red to pink cream
Odor	: Characteristic
Odor Threshold	: Not available
pH	: 3.5 - 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 applicable
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	: 0.0967 - 1.06
Solubility	: Dispersible.
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:** 3.5 - 4.5

**Eye Damage/Irritation:** Not classified

**pH:** 3.5 - 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

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**Specific Target Organ Toxicity (Single Exposure):** Not classified

**Aspiration Hazard:** Not classified

**Symptoms/Injuries After Inhalation:** Prolonged exposure may cause irritation.

**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 expected under normal conditions of use.

### Information on Toxicological Effects - Ingredient(s)

**LD50 and LC50 Data:**

<b>White mineral oil, petroleum (8042-47-5)</b>	
LD50 Oral Rat	> 5000 mg/kg
<b>Benzoic acid, 4-amino-, ethyl ester (94-09-7)</b>	
LD50 Oral Rat	3042 mg/kg
<b>Polyethylene glycol (25322-68-3)</b>	
LD50 Oral Rat	22 g/kg
LD50 Dermal Rabbit	> 20 ml/kg

## SECTION 12: ECOLOGICAL INFORMATION

### Toxicity

**Ecology - General:** Not classified.

<b>White mineral oil, petroleum (8042-47-5)</b>	
LC50 Fish 1	> 10000 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus)
<b>Benzoic acid, 4-amino-, ethyl ester (94-09-7)</b>	
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

<b>Orajel™ Medicated Daytime &amp; Nighttime Teething Gels</b>	
Persistence and Degradability	Not established.

### Bioaccumulative Potential

<b>Orajel™ Medicated Daytime &amp; Nighttime Teething Gels</b>	
Bioaccumulative Potential	Not established.
<b>White mineral oil, petroleum (8042-47-5)</b>	
Log POW	> 6
<b>Benzoic acid, 4-amino-, ethyl ester (94-09-7)</b>	
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.

**Additional Information:** Container may remain hazardous when empty. Continue to observe all precautions.

**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

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### SECTION 15: REGULATORY INFORMATION

#### US Federal and International Regulations

<b>Orajel™ Medicated Daytime &amp; Nighttime Teething Gels</b>	
<b>SARA Section 311/312 Hazard Classes</b>	Immediate (acute) health hazard
<b>White mineral oil, petroleum (8042-47-5)</b>	
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 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) Listed on CICR (Turkish Inventory and Control of Chemicals) Listed on the TCSI (Taiwan Chemical Substance Inventory)	
<b>Benzoic acid, 4-amino-, ethyl ester (94-09-7)</b>	
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 Listed on INSQ (Mexican National Inventory of Chemical Substances) Listed on the TCSI (Taiwan Chemical Substance Inventory)	
<b>Polyethylene glycol (25322-68-3)</b>	
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)	
<b>EPA TSCA Regulatory Flag</b>	XU - XU - indicates a substance exempt from reporting under the Inventory Update Reporting Rule, i.e, Partial Updating of the TSCA Inventory Data Base Production and Site Reports (40 CFR 710(C)).

#### US State Regulations

Neither this product nor its chemical components appear on any US state lists.

#### Canadian Regulations

<b>White mineral oil, petroleum (8042-47-5)</b>	
Listed on the Canadian DSL (Domestic Substances List)	
<b>Benzoic acid, 4-amino-, ethyl ester (94-09-7)</b>	

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Listed on the Canadian DSL (Domestic Substances List)
<b>Polyethylene glycol (25322-68-3)</b>
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** : **06/06/2022**

**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:

Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Asp. Tox. 1	Aspiration hazard Category 1
Skin Sens. 1	Skin sensitization, Category 1
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H304	May be fatal if swallowed and enters airways
H317	May cause an allergic skin reaction
H335	May cause respiratory irritation
H402	Harmful to aquatic life

*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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