

1. Product and Company Identification

Material name	GABLOFEN® (Baclofen Injection)
Version #	01
Issue date	02-20-2014
CAS #	Mixture
Synonym(s)	GABLOFEN® (Baclofen Injection)
Manufacturer information	Mallinckrodt 675 McDonnell Blvd. Hazelwood, MO 63042 24 Hour Emergency 314-654-1600 Chemtrec 800-424-9300 Customer Service 888-744-1414
Item code	45945-151-01, 45945-155-01, 45945-155-02, 45945-156-01, 45945-156-02, 45945-157-01, 45945-157-02, 22-462 SN0004

2. Hazards Identification

Emergency overview	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.
OSHA regulatory status	May be harmful if swallowed. May cause central nervous system effects. 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.
Potential health effects	
Routes of exposure	Ingestion. Skin contact.
Eyes	Not relevant, due to the form of the product.
Skin	Contact with skin may cause irritation. Due to the small packaging the risk of skin contact is minimal.
Inhalation	Not relevant, due to the form of the product.
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.
Potential environmental effects	Ecological injuries are not known or expected under normal use.

3. Composition / Information on Ingredients

Hazardous components	CAS #	Percent
BACLOFEN	1134-47-0	< 0.1
Non-hazardous components	CAS #	Percent
Saline Solution	7732-18-5	> 99

4. First Aid Measures

First aid procedures

Eye contact	Not relevant, due to the form of the product.
Skin contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Inhalation	Not relevant, due to the form of the product.
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.

General advice If you feel unwell, seek medical advice (show the label where possible).

5. Fire Fighting Measures

Flammable properties	Not flammable by OSHA criteria.
Extinguishing media	
Suitable extinguishing media	Use any media suitable for the surrounding fires.
Fire fighting equipment/instructions	As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) 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 MSDS for additional personal protection advice when handling this product. Avoid contact with spilled material.
Environmental precautions	Avoid release to the environment.
Methods for cleaning up	Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the MSDS.

7. Handling and Storage

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

8. Exposure Controls / Personal Protection

Engineering controls	Not relevant, due to the form of the product.
Personal protective equipment	
Eye / face protection	Not relevant, due to the form of the product.
Skin protection	Wear protective gloves.
Respiratory protection	Not relevant, due to the form of the product.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. Physical & Chemical Properties

Appearance	Clear.
Physical state	Liquid.
Form	Liquid.
Color	Colorless.
Odor	Odorless.
Odor threshold	Not available.
pH	5 - 7

Vapor density	Not available.
Boiling point	212 °F (100 °C)
Melting point/Freezing point	32 °F (0 °C)
Solubility (water)	Not available.
Specific gravity	1
Relative density	Not available.
Flash point	Not available.
Flammability limits in air, upper, % by volume	Not available.
Flammability limits in air, lower, % by volume	Not available.
Auto-ignition temperature	Not available.
Concentration	Not available.
Specific activity	Not available.

10. Chemical Stability & Reactivity Information

Chemical stability	Material is stable under normal conditions.
Conditions to avoid	Heat. Freezing.
Incompatible materials	None known.
Hazardous decomposition products	No hazardous decomposition products are known.
Possibility of hazardous reactions	Hazardous polymerization does not occur.

11. Toxicological Information

Toxicological data		
Components	Species	Test Results
BACLOFEN (CAS 1134-47-0)		
<i>Acute</i>		
<i>Oral</i>		
LD50	Mouse	103 mg/kg
	Rat	145 mg/kg

* Estimates for product may be based on additional component data not shown.

Acute effects	May be harmful if swallowed.
Local effects	May cause central nervous system effects.
Chronic effects	May cause cardiac disturbances including failure. Can cause cardiovascular effects.
Carcinogenicity	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

12. Ecological Information

Ecotoxicological data			
Components		Species	Test Results
BACLOFEN (CAS 1134-47-0)			
Acute			
Algae	IC50	Algae	> 100 mg/l, 72 hours
Crustacea	EC50	Daphnia magna	> 100 mg/l, 48 hours

* Estimates for product may be based on additional component data not shown.

Ecotoxicity	This product has no known eco-toxicological effects.
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Environmental effects	An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.
Persistence and degradability	No data is available on the degradability of this product.

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.
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14. Transport Information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

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). CERCLA/SARA Hazardous Substances - Not applicable. TSCA exempt status.
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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
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SARA 302 Extremely hazardous substance No

SARA 311/312 Hazardous chemical No

Inventory status

Country(s) or region	Inventory name	On inventory (yes/no)*
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)

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.
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16. Labeling Info

Label Hazard Warning	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.
Label Precautions	-
Label First Aid	-

17. Other Information

NFPA ratings	Health: 0 Flammability: 0 Instability: 0
Disclaimer	Mallinckrodt 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. MALLINCKRODT 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, MALLINCKRODT WILL NOT BE RESPONSIBLE FOR DAMAGES RESULTING FROM USE OF OR RELIANCE UPON THIS INFORMATION.