SAFETY DATA SHEET

PRODUCT: BACLOFEN TABLETS, USP

1. IDENTIFICATION

Common/Trade Name (as labeled): Baclofen Tablets, USP

Chemical Name (for active ingredient): 4-amino-3-(4-chlorophenyl)-butanoic acid.

Molecular formula (for active ingredient): $C_{10}H_{12}ClNO_2$

Molecular Weight (of active ingredient): 213.66 g/mol

Product Group (for active ingredient): N/A

Intended Use: Pharmaceutical product used for muscle relaxant and antispastic.

Drug Application Holder: Innogenix, LLC.
8200 New Horizons Blvd
Amityville, NY 11701

Emergency Phone: 1-844-466-6469

2. HAZARD(S) IDENTIFICATION

Primary Routes of Administration: Oral (Ingestion)

For side effects, which could