

SAFETY DATA SHEET



GABLOFEN[®]

1) PRODUCT AND COMPANY IDENTIFICATION

Product name:	GABLOFEN[®]
Synonyms:	Baclofen Injection
CAS Number:	Mixture
Chemical Family:	Gamma-aminobutyric acid (GABA) ergic agonist
Recommended Use:	Muscle Relaxer / Antispastic Agent – (Prescription Drug to be Administered by Medical Professionals)
Manufacturer:	Piramal Critical Care, Inc 261 Brodhead Road Bethlehem, PA 18017
Important Phone Numbers:	Customer Service: 610-974-9760 24 Hour Emergency: 484-895-5734
24 Hour Emergency Number:	CHEMTREC 1-800-424-9300 (For Transportation in US and Canada)

2) HAZARDS IDENTIFICATION

Physical Hazard:	Not classified
Health Hazard:	Not classified
Environmental Hazards:	Not Classified
OSHA Defined Hazards:	Not Classified
Labeling Contains:	BACLOFEN, Saline Solution
Label Elements:	None
Hazard Symbol:	None
Signal Word:	None
Hazard Statements:	The mixture does not meet the criteria for classification
Precautionary Statements:	

Prevention:	Observe good industrial hygiene practices
Response:	Wash hands after handling
Storage:	Store away from incompatible materials
Dispose:	Dispose of waste and residues in accordance with local authority requirements. (None known)

Hazard(s) Not**Otherwise Classified (HNOC):** None Known

Supplemental Information: The hazard warnings associated with this product are based on the individual ingredients included in the finished dosage form of the pharmaceutical product. The supplied package insert (approved labeling) 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. flavors 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 labeling requirements under that Act by the Food and Drug Administration are exempted from the requirements of the Hazard Communication Standard.

All Piramal finished products are labeled 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 labeling) which provides necessary drug safety information.

3) COMPOSITION/INFORMATION ON INGREDIENTS

<u>Chemical Name</u>	<u>CAS Number</u>	<u>%</u>
Saline Solution	7732-18-5	>99
BACLOFEN	1134-47-0	<0.1

4) FIRST AID MEASURES

Inhalation:	Move to fresh air. Call a physician if symptoms develop or persist.
Skin Contact:	Rinse skin with water/shower. Get medical attention if irritation develops and persists
Eye Contact:	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion:	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.

Symptoms/Effects:	Headache. Drowsiness. Muscle weakness. Direct contact with eyes may cause temporary irritation. May cause respiratory irritation. May cause skin irritation.
General Information:	If you feel unwell, seek medical advice (show label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves
Note to Physician:	Treat symptomatically

5) FIRE FIGHTING MEASURES

Flammable Properties:	This product is not flammable
Specific Methods:	In the event of a fire, cool tanks with water spray. Move containers from fire area if you can do so without risk. Cool containers exposed to flames with water until well after the fire is out. Use standard fire fighting procedures and consider the hazards of other involved materials.
Flammable Limits in air-lower (%):	N/A
Flammable Limits in air-upper (%):	N/A
Auto ignition:	N/A
Extinguishing Media:	Use media suitable for the surrounding fire(s).
Fire Fighting Instructions:	As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH approved or equivalent, and full protective gear.
Fire and Explosion Hazard:	No unusual fire or explosion hazards noted
Specific Hazards Arising from the Chemical:	During fire, gases hazardous to health may be formed

6) ACCIDENTAL RELEASE MEASURES

In Case of Spill or Leak:	Large Spills: 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, earth, 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.
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.

Environmental Precautions: Avoid release to the environment

7) HANDLING AND STORAGE

Handling: Do not handle until all safety precautions have been read and understood. Avoid any exposure. Do not ingest. Wash thoroughly after handling. When using do not eat, drink, or smoke. Avoid release to the environment. Handle and open container with care.

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.

8) EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls: Ensure adequate ventilation, especially in confined areas.

Eye Protection: Wear safety glasses with side shields or goggles.

Skin Protection: Wear protective gloves. Wear suitable protective clothing

Respiratory Protection: No protection is ordinarily required under normal conditions of use and with adequate ventilation. In case of insufficient ventilation wear suitable respiratory equipment.

Thermal Hazards: Wear appropriate thermal protective clothing when necessary

Occupational Exposure Limits: No exposure limits noted for ingredient(s)

9) PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Clear

Physical State: Liquid

Color: Colorless

Odor: Odorless

Odor Threshold: Not available

pH: 5-7

Boiling Point: 100° C (212° F)

Melting/Freezing Point: 32° F (0° C)

Vapor Pressure: Not available

Vapor Density: Not available

Relative Density: Not available

Evaporation Rate: N/A

Water Solubility: Not available

Specific Gravity: Not available

Flash Point: N/A

Explosive Limits: N/A

Ignition Temperature: N/A

Flammability (solid/gas): Not available

Partition coefficient: Not available

Viscosity: Not available

10) STABILITY AND REACTIVITY

Stability:	Material is stable under normal conditions
Incompatibility:	Strong oxidizing agents
Polymerization:	Not available
Hazardous Decomposition Products:	No hazardous decomposition products are known
Conditions to Avoid:	Heat. Freezing.
Reactivity:	This product is stable and non-reactive under normal conditions of use, storage, and transport.

