



## SAFETY DATA SHEET

### BACLOFEN Injection Single-dose vials of 40,000 mcg per 20 mL (2,000 mcg/mL)

#### 1. Identification

**Product Identifier:** Baclofen

**Synonyms:** Baclon, Gablofen, Lioresal, Benzenepropanoic acid, beta-(aminomethyl)-4-chloro-(9CI) Hydrocinnamic acid, beta-(aminomethyl)-p-chlorobeta-(4-Chlorophenyl) gaba beta-(Aminomethyl)-4-chlorobenzenepropanoic acid, beta-(Aminomethyl)-p-chlorohydrocinnamic acid, beta-(p-Chlorophenyl)-gamma-aminobutyric acid, gamma-Amino-beta-(p-chlorophenyl)butyric acid

**National Drug Code (NDC):**

2000 ug/mL	USP 14789-0161-05
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**Recommended Use:** Pharmaceutical

**Company:** Nexus Pharmaceuticals, LLC.  
400 Knightsbridge Pkwy  
Lincolnshire IL, 60069  
USA

**Contact Phone:** (847) 996-3790

**Website:** [www.nexuspharma.net](http://www.nexuspharma.net)

**Emergency Contact:** Chemtrec (24 hours): 1-800-424-9300  
Email: [CHEMTREC@chemtrec.com](mailto:CHEMTREC@chemtrec.com)

## **2. Hazard(s) Identification**

**Physical Hazards:** Not classifiable.

**Health Hazards:** Not classified.

**Classification of the  
Substance or Mixture:**

The hazard warnings associated with this product are based on the individual ingredients included in the finished dosage form of the pharmaceutical product.

This product is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

**Symbol(s):** **None.**

**Signal Word:** None.

**Hazard Statement(s):** This mixture does not meet the classification criteria.

**Precautionary Statement(s):** Observe good industrial hygiene practices. Wash hands after handling.

**Hazards Not Otherwise Classified:** None known.

**Supplementary Information:** The hazard warnings associated with this product are based on individual ingredients included in the finished dosage form of the pharmaceutical product. The supplied package insert (approved labelling) provides the necessary drug safety information. As per 29 CFR 1910.1200(b)(5)(iii), any food, food additive, color additive, drug, cosmetic, or medical or veterinary device or product, including materials intended for use as ingredients in such products (e.g. flavours and fragrances), as such terms are defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and regulations issued under that Act, when they are subject to the labelling requirements under that Act by the Food and Drug Administration are exempted from the requirements of the Hazard Communication Standard. All finished products are labelled in compliance with the requirements of the Food and Drug Administration (FDA) and must be used in the prescribed manner. Each package of the finished pharmaceutical product is supplied with a package insert (approved labelling) which provides necessary drug safety information.

### 3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Baclofen	1134-47-0	Benzenepropanoic acid	$C_{10}H_{12}ClNO_2$	213.7	< 0%
Sodium Chloride (in solution)	7647-14-5	Salt	NaCl	58.44	> 99%

**Inactive Ingredients:** Water for Injection.

### 4. First Aid Measures

<b>Ingestion:</b>	IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. Never give anything by mouth to a victim who is unconscious or is having convulsions. Do not induce vomiting without advice from poison control center. Rinse mouth. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.
<b>Eye Contact:</b>	Rinse with water. Get medical attention if irritation develops and persists.
<b>Skin Contact:</b>	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
<b>Inhalation:</b>	Move to fresh air. Call a physician if symptoms develop or persist.
<b>Protection of First-Aiders:</b>	Use personal protective equipment as needed (see section 8).
<b>Signs and Symptoms:</b>	Headache. Drowsiness. Muscle weakness. Direct contact with eyes may cause temporary irritation. May cause respiratory irritation. May cause skin irritation.
<b>Medical Conditions Aggravated by Exposure:</b>	Hypersensitivity to any of the components of the product.
<b>Notes to Physician:</b>	Treat supportively and symptomatically.

