



GRAVOL™ IM Dimenhydrinate Injection (NA GHS 2024)

Safety Data Sheet

According To Federal Register / Vol. 89, No. 98 / Monday, May 20, 2024 / Rules And Regulations And According To The Hazardous Products Regulation (December 15, 2022).

Date of Issue: 03/03/2025

Version: 1.0

SECTION 1: IDENTIFICATION

Product Identifier

Product Form: Mixture

Product Name: GRAVOL™ IM Dimenhydrinate Injection (NA GHS 2024)

Product Code: 42017487

Recommended Use and Restrictions on Use

Use of the Substance/Mixture: Nausea Relief

Restrictions On Use: No restrictions on use.

Name, Address, and Telephone of the Responsible Party

Company

Church & Dwight Co. Inc.
500 Charles Ewing Blvd
Ewing Township, NJ 08628
T 1-800-524-1328

www.churchdwight.com

Company

Church and Dwight Canada Corp.
635 Secretariat Ct
Mississauga, ON L5S 0A5

www.churchdwight.ca

www.econsumeraffairs.com/churchdwight/contactus

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/2022-272.

Hazards associated with known or reasonably anticipated uses

If this product is used in unforeseeable chemical processes and not used as intended or reasonable, the hazards listed in Section 2.3 cannot cover all chemistries. Therefore, a Process Hazard Analysis (PHA) or other hazard assessment for additional specific end uses should be performed to ensure that hazards are fully understood, and adequate safety measures are in place. See Section 10 for relevant reactivity and stability information.

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	Synonyms	Product Identifier	% *	GHS Ingredient Classification
1,2-Propanediol	1,2-Propylene glycol / 1,2-Dihydroxypropane / Propane-1,2-diol / Propylene glycol	(CAS-No.) 57-55-6	30 - 60	Not classified.
1H-Purine-2,6-dione, 8-chloro-3,7-dihydro-1,3-dimethyl-, compound	Dimenhydrinate / Theophylline, 8-chloro-, compound with 2-	(CAS-No.) 523-87-5	3 - 7	Acute Tox. 4 (Oral), H302

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with 2-(diphenylmethoxy)-N,N-dimethylethanamine (1:1)	(diphenylmethoxy)-N,N-dimethylethylamine (1:1) / Dimenhydramine			
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Full text of H-statements: see section 16

*Percentages are listed in weight by weight percentage (w/w%). The actual concentration of ingredient(s) is withheld as a trade secret in accordance with the Hazardous Products Regulations (HPR) SOR/2022-272 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 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: Pharmaceutical Agent. Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.

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). Chlorine compounds. 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 prolonged contact with eyes, skin and clothing. Avoid breathing (vapor, mist, spray). If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

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.

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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 any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

Methods for Cleaning Up: Clean up spills and dispose of waste safely. Absorb and/or contain spill with inert material. 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: Accidental injection may cause pain and swelling at the injection site. Sharps should be handled appropriately to minimize risk of accidents. If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens. 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. Pregnant or possibly pregnant women must use special care while handling this material. Needle sticks should be reported immediately.

Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Keep container closed when not in use. Store at room temperature (15 – 30 °C / 49 – 86 °F). Protect from freezing. 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.

1,2-Propanediol (57-55-6)		
USA AIHA	WEEL TWA	10 mg/m ³
Ontario	OEL TWA EV	10 mg/m ³ (for assessing the visibility in a work environment where 1,2-Propylene glycol aerosol is present-aerosol only) 155 mg/m ³ (aerosol and vapor)
Ontario	OEL TWA EV	50 ppm (aerosol and vapor)

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.

Personal Protective Equipment: For occupational/workplace settings and bulk quantities: Gloves. Protective clothing. Protective goggles.



Materials for Protective Clothing: For occupational/workplace settings and bulk quantities: Chemically resistant materials and fabrics.

Hand Protection: For occupational/workplace settings and bulk quantities: Wear protective gloves.

Eye and Face Protection: For occupational/workplace settings and bulk quantities: Chemical safety goggles.

Skin and Body Protection: For occupational/workplace settings and bulk quantities: Wear suitable protective clothing.

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Respiratory Protection: For occupational/workplace settings and bulk quantities: 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	: Liquid
Color	: Clear colorless solution in 1 mL glass ampoule
Odor	: None
Odor Threshold	: No data available
pH	: 6.4 – 7.2
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)	: Not applicable
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	: 1.0457 – 1.0497
Specific Gravity	: No data available
Solubility	: No data available
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity, Kinematic	: No data available
Particle Aspect Ratio	: Not applicable
Particle Aggregation State	: Not applicable
Particle Agglomeration State	: Not applicable
Particle Specific Surface Area	: Not applicable
Particle Dustiness	: Not applicable

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, Including those Associated with Foreseeable Emergencies:

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:

Thermal decomposition may produce: Carbon oxides (CO, CO₂). Chlorine compounds. Nitrogen oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

Information on Toxicological Effects - Product

Likely routes of exposure: Dermal, Eye Contact, Inhalation, Oral.

Acute Toxicity (Oral): Not classified.

Acute Toxicity (Dermal): Not classified.

Acute Toxicity (Inhalation): Not classified.

LD50 and LC50 Data: No additional information available.

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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.

Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data:

1H-Purine-2,6-dione, 8-chloro-3,7-dihydro-1,3-dimethyl-, compound with 2-(diphenylmethoxy)-N,N-dimethylethanamine (1:1) (523-87-5)

LD50 Oral Rat	1320 mg/kg (Source: NLM_CIP)
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1,2-Propanediol (57-55-6)

LD50 Oral Rat	20 g/kg (Source: NLM_CIP)
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LD50 Dermal Rabbit	20800 mg/kg (Source: NLM_CIP)
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SECTION 12: ECOLOGICAL INFORMATION

Toxicity

Ecology - General: Not classified.

1,2-Propanediol (57-55-6)

LC50 Fish	51600 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static] Source: IUCLID)
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EC50 Crustacea	10000 mg/l (Exposure time: 24 h - Species: Daphnia magna)
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LC50 Fish	41 – 47 ml/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static] Source: EPA)
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EC50 Crustacea	1000 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
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ErC50 Algae	1000 mg/l
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NOEC Chronic Crustacea	1000 mg/l
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NOEC Chronic Algae	1000 mg/l
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Persistence and Degradability

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Persistence and Degradability	Not established.
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Bioaccumulative Potential

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Bioaccumulative Potential	Not established.
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1,2-Propanediol (57-55-6)

BCF Fish	1
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Partition coefficient n-octanol/water (Log Pow)	-0.92
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Mobility in Soil

No additional information available

Other Adverse Effects

Other Information: Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Product contaminated with biological materials should preferably be incinerated.

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.

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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

1H-Purine-2,6-dione, 8-chloro-3,7-dihydro-1,3-dimethyl-, compound with 2-(diphenylmethoxy)-N,N-dimethylethanamine (1:1) (523-87-5)

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 KECL/KECI (Korean Existing Chemicals Inventory)
Listed on NZIoC (New Zealand Inventory of Chemicals)
Listed on INSQ (Mexican National Inventory of Chemical Substances)
Listed on the TCSI (Taiwan Chemical Substance Inventory)
Listed on the NCI (Vietnam - National Chemical Inventory)

1,2-Propanediol (57-55-6)

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 the Canadian IDL (Ingredient Disclosure List)
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 Chemical Inventory)
Listed on Thailand Existing Chemicals Inventory (DIW)

US State Regulations

1,2-Propanediol (57-55-6)

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

Canadian Regulations

1H-Purine-2,6-dione, 8-chloro-3,7-dihydro-1,3-dimethyl-, compound with 2-(diphenylmethoxy)-N,N-dimethylethanamine (1:1) (523-87-5)

Listed on the Canadian DSL (Domestic Substances List)

1,2-Propanediol (57-55-6)

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 : 03/03/2025

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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/2022-272.

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:

H302	Harmful if swallowed.
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Glossary of Data Source Abbreviations

ATSDR: Agency for Toxic Substances and Disease Registry (U.S. Department of Health and Human Services)	FOOD_JOURN: Food Research Journal (1956)
AU_WES: Australia WES	IARC: The International Agency for Research on Cancer
CHEMVIEW: ChemView (U.S. Environmental Protection Agency)	IDLH: National Institute for Occupational Health and Safety Immediately Dangerous to Life or Health Value Profiles
EC_RAR: European Commission Renewal Assessment Report	IUCLID: International Uniform Chemical Information Database
EC_SCOEL: European Commission Scientific Committee on Occupational Exposure Limits	JAPAN_GHS: Japan GHS Basis for Classification Data
ECETOC: European Centre for Ecotoxicology and Toxicology of Chemicals Reports	JP_J-CHECK: Japan J-Check
ECHA_API: European Chemicals Agency API	KR_NIER: South Korea National Institute of Environmental Research Evaluations
ECHA_RAC: ECHA Committee for Risk Assessment	NICNAS: Australia National Industrial Chemicals Notification and Assessment Scheme
EFSA: European Food Safety Authority	NIOSH: National Institute for Occupational Health and Safety (U.S. Department of Health and Human Services)
EPA: U.S. Environmental Protection Agency	NLM_CIP: National Library of Medicine ChemID plus database
EPA_AEGL: Acute Exposure Guideline Levels (U.S. Environmental Protection Agency)	NLM_HSDB: National Library of Medicine Hazardous Substance Data Bank
EPA_FIFRA: Federal Insecticide, Fungicide, and Rodenticide Act Reregistration Eligibility Decision (U.S. Environmental Protection Agency)	NLM_PUBMED: National Library of Medicine PubMed database
EPA_HPVC: High Production Volume Chemicals (U.S. Environmental Protection Agency)	NTP: National Toxicology Program
EPA_TRED: Risk Assessment for Tolerance Reassessment Eligibility Decision (U.S. Environmental Protection Agency)	NZ_CCID: New Zealand Chemical Classification and Information Database
EU_CLH: European Union Harmonised Classification and Labelling Proposal	OECD_EHSP: Environment, Health, and Safety Publication (Organisation for Economic Co-operation and Development)
EU_RAR: European Union Risk Assessment Report	OECD_SIDS: Screening Information Data Sets (Organisation for Economic Co-operation and Development)
	WHO: World Health Organization

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.

NA GHS SDS 2024 (Can, US)