SECTION 1: IDENTIFICATION

Product Identifier

Product Name: Sodium Chloride Injection USP 0.9%
Other Name: Sodium Chloride Injection 9mg/ml
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: Not classified as hazardous substance or mixture.

Label Elements

Signal Word: Not a hazardous substance or mixture
Hazard Statements: Not classified in accordance with international standards for workplace safety.

SECTION 3: COMPOSITION/ INFORMATION OF INGREDIENTS

Ingredients	CAS Number	Quantity	Acute toxicity, LD50, Oral Rat
Sodium Chloride	7647-14-5	9.0 mg/mL	3550 mg/kg
Sodium Hydroxide	1310-73-2	For pH adjustment	No data available
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.

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. For details information refer to the product packaging.

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 (water = 1)
pH:	4.5 – 7.0
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:	No data available
Incompatibility:	No data available
Hazardous Decomposition Products:	No data available

SECTION 11: TOXIOLOGICAL INFORMATION

Acute toxicity (Species, Root, Endpoint, Dose)

Sodium Chloride

Rat	Oral	LD50	3,550 mg/kg
Rabbit	Dermal	LD50	> 10,000 mg/kg
Rat	Inhalation	LC50 – 1hr	> 42,000 mg/m^3

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 data available

SECTION 12: ECOLOGICAL INFORMATION

Toxicity

Sodium Chloride
Toxicity to fish
LC50 – Lepomis macrochirus (Bluegill) - 5840 mg/l – 96 hr

Toxicity to daphnia and other aquatic invertebrates
LC50 – Daphnia magna (Water flea) - 1661 mg/l – 48 hr

Sodium Hydroxide
Toxicity to fish
LC50 - Gambusia affinis (Mosquito fish) - 125 mg/l - 96 h
LC50 - Oncorhynchus mykiss (rainbow trout) - 45.4 mg/l - 96 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.

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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