## **5. Firefighting Measures**

**Suitable Extinguishing Media:** Use extinguishing media (water spray (fog), foam, dry powder, or carbon dioxide as appropriate) for type of surrounding fire.

**Unsuitable Extinguishing Media:** Not determined.

### **Specific Hazards Arising from the Chemical:**

**Hazardous Combustion Products:** These products include carbon oxides, and other hazardous products of combustion.

**Other Specific Hazards:** Closed containers may explode from the heat of fire.

### **Special Protective Equipment**

**Precautions for FireFighters** Wear self-contained breathing apparatus and full protective gear.

## **6. Accidental Release Measures**

**Personal Precautions:** No special precautions are necessary beyond normal good hygiene practices. See Section 8 of the SDS for additional personal protection advice when handling this product.

**Personal Protective Equipment:** For personal protection see section 8.

**Methods for Cleaning Up:** Stop the flow of material if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading, Absorb in vermiculite, dry sand, carth, or similar material and place in container for proper disposal. Flush area with water.  
Small Spills: Wipe up with absorbent material (e.g. cloth, fleece).

Clean surface thoroughly to remove residual contamination. Never return spills to original containers for reuse.

**Environmental Precautions:** Contain material and prevent release to basements, confined spaces, waterways or soil.

**Reference to Other Sections:** Refer to Sections 8, 12 and 13 for further information.

## **7. Handling and Storage**

**Precautions for Safe Handling:** Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices. Wash thoroughly after handling; do not eat, drink, or smoke.

**Conditions for Safe Storage:** Keep container tightly closed. Keep container dry. Keep away from heat. Keep at temperature not exceeding 30°C/ 86°F. Keep from freezing. Do not heat sterilize. Keep out of reach of children. Use care in handling/storage.

**Specific End Use:** Pharmaceuticals

## **8. Exposure Controls/Personal Protection**

**Occupational Exposure Guidelines:** Not established.

**Engineering Controls:** Not required during the normal use of this product.

**Respiratory Protection:** Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

**Eyes:** Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

**Hand:** Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

**Skin:** Protective laboratory coat, apron, or disposable garment.

## **9. Physical and Chemical Properties**

<b>Physical State/Color:</b>	Clear, colorless liquid.
<b>Odor:</b>	No data available.
<b>Odor Threshold:</b>	No data available.
<b>pH:</b>	5.0 to 7.0.
<b>Melting Point:</b>	No data available.
<b>Freezing Point:</b>	0 degrees Celcius.
<b>Boiling Point:</b>	100 degrees Celsius.
<b>Flash Point:</b>	No data available.
<b>Evaporation Rate:</b>	No data available.
<b>Flammability (solid, gas):</b>	No data available.
<b>Flammability Limit - Lower:</b>	No data available.
<b>Flammability Limit - Upper:</b>	No data available.
<b>Vapor Pressure:</b>	No data available.
<b>Vapor Density:</b>	No data available.
<b>Relative Density:</b>	No data available.
<b>Solubility(ies):</b>	Miscible in water.
<b>Partition Coefficient (n-octanol/water):</b>	No data available.
<b>Auto-Ignition Temperature:</b>	No data available.
<b>Decomposition Temperature:</b>	No data available.
<b>Viscosity:</b>	No data available.

## **10. Stability and Reactivity**

<b>Reactivity:</b>	The product is stable and non-reactive under normal conditions of use, storage, and transport.
<b>Chemical Stability:</b>	Stable under recommended storage conditions.
<b>Possibility of Hazardous Reactions:</b>	No data available.
<b>Conditions to Avoid (e.g., static discharge, shock, or vibration):</b>	No data available.
<b>Incompatible Materials:</b>	Strong oxidizing materials.
<b>Hazardous Decomposition Products:</b>	No data available.