11) TOXICOLOGICAL INFORMATION**Information on likely routes of exposure**

Ingestion:	May be harmful if swallowed. May produce cardiac damage. May cause central Nervous system effects. Headache. Drowsiness. Muscle Weakness. Due to the small packaging the risk of ingestion is minimal.
Inhalation:	May cause respiratory irritation
Skin Contact:	Contact with skin may cause irritation. Due to small packaging the risk of skin contact is minimal.
Eye Contact:	Direct contact with eyes may cause temporary irritation.

BACLOFEN (CAS# 1134-47-0)

LD₅₀	145 mg/kg oral-rat
LC₅₀	Not available
LD₅₀	103 mg/kg oral mouse
LC₅₀	Not available
Acute Toxicity:	Not hazardous at low percentage of Baclofen which is toxic if swallowed.
Respiratory effects:	Not hazardous at low percentages of Baclofen which is associated with allergic respiratory reactions and/or respiratory irritation.
Skin Effects:	Not hazardous at low percentages of Baclofen which is associated with allergic skin reactions and / or skin irritancy.
Eye Effects:	Not hazardous at low percentages of Baclofen which is associated with eye irritancy
Gastrointestinal effects:	May be harmful if swallowed
Nervous System effects:	May cause central nervous system effects
Chronic Toxicity:	May cause cardiac disturbances including failure. Can cause cardiovascular effects.
Carcinogenic Effects:	This product is not considered carcinogenic by OSHA, IARC, NTP, and ACGIH.

Mutagenic Effects:	No data available to indicate product or any components present at greater than 0.1% are Mutagenic or Genotoxic.
Reproductive Toxicity:	Not hazardous at low percentage of Baclofen which may damage fertility of unborn child.
FDA Pregnancy Category - Intrathecal:	C
Specific Target Organ Toxicity:	Due to lack of data classification not possible
Aspiration Hazard:	Due to lack of data classification not possible
Symptoms related to the Physical, Chemical, and Toxicological Characteristics:	May cause headache, drowsiness, muscle weakness. Direct contact with eyes may cause temporary irritation. May cause respiratory irritation. May cause skin irritation.

12) ECOLOGICAL INFORMATION

Ecotoxicity Effects:	This product has no known eco-toxicological effects
Bioaccumulation:	No data available
Degradability:	No data available on the degradability of this product
Mobility in Soil:	No data available
Other Adverse Effects:	An environmental hazard cannot be excluded in the event of improper/unprofessional handling or disposal.

BACLOFEN (CAS# 1134-47-0)

Acute:

IC50	>100 mg/l, 72-hours (Algae)
EC50	>100 mg/l, 48-hours (Daphnia magna)

13) DISPOSAL CONSIDERATIONS

Disposal Instructions:	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.
Hazardous Waste Code:	The assigned waste codes, if applicable are the responsibility of the end user.
Contaminated Packaging:	Empty containers should be taken to an approved waste handling site for recycling or disposal.

14) TRANSPORT INFORMATION

DOT: Not regulated as dangerous goods

IATA: Not regulated as dangerous goods

IMDG: Not regulated as dangerous goods

Bulk Transportation: This substance/mixture is not intended to be transported in bulk

15) REGULATORY INFORMATION

US Federal Regulations: This material is not subject to the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200 (b)(5)(iii)

TSCA Section 12(b) Export Notification (40 CFR 707, Subpart D) – Not Regulated

CERCLA Hazardous Substance List (40 CFR 302.4) – Not Listed

CERCLA (Superfund) Reportable Quantity - None

SARA 304 Emergency Release Notification – Not Regulated

SARA 302 Extremely Hazardous Substance – Not Listed

SARA 311/312 Hazardous Chemical – No

OSHA Specifically Regulated Substances (29 CFR 1010.1001-1050) – Not Listed

Superfund Amendments and Reauthorization of 1986 (SARA)

Hazard Categories: Immediate Hazard – No
Delayed Hazard – No
Fire Hazard – No
Pressure Hazard – No
Reactivity Hazard – No

Other Federal Regulations:

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List – Not Regulated

Clean Air Act (CAA) Section 112 (r) Accidental Release Prevention (40 CFR 68.130) – Not Regulated

Safe Drinking Water Act (SDWA) – Not Regulated

Federal Food and Drug Administration (FDA) - Regulated

US State Regulations:

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65) – This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

US Massachusetts RTK – Substance List – Not regulated

US New Jersey Worker and Community Right-to-Know Act – Not Listed

US Pennsylvania Worker and Community Right-to-Know Law – Not Listed

US Rhode Island RTK – Not regulated

US California Proposition 65 – Not listed

International Inventories:

Country/Region	Inventory Name	On Inventory*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Unites States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16) OTHER INFORMATION

Piramal provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. This document is intended only as a guide to the appropriate precautionary handling of the material by a properly trained person using this product. Individuals receiving the information must exercise their independent judgment in determining its appropriateness for a particular purpose. PIRAMAL MAKES NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE INFORMATION SET FORTH HEREIN OR THE PRODUCT TO WHICH THE INFORMATION REFERS. ACCORDINGLY, PIRAMAL WILL NOT BE RESPONSIBLE FOR DAMAGES RESULTING FROM USE OF OR RELIANCE UPON THIS INFORMATION.