SECTION 1: IDENTIFICATION

Product Identifier

Product Name: Dimenhydrinate Injection USP with Preservative
Other Name: Dimenhydrinate Injection 50 mg/mL
Chemical Family: Mixture

Product Use: Pharmaceutical (Intramuscular and Intravenous, used as antiemetic agent)

Supplier: **Teligent Canada Inc.**
5995 Avebury Road, Suite 804
Mississauga, Ontario L5R 3P9
1-800-656-0793

Manufacturer: **Teligent OÜ**
Akadeemia tee 21/5, Tallinn, Estonia

Emergency Phone Number:
Chemical Emergency Response Unit (Canada): 1-613-946-5690
Poison Control Center (US): 1-800-222-1222

SECTION 2: HAZARD IDENTIFICATION

This pharmaceutical product is for human use under prescribed dosage form. Under normal handling and use, and in a manner consistent with the labeled instructions, this product is not chemically hazardous.

Classification of the Substance or Mixture

GHS Classification

Acute Toxicity	Category 4
Eye Irritation	Category 2A
Sensitization, Skin	Category 2

GHS Label Elements, Including Hazard and Precautionary Statements

Pictogram:

Signal Word: Warning

Hazard Statements:

H301	Harmful if swallowed.
H410	Very toxic to aquatic life with long lasting effects
H315	Causes skin irritation
H319	Causes serious eye irritation

Precautionary statements: Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
Wash thoroughly after handling.
Wear protective gloves/protective clothing/eye protection/face protection.
Take off contaminated clothing and wash before reuse.
Dispose of contents/container in accordance with all local and national regulations.

SECTION 3: COMPOSITION/ INFORMATION OF INGREDIENTS

Composition of 5 mL Dosage (with Preservative)

Ingredients	CAS Number	Quantity	Acute toxicity, LD50, Rat
Dimenhydrinate	523-87-5	50 mg/mL	1320 mg/kg (Oral)
Propylene Glycol	57-55-6	520 mg/mL	20000 mg/kg (Oral)
Sodium Methylparaben	5026-62-0	1 mg/mL	> 5000 mg/kg (Oral)
Sodium Propylparaben	35285-69-9	0.1 mg/mL	> 3700 mg/kg (Oral)
Hydrochloric Acid	7647-01-0	For pH adjustment	No data available
Water for Injection	7732-18-5	-	Not applicable

SECTION 4: FIRST AID MEASURES

After Eye Contact: Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.

After Skin Contact: Remove clothing and wash affected skin with plenty of soap and water. If irritation occurs or persists, get medical attention.

After Inhalation: Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

After Ingestion: Never give anything by mouth to an unconscious person. Rinse mouth with water. Get medical attention.

SECTION 5: FIRE FIGHTING MEASURES

Fire Fighting Instructions: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Hazardous Combustion Products: May emit toxic fumes of nitrogen oxides and hydrogen chloride.

Fire/Explosion Hazards: Flammable liquid. Vapors will form flammable or explosive mixtures with air at room temperature. Vapors are heavier than air and may travel along surfaces to remote ignition sources and flash back.

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

SECTION 7: HANDLING AND STORAGE

Precautions for Safe Handling

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. Use with adequate ventilation. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store at controlled temperature between 15 and 30 °C. Protect from freezing. Protect from light.

SECTION 8: EXPOSURE CONTROLS AND PERSONAL PROTECTION

Control parameters

Dimenhydrinate
No data available

Propylene Glycol
Ontario, OHS OEL- TWAs: 155 mg/m^3

Personal Protection Equipment

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Eye Protection: Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin Protection: Wear protective clothing with long sleeves to avoid skin contact. Wash hands and arms thoroughly with water after handling this product.

Hand Protection: Protective gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Respiratory Protection: Respiratory protection is not required. Where protection from nuisance levels of dusts are desired, wear an appropriate respirator with a protection factor sufficient to control exposures.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Liquid
Colour:	Colourless
Odour:	No data available
Odour threshold:	No data available
Molecular Formula:	Mixture
Molecular Weight:	Mixture
Specific Gravity:	1.048 g/mL
pH:	6.4 – 7.2
Boiling Point:	Mixture
Freezing Point:	Mixture
Solubility in Water:	Miscible in water
Flash Point:	No data available
Vapor Density:	No data available
Vapor Pressure:	No data available
Evaporation Rate:	No data available
Partition Coefficient:	No data available
Flammability:	No data available
Auto-ignition Temperature:	No data available
Decomposition Temperature:	No data available
Viscosity:	No data available

SECTION 10: STABILITY AND REACTIVITY

Reactivity:	No data available
Chemical Stability:	Stable under normal conditions of use.
Possibility of Hazardous Reactions:	No data available
Conditions to Avoid:	Direct sunlight, conditions that might generate heat, and sources of ignition.

Incompatibility: No data available
Hazardous Decomposition Products: Hazardous decomposition products formed under fire conditions: Carbon oxides, Nitrogen oxides (NOx), Sulphur oxides.

SECTION 11: TOXIOLOGICAL INFORMATION

Acute toxicity (Species, Root, Endpoint, Dose)

Dimenhydrinate

Rat	Oral	LD50	1320 mg/kg

Propylene Glycol

Mouse	Oral	LD50	22000 mg/kg
Rat	Oral	LD50	20000 mg/kg
Rabbit	Dermal	LD50	820 mg/kg

Repeated dose toxicity
No data available
Other information on acute toxicity
No data available
Skin corrosion/irritation
No data available
Serious eye damage/eye irritation
No data available
Respiratory or skin sensitization
No data available
Germ cell mutagenicity
No data available
Carcinogenicity
Carcinogenicity of the mixture has not been determined. None of the components of this formulation are listed as human carcinogen by IARC, ACGIH or OSHA.
Reproductive toxicity
No data available
Teratogenicity
No data available

SECTION 12: ECOLOGICAL INFORMATION

Toxicity

Dimenhydrinate
No data available

Propylene Glycol

Pimephales promelas (fathead minnow)	NOEC	52930 mg/l - 96 h
Daphnia (water flea)	NOEC	13020 mg/l - 48 h

Hydrochloric Acid
Toxicity to fish
LC50 – Lepomis macrochirus (Bluegill) - 24.6 mg/l – 96 hr

Toxicity to daphnia and other aquatic invertebrates
EC50 – Daphnia magna (Water flea) – 4.91 mg/l – 48 hr

Persistence and degradability
No data available

Bioaccumulative potential
No data available

Mobility in soil
No data available

Other adverse effects
No data available

SECTION 13: DISPOSAL CONSIDERATIONS

Waste Disposal: Dispose of in accordance with all applicable federal, state and local regulations. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases.

Packaging: Dispose of in accordance with all applicable federal, state and local regulations. Handle packaging in the same way as the product itself. If not officially specified differently, packaging may be treated like household waste or recycled.

SECTION 14: TRANSPORTATION INFORMATION

Not regulated for transport under USDOT (transportation by land), IATA (transportation by air) or IMDG (transportation by sea) regulations.

SECTION 15: REGULATORY INFORMATION

The product described in this SDS is regulated under the Federal Food, Drug and Cosmetics Act and is safe to use as per directions on container, box or accompanying literature (where applicable).

SECTION 16: OTHER INFORMATION

The information contained in this Safety Data Sheet has been compiled from information believed to be accurate. While we believe that the data presented here is factual, Teligent Canada Inc. and its affiliates make no warranty or representation, nor assumes any responsibility in conjunction with the use of this information.

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