## **11. Toxicological Information**

### **Information on the Likely Routes of Exposure:**

<b>Inhalation:</b>	May cause respiratory tract irritation.
<b>Ingestion:</b>	May be harmful if swallowed. May produce cardiac damage. May cause central Nervous system effects. Headache. Drowsiness. Muscle Weakness.
<b>Skin Contact:</b>	May cause skin irritation.
<b>Eye Contact:</b>	May cause eye irritation.

### **Symptoms Related to the Physical,**

### **Chemical and Toxicological Characteristics:**

See Section 4. May cause headache, drowsiness, muscle weakness. Direct contact with eyes may cause temporary irritation. May cause respiratory irritation. May cause skin irritation.

### **Delayed and Immediate Effects of Exposure:**

May cause headache, drowsiness, muscle weakness. Direct contact with eyes may cause temporary irritation. May cause respiratory irritation. May cause skin irritation.

### **Acute Toxicity – Oral:**

IC50, Algae: > 100 mg/L (Baclofen)

### **Acute Toxicity – Dermal:**

EC50, Daphnia magna: > 100 mg/L, 48 Hours (Baclofen)

<b>Acute Toxicity – Inhalation:</b>	No data available.
<b>Corrosivity:</b>	No data available.
<b>Dermal Irritation:</b>	No data available.
<b>Eye Irritation:</b>	No data available.
<b>Sensitization:</b>	No data available.
<b>Toxicokinetics/Metabolism:</b>	No data available.
<b>Target Organ Effects:</b>	Possible target organs include the brain, and central nervous system.
<b>Reproductive Effects:</b>	Not hazardous at low percentage, concentrated Baclofen may damage fertility of unborn child..
<b>Carcinogenicity:</b>	
National Toxicology Program (NTP):	Not considered to be a carcinogen.
International Agency for Research on Cancer (IARC):	Not considered to be a carcinogen.
Occupational Safety and Health Administration (OSHA):	Not considered to be a carcinogen.
<b>Mutagenicity:</b>	No data available.
<b>Aspiration Hazard:</b>	No data available.

## **12. Ecological Information**

### **Ecotoxicity**

Aquatic:	No data available.
Terrestrial:	No data available.
Persistence and Degradability:	No data available.
Bioaccumulative Potential:	No data available.
Mobility in Soil:	No data available.
Other Adverse Effects:	An environmental hazard cannot be excluded in the event of improper/unprofessional handling or disposal.

## **13. Disposal Consideration**

This product in its present state when discarded or disposed of is not a hazardous waste according to Federal Regulations (40 CFR 261.4(b)(4)). Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste. Dispose in accordance with all applicable regulations.

## **14. Transport Information**

UN Number:	Not applicable.
UN Proper Shipping Name:	Not applicable.
Transport Hazard Class(es):	Not applicable.
Packing Group:	Not applicable.
DOT:	Not regulated as a hazardous material.
International Air Transport Association (IATA):	Not regulated as a dangerous good.
International Maritime Dangerous Good (IMDG):	Not regulated as a dangerous good.

## **15. Regulatory Information**

### **International Regulations:**

**Ozone depleting substance:** Not applicable

**Persistent Organic Pollutant:** Not applicable

**The Rotterdam Convention** Not applicable

### **US Federal Regulations:**

**TSCA Inventory** This product is a drug regulated by the Food and Drug Administration (FDA), and is not regulated by TSCA.

**CERCLA Hazardous Substance and Reportable Quantity:** Not listed.

**SARA 313:** Not listed.

**SARA 302:** Not listed.

**DEA:** Not listed.

### **State Regulations**

**Massachusetts:** Not listed.

**New Jersey:** Not listed.

**Pennsylvania:** Not listed.

**California Proposition 65:** Not listed.

## **16. Other Information**

### **NFPA Rating: (Baclofen injection)**

Health: 0

Flammability: 0

Reactivity: 0

### **HMIS Classification: (Baclofen injection)**

Health: 0

Flammability: 0

Physical Hazard: 0

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