

**1. Identification**

<b>Product identifier</b>	<b>GABLOFEN® (Baclofen Injection)</b>		
<b>CAS #</b>	Mixture		
<b>Other means of identification</b>			
<b>SDS number</b>	GABLF		
<b>Synonyms</b>	GABLOFEN® (Baclofen Injection)		
<b>Recommended use</b>	Not available.		
<b>Recommended restrictions</b>	None known.		
<b>Manufacturer/Importer/Supplier/Distributor information</b>			
<b>Manufacturer</b>			
<b>Company name</b>	Mallinckrodt		
<b>Address</b>	675 McDonnell Blvd. Hazelwood, MO 63042		
<b>Telephone</b>	Not available.		
<b>E-mail</b>	Not available.		
<b>Emergency phone number</b>	Customer Service	888-744-1414	
	24 Hour Emergency	314-654-1600	
	Chemtec	800-424-9300	
<b>Item code</b>	45945-151-01, 45945-155-01, 45945-155-02, 45945-156-01, 45945-156-02, 45945-157-01, 45945-157-02		

**2. Hazard(s) identification**

<b>Physical hazards</b>	Not classified.
<b>Health hazards</b>	Not classified.
<b>Environmental hazards</b>	Not classified.
<b>OSHA defined hazards</b>	Not classified.

\*Hazards not stated here are "Not classified", "Not applicable" or "Classification not possible".

**Labeling**

**Contains** BACLOFEN, Saline Solution

**Label elements**

**Hazard symbol** None.

**Signal word** None.

**Hazard statement** The mixture does not meet the criteria for classification.

**Precautionary statement**

**Prevention** Observe good industrial hygiene practices.

**Response** Wash hands after handling.

**Storage** Store away from incompatible materials.

**Disposal** Dispose of waste and residues in accordance with local authority requirements.

**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 Mallinckrodt 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

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### Mixtures

Chemical name	Common name and synonyms	CAS number	%
Saline Solution		7732-18-5	> 99
BACLOFEN		1134-47-0	< 0.1

**Composition comments** All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

## 4. First-aid measures

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<b>Inhalation</b>	Move to fresh air. Call a physician if symptoms develop or persist.
<b>Skin contact</b>	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	Rinse with water. Get medical attention if irritation develops and persists.
<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>Most important symptoms/effects, acute and delayed</b>	Headache. Drowsiness. Muscle weakness. Direct contact with eyes may cause temporary irritation. May cause respiratory irritation. May cause skin irritation.
<b>Indication of immediate medical attention and special treatment needed</b>	Treat symptomatically.
<b>General information</b>	If you feel unwell, seek medical advice (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

## 5. Fire-fighting measures

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<b>Flammable properties</b>	The product is not flammable.
<b>Suitable extinguishing media</b>	Use any media suitable for the surrounding fires.
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for firefighters</b>	As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.
<b>Fire-fighting equipment/instructions</b>	In the event of fire, cool tanks with water spray. Move containers from fire area if you can do so without risk.
<b>Specific methods</b>	Cool containers exposed to flames with water until well after the fire is out. Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

## 6. Accidental release measures

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<b>Personal precautions, protective equipment and emergency procedures</b>	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. Avoid contact with spilled material.
<b>Methods and materials for containment and cleaning up</b>	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 or earth and place into containers. Following product recovery, 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 in original containers for re-use. For waste disposal, see section 13 of the SDS.
<b>Environmental precautions</b>	Avoid release to the environment.

## 7. Handling and storage

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<b>Precautions for safe handling</b>	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.
<b>Conditions for safe storage, including any incompatibilities</b>	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 the reach of children. Use care in handling/storage.

## 8. Exposure controls/personal protection

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<b>Occupational exposure limits</b>	No exposure limits noted for ingredient(s).
<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
<b>Appropriate engineering controls</b>	Ensure adequate ventilation, especially in confined areas.
<b>Individual protection measures, such as personal protective equipment</b>	
<b>Eye/face protection</b>	Wear safety glasses with side shields (or goggles).
<b>Skin protection</b>	
<b>Hand protection</b>	Wear protective gloves.
<b>Other</b>	Wear suitable protective clothing.
<b>Respiratory protection</b>	No protection is ordinarily required under normal conditions of use and with adequate ventilation. In case of insufficient ventilation, wear suitable respiratory equipment.
<b>Thermal hazards</b>	Wear appropriate thermal protective clothing, when necessary.
<b>General hygiene considerations</b>	Handle in accordance with good industrial hygiene and safety practice.

## 9. Physical and chemical properties

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<b>Appearance</b>	Clear.
<b>Physical state</b>	Liquid.
<b>Form</b>	Liquid.
<b>Color</b>	Colorless.
<b>Odor</b>	Odorless.
<b>Odor threshold</b>	Not available.
<b>pH</b>	5 - 7
<b>Melting point/freezing point</b>	32 °F (0 °C)
<b>Initial boiling point and boiling range</b>	212 °F (100 °C)
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.

