

SECTION 1: IDENTIFICATION

Product Identifier

Product Name: Baclofen Injection
Other Name: Baclofen (As 0.05 mg/mL, 0.5 mg/mL or 2 mg/mL Baclofen)
Chemical Names: Lioresal; 4-Amino-3-(4-chlorophenyl) butanoic acid; Baclofen; DL-Baclofen
Chemical Family: Mixture

Product Use: Pharmaceutical (intrathecal injection and infusion only)

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, Oral	Category 3
Sensitization, Skin	Category 1
Respiratory Sensitization	Category 1
Reproductive Toxicity	Category 1
Specific target organ toxicity - single exposure	Category 3, respiratory system

GHS Label Elements, Including Hazard and Precautionary Statements

Pictogram:



Signal Word: Danger

Hazard Statements: Toxic if swallowed.
 May cause an allergic skin reaction.

Causes serious eye irritation.
 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
 May cause respiratory irritation.
 May damage fertility or the unborn child.

Precautionary statements: Obtain special instructions before use.
 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
 Wear protective gloves.
If Swallowed: Immediately call a poison center or doctor/ physician.
If In Eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If exposed or concerned: Get medical advice/attention.

SECTION 3: COMPOSITION/ INFORMATION OF INGREDIENTS

Ingredients	CAS Number	Quantity	Acute toxicity, LD50 (Oral, Rat)
Baclofen	1134-47-0	0.05 or 0.5 or 2 mg/mL	No data available
Sodium Chloride	7647-14-5	8.8 mg/mL	3550 mg/kg
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. Get medical attention.

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. Do not heat sterilize. For details information refer to the product packaging.

Incompatible Materials: No data available

SECTION 8: EXPOSURE CONTROLS AND PERSONAL PROTECTION

Control parameters**Baclofen**

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:	1.01 g/mL
pH:	5.5 – 6.8
Boiling Point:	Mixture
Freezing Point:	Mixture
Solubility in Water:	Slightly 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:	No data available

SECTION 11: TOXIOLOGICAL INFORMATION

Acute toxicity (Species, Root, Endpoint, Dose)

Baclofen

Rat	Intravenous	LD50	78	mg/kg
Mice	Intravenous	LD50	45	mg/kg

Sodium Chloride

Rat	Oral	LD50	3550	mg/kg
Rabbit	Dermal	LD50	> 10000	mg/kg
Rat	Inhalation	LC50 – 1hr	> 42000	mg/m ³

Repeated dose toxicity

No effects evident in rats and dogs, Spinal cord inflammation observed in 1 out of 3 rabbits.

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 effects evident

Carcinogenicity

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

Reproductive toxicity

No effects evident at non-maternally toxic dose (2.1 times the maximum, oral mg/kg). Omphalocoeles in rats, delayed fetal growth in rats and rabbits are seen at maternally toxic dose (8.3 times the maximum, oral mg/kg).

Teratogenicity

No effect evident in mice, rats and rabbits at doses up to 125-times.

SECTION 12: ECOLOGICAL INFORMATION

Toxicity

Baclofen

No data available

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

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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