



Orajel™ Moisturelock Cold Sore Treatment - (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).
Revision Date: 06/06/2022 Date of Issue: 08/07/2017 Supersedes Date: 07/04/2021 Version: 2.2

SECTION 1: IDENTIFICATION

Product Identifier

Product Form: Mixture

Product Name: Orajel™ Moisturelock Cold Sore Treatment - (NA GHS 2015 - EN)

Product Code: 40501116

Synonyms: Orajel™ Cold Sore Relief & Concealer

Intended Use of the Product

Cold sore treatment

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

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. Overexposure may cause methemoglobinemia. Initial manifestation of methemoglobinemia is cyanosis, characterized by navy lips, tongue and mucous membranes, with skin color being

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slate grey. Further manifestation is characterized by headache, weakness, dyspnea, dizziness, stupor, respiratory distress and death due to anoxia.

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	10 - 30	Skin Sens. 1, H317 Aquatic Acute 3, H402
Titanium dioxide**	(CAS No) 13463-67-7	0.998 – 1.003	Carc. 2, H351

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%).

** There have been studies performed in animals that suggest Titanium Dioxide may cause lung cancer through inhalation. However, this hazard is not associated with other routes of exposure. Since this product is in a paste form, the Titanium Dioxide is not able to become airborne and cannot be inhaled. Thus, the hazards usually associated with Titanium Dioxide are not applicable to this product.

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: 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. Overexposure may cause methemoglobinemia.

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.

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

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)

Cold sore treatment

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.

Titanium dioxide (13463-67-7)		
Mexico	OEL TWA (mg/m ³)	10 mg/m ³
Mexico	OEL STEL (mg/m ³)	20 mg/m ³
USA ACGIH	ACGIH TWA (mg/m ³)	10 mg/m ³
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen
USA OSHA	OSHA PEL (TWA) (mg/m ³)	15 mg/m ³ (total dust)
USA IDLH	US IDLH (mg/m ³)	5000 mg/m ³
Alberta	OEL TWA (mg/m ³)	10 mg/m ³
British Columbia	OEL TWA (mg/m ³)	10 mg/m ³ (total dust) 3 mg/m ³ (respirable fraction)
Manitoba	OEL TWA (mg/m ³)	10 mg/m ³
New Brunswick	OEL TWA (mg/m ³)	10 mg/m ³

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Newfoundland & Labrador	OEL TWA (mg/m ³)	10 mg/m ³
Nova Scotia	OEL TWA (mg/m ³)	10 mg/m ³
Nunavut	OEL STEL (mg/m ³)	20 mg/m ³
Nunavut	OEL TWA (mg/m ³)	10 mg/m ³
Northwest Territories	OEL STEL (mg/m ³)	20 mg/m ³
Northwest Territories	OEL TWA (mg/m ³)	10 mg/m ³
Ontario	OEL TWA (mg/m ³)	10 mg/m ³
Prince Edward Island	OEL TWA (mg/m ³)	10 mg/m ³
Québec	VEMP (mg/m ³)	10 mg/m ³ (containing no Asbestos and <1% Crystalline silica-total dust)
Saskatchewan	OEL STEL (mg/m ³)	20 mg/m ³
Saskatchewan	OEL TWA (mg/m ³)	10 mg/m ³
Yukon	OEL STEL (mg/m ³)	20 mg/m ³
Yukon	OEL TWA (mppcf) OEL TWA (mg/m ³)	30 mppcf 10 mg/m ³

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.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Information on Basic Physical and Chemical Properties

Physical State	: Liquid
Appearance	: Opaque, light green ointment
Odor	: Characteristic
Odor Threshold	: Not available
pH	: Not available
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

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Relative Density	: Not available
Specific Gravity	: Not available
Solubility	: Not available
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

Eye Damage/Irritation: Not classified

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

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified. (There have been studies performed in animals that suggest Titanium Dioxide may cause lung cancer through inhalation. However, this hazard is not associated with other routes of exposure. Since this product is in a paste form, the Titanium Dioxide is not able to become airborne and cannot be inhaled. Thus, the hazards usually associated with Titanium Dioxide are not applicable to this product.)

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Reproductive Toxicity: Not classified

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. Overexposure may cause methemoglobinemia.

Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data:

Titanium dioxide (13463-67-7)	
LD50 Oral Rat	> 10000 mg/kg
Benzoic acid, 4-amino-, ethyl ester (94-09-7)	
LD50 Oral Rat	3042 mg/kg
Titanium dioxide (13463-67-7)	
IARC Group	2B
OSHA Hazard Communication Carcinogen List	In OSHA Hazard Communication Carcinogen list.

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])

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LC50 Fish 2	24.9 - 26.9 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
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Persistence and Degradability

Orajel™ Moisturelock Cold Sore Treatment	
Persistence and Degradability	Not established.

Bioaccumulative Potential

Orajel™ Moisturelock Cold Sore Treatment	
Bioaccumulative Potential	Not established.

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.

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

SECTION 15: REGULATORY INFORMATION

US Federal and International Regulations

Orajel™ Moisturelock Cold Sore Treatment	
SARA Section 311/312 Hazard Classes	Immediate (acute) health hazard

Titanium dioxide (13463-67-7)	
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	
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)	

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)	

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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)
Listed on the TCSI (Taiwan Chemical Substance Inventory)

US State Regulations

Titanium dioxide (13463-67-7)

U.S. - California - Proposition 65 - Carcinogens List

WARNING: This product contains chemicals known to the State of California to cause cancer.

Titanium dioxide (13463-67-7)

U.S. - Massachusetts - Right To Know List
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List

Canadian Regulations

Titanium dioxide (13463-67-7)

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 : 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:

Acute Tox. 4 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 4
Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Carc. 2	Carcinogenicity Category 2
Flam. Sol. 2	Flammable solids Category 2
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
H228	Flammable solid
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H332	Harmful if inhaled
H335	May cause respiratory irritation
H351	Suspected of causing cancer
H402	Harmful to aquatic life

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