**Upper/lower flammability or explosive limits**

<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.

**Vapor pressure** Not available.

**Vapor density** Not available.

**Relative density** Not available.

**Solubility(ies)**

**Solubility (water)** Not available.

**Partition coefficient (n-octanol/water)** Not available.

**Auto-ignition temperature** Not available.

**Decomposition temperature** Not available.

**Viscosity** Not available.

**Other information**

**Specific gravity** 1

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**10. Stability and reactivity**

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**Reactivity** The product is stable and non-reactive under normal conditions of use, storage and transport.

**Chemical stability** Material is stable under normal conditions.

**Possibility of hazardous reactions** Hazardous polymerization does not occur.

**Conditions to avoid** Heat. Freezing.

**Incompatible materials** Strong oxidizing agents.

**Hazardous decomposition products** No hazardous decomposition products are known.

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**11. Toxicological information**

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**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 the small packaging the risk of skin contact is minimal.

**Eye contact** Direct contact with eyes may cause temporary irritation.

**Symptoms related to the physical, chemical and toxicological characteristics** Headache. Drowsiness. Muscle weakness. Direct contact with eyes may cause temporary irritation. May cause respiratory irritation. May cause skin irritation.

**Information on toxicological effects**

**Acute toxicity** Not hazardous at low percentage of Baclofen which is toxic if swallowed.

**Chronic effects** May cause cardiac disturbances including failure. Can cause cardiovascular effects.

Components	Species	Test Results
BACLOFEN (CAS 1134-47-0)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Mouse	103 mg/kg
	Rat	145 mg/kg
<b>Skin corrosion/irritation</b>	Not hazardous at low percentage of Baclofen which is associated with skin irritancy.	
<b>Serious eye damage/eye irritation</b>	Not hazardous at low percentage of Baclofen which is associated with eye irritancy.	
<b>Respiratory or skin sensitization</b>		
<b>Respiratory sensitization</b>	Not hazardous at low percentage of Baclofen which is associated with allergic respiratory reactions.	
<b>Skin sensitization</b>	Not hazardous at low percentage of Baclofen which is associated with allergic skin reactions.	
<b>Germ cell mutagenicity</b>	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
<b>Carcinogenicity</b>	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.	
<b>Reproductive toxicity</b>	Not hazardous at low percentage of Baclofen which may damage fertility or the unborn child.	
<b>Specific target organ toxicity - single exposure</b>	Not hazardous at low percentage of Baclofen which is associated with respiratory irritation.	
<b>Specific target organ toxicity - repeated exposure</b>	Due to lack of data the classification is not possible.	
<b>Aspiration hazard</b>	Due to lack of data the classification is not possible.	

## 12. Ecological information

<b>Ecotoxicity</b>	This product has no known eco-toxicological effects.		
<b>Components</b>			
<b>Species</b>			
<b>Test Results</b>			
BACLOFEN (CAS 1134-47-0)			
<i>Acute</i>			
Algae	IC50	Algae	> 100 mg/l, 72 hours
Crustacea	EC50	Daphnia magna	> 100 mg/l, 48 hours
<b>Persistence and degradability</b>	No data is available on the degradability of this product.		
<b>Bioaccumulative potential</b>	No data available.		
<b>Mobility in soil</b>	No data available.		
<b>Other adverse effects</b>	An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.		

## 13. Disposal considerations

<b>Disposal instructions</b>	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.
<b>Hazardous waste code</b>	Waste codes should be assigned by the user based on the application for which the product was used. The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Waste from residues / unused products</b>	Dispose of in accordance with local regulations.
<b>Contaminated packaging</b>	Empty containers should be taken to an approved waste handling site for recycling or disposal.

## 14. Transport information

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### DOT

Not regulated as dangerous goods.

### IATA

Not regulated as dangerous goods.

### IMDG

Not regulated as dangerous goods.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** This substance/mixture is not intended to be transported in bulk.

## 15. Regulatory information

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**US federal regulations** This material is not subject to the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200 (b)(5)(iii).  
CERCLA/SARA Hazardous Substances - Not applicable.  
TSCA exempt status.

### TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

### CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

### SARA 304 Emergency release notification

Not regulated.

### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

### CERCLA (Superfund) reportable quantity

None

### Superfund Amendments and Reauthorization Act of 1986 (SARA)

**Hazard categories** Immediate Hazard - No  
Delayed Hazard - No  
Fire Hazard - No  
Pressure Hazard - No  
Reactivity Hazard - No

### SARA 302 Extremely hazardous substance

Not listed.

**SARA 311/312 Hazardous chemical** 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.

**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**

<b>Country(s) or region</b>	<b>Inventory name</b>	<b>On inventory (yes/no)*</b>
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
United 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, including date of preparation or last revision**

**Issue date** 03-19-2015

**Revision date** 05-04-2015

**Version #** 02

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**Revision Information** Product and Company Identification: Product Codes  
Toxicological Information: Toxicological Data