

SECTION 1: IDENTIFICATION

Product Identifier

Product Name: Dobutamine Injection USP
Other Name: Dobutamine Hydrochloride 12.5 mg/ml Injection
Chemical Family: Mixture

Product Use: Pharmaceutical (Solution for Injection)

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, Inhalation | Category 4 |
| Acute toxicity, Dermal | Category 4 |
| Acute toxicity, Oral | Category 4 |
| Reproductive toxicity | Category 2 |

GHS Label Elements, Including Hazard and Precautionary Statements

Pictogram:



Signal Word:

Warning

Hazard Statements:

| | |
|------|--|
| H302 | Harmful if swallowed. |
| H312 | Harmful in contact with skin. |
| H332 | Harmful if inhaled. |
| H361 | Suspected of damaging fertility or the unborn child. |

Precautionary statements:

Obtain special instructions before use.
 Avoid breathing dust/fume/gas/mist/vapors/spray.
 Wash ... thoroughly after handling.
 Do not eat, drink or smoke when using this product.
 Wear protective gloves/protective clothing/eye protection/face protection.
 IF SWALLOWED: call a POISON CENTER/doctor/... IF you feel unwell.
 IF ON SKIN: wash with plenty of water.
 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

SECTION 3: COMPOSITION/ INFORMATION OF INGREDIENTS

| Ingredients | CAS Number | Quantity | Acute toxicity, LD50 (Oral, Rat) |
|------------------------------|------------|-------------------|----------------------------------|
| Dobutamine Hydrochloride | 49745-95-1 | 12.5 mg/mL | 2296 mg/kg |
| Sodium Metabisulfite | 7681-57-4 | 0.22 mg/mL | 1540 mg/kg |
| Hydrochloric Acid | 7647-01-0 | For pH adjustment | No data available |
| Purified 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.

SECTION 5: FIRE FIGHTING MEASURES

Conditions of Flammability: Not Flammable or Combustible

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

Explosion Hazards: Not applicable.

Extinguishing Media: Use extinguishing media appropriate to surrounding fire conditions, such as water spray, dry chemical, alcohol-resistant foam, carbon dioxide.

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 room temperature between 15 and 30°C. Protect from light. Protect from freezing. For details information refer to the product packaging.

Incompatible Materials: Avoid exposure to light. Vial stopper contains no dry natural rubber.

SECTION 8: EXPOSURE CONTROLS AND PERSONAL PROTECTION

Control parameters

No data available

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: | Not applicable |
| Odour threshold: | No data available |
| Molecular Formula: | Mixture |
| Molecular Weight: | Mixture |
| Specific Gravity: | 1.0013 g/mL |
| pH: | 2.5 – 5.5 |
| Boiling Point: | Mixture |
| Freezing Point: | Mixture |
| Solubility in Water: | Soluble |
| 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. Protect from freezing. |
| Incompatibility: | No data available |
| Hazardous Decomposition Products: | Hazardous decomposition products may formed under fire conditions:- Carbon oxides, Nitrogen oxides (NOx), Oxides of phosphorus, Cobalt/cobalt oxides. |

SECTION 11: TOXIOLOGICAL INFORMATION

Acute toxicity (Species, Root, Endpoint, Dose)

Product Mixture

| | | | |
|-------|-------------|------|---------------|
| Mouse | Intravenous | LD50 | 68 - 73 mg/kg |
| Rat | Intravenous | LD50 | 80 - 97 mg/kg |

Dobutamine Hydrochloride

| | | | |
|-------|------|------|------------|
| Rat | Oral | LD50 | 2296 mg/kg |
| Mouse | Oral | LD50 | 1324 mg/kg |

Sodium Metabisulfite

| | | | |
|-----|--------|------|--------------|
| Rat | Oral | LD50 | 1540 mg/kg |
| Rat | Dermal | LD50 | > 2000 mg/kg |

Repeated dose toxicity: (Duration, Species, Route, Dose, Target Organ)

| | | | | |
|-----------|-----|-------------|------------------------|----------------------------|
| 2 Week(s) | Dog | Intravenous | 25, 50, 100 mcg/kg/min | Blood |
| 2 Week(s) | Rat | Intravenous | 10mg/kg/daily | Heart Increased heart rate |

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

None of the components of this formulation are listed as a carcinogen by IARC, ACGIH or OSHA.

Reproductive toxicity

No data available

Teratogenicity

No effect evident in rats and rabbits

SECTION 12: ECOLOGICAL INFORMATION

Toxicity

Dobutamine Hydrochloride

No data available

Sodium Metabisulfite

Toxicity to fish

LC50 – Oncorhynchus mykiss (Rainbow Trout) - 150- 220 mg/l – 96 hr

Toxicity to daphnia and other aquatic invertebrates

EC50 – Daphnia magna (Water flea) - 89 mg/l – 24 hr

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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