

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: 12/01/2022 Version: 1.0

SECTION 1: IDENTIFICATION

<u>Product Identifier</u> <u>Product Form: Mixture</u>

Product Name: GRAVOL™ Kids Suppositories (NA GHS 2015)

Product Code: 40501367, 40501368

Synonyms: GRAVOL™ Kids Suppositories 25 mg, GRAVOL™ Suppositories 100 mg

Intended Use of the Product

Nausea Relief

Name, Address, and Telephone of the Responsible Party

Company Company

Church & Dwight Co. Inc. Church and Dwight Canada Corp.

500 Charles Ewing Blvd 5485 Ferrier

Ewing Township, NJ 08628 Montreal, Qc, H4P 1M6 T 1-800-524-1328 www.churchdwight.ca

<u>www.churchdwight.com</u> <u>http://www.econsumeraffairs.com/churchdwight/contactus.htm</u>

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: VelocityEHS (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

Not classified

Label Elements

GHS-US/CA Labeling

No labeling applicable according to 29 CFR 1910.1200 and the Hazardous Products Regulations (HPR) SOR/2015-17.

Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions. Titanium dioxide is bound in the matrix of the product and is not respirable under normal use.

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	80-100	Not classified
Titanium dioxide	(CAS-No.) 13463-67-7	0.1-1	Not classified

Full text of H-statements: see section 16

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).

12/01/2022 EN (English US) 1/7

^{*}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%).

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).

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 5 minutes. Obtain medical attention if irritation develops or persists.

Eye Contact: Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Obtain medical attention if irritation develops or persists.

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

Most Important Symptoms and Effects Both Acute and Delayed

General: Not expected to present a significant hazard under anticipated conditions of normal use.

Inhalation: Prolonged exposure may cause irritation. **Skin Contact:** Prolonged exposure may cause skin irritation.

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, 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). Titanium 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 prolonged contact with eyes, skin and clothing. Avoid breathing dust.

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.

12/01/2022 EN (English US) 2/7

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).

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

Specific End Use(s)
Nausea Relief

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)					
USA AIHA	WEEL TWA	10 mg/m³ (molecular weight>200-aerosol)			
Titanium dioxide (13463-67-	Titanium dioxide (13463-67-7)				
USA ACGIH	ACGIH OEL TWA	10 mg/m³			
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen			
USA OSHA	OSHA PEL (TWA) [1]	15 mg/m³ (total dust)			
USA NIOSH	NIOSH REL (TWA)	2.4 mg/m³ (CIB 63-fine)			
		0.3 mg/m³ (CIB 63-ultrafine, including engineered			
		nanoscale)			
USA IDLH	IDLH	5000 mg/m ³			
Alberta	OEL TWA	10 mg/m³			
British Columbia	OEL TWA	10 mg/m³ (total dust)			
		3 mg/m³ (respirable fraction)			
Manitoba	OEL TWA	10 mg/m³			
New Brunswick	OEL TWA	10 mg/m ³			
Newfoundland & Labrador	OEL TWA	10 mg/m³			
Nova Scotia	OEL TWA	10 mg/m³			
Nunavut	OEL STEL	20 mg/m ³			
Nunavut	OEL TWA	10 mg/m³			
Northwest Territories	OEL STEL	20 mg/m ³			
Northwest Territories	OEL TWA	10 mg/m ³			
Ontario	OEL TWA	10 mg/m ³			
Prince Edward Island	OEL TWA	10 mg/m ³			
Québec	VEMP (OEL TWA)	10 mg/m³ (containing no Asbestos and <1% Crystalline			
		silica-total dust)			
Saskatchewan	OEL STEL	20 mg/m ³			
Saskatchewan	OEL TWA	10 mg/m³			
Yukon	OEL STEL	20 mg/m ³			
Yukon	OEL TWA	30 mppcf			
		10 mg/m³			

Exposure Controls

Appropriate Engineering Controls: For occupational/workplace settings: Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

12/01/2022 EN (English US) 3/7

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).

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: For occupational/workplace settings: 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 White suppository

Odor None

Odor Threshold No data available Ηα No data available **Evaporation Rate** No data available **Melting Point** No data available No data available **Freezing Point Boiling Point** No data available **Flash Point** No data available No data available **Auto-ignition Temperature Decomposition Temperature** No data available **Flammability** 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** No data available **Specific Gravity** No data available Solubility No data available Partition Coefficient: N-Octanol/Water No data available

SECTION 10: STABILITY AND REACTIVITY

Reactivity:

Viscosity

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:

Not expected to decompose under ambient conditions.

12/01/2022 EN (English US) 4/7

No data available

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).

SECTION 11: TOXICOLOGICAL INFORMATION

<u>Information on Toxicological Effects - Product</u>

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: Not classified

Eye Damage/Irritation: Not classified

Respiratory or Skin Sensitization: Not classified

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): Not classified

Aspiration Hazard: Not classified

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

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes. **Symptoms/Injuries After Ingestion:** Ingestion may cause adverse effects.

Chronic Symptoms: None known.

<u>Information on Toxicological Effects - Ingredient(s)</u>

LD50 and LC50 Data:

ED30 and EC30 Data:		
Polyethylene glycol (25322-68-3)		
LD50 Oral Rat	22 g/kg	
LD50 Dermal Rabbit	> 20 g/kg	
Titanium dioxide (13463-67-7)		
LD50 Oral Rat	> 10000 mg/kg	
LC50 Inhalation Rat	5.09 mg/l/4h	
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. **Persistence and Degradability**

GRAVOL™ Kids Suppositories (NA GHS 2015)	
Persistence and Degradability	Not established.

Bioaccumulative Potential

GRAVOL™ Kids Suppositories (NA GHS 2015)	
Bioaccumulative Potential	Not established.

Mobility in Soil

No additional information 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.

12/01/2022 EN (English US) 5/7

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).

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

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

 $\ensuremath{\mathsf{XU}}$ - $\ensuremath{\mathsf{XU}}$ - indicates a substance exempt from reporting under the

Chemical Data Reporting Rule, (40 CFR 711).

Titanium dioxide (13463-67-7)

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 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 INSQ (Mexican National Inventory of Chemical Substances)

Listed on the TCSI (Taiwan Chemical Substance Inventory)

Listed on the NCI (Vietnam - National Chemicals Inventory)

US State Regulations

Titanium dioxide (13463-67-7)

U.S. - New Jersey - Right to Know Hazardous Substance List

U.S. - Pennsylvania - RTK (Right to Know) List

U.S. - Massachusetts - Right To Know List

Canadian Regulations

Polyethylene glycol (25322-68-3)

Listed on the Canadian DSL (Domestic Substances List)

Titanium dioxide (13463-67-7)

12/01/2022 EN (English US) 6/7

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).

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 Other Information

- : 12/01/2022
- : 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:

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.

Church&Dwight NA GHS SDS 2015

12/01/2022 EN (English US) 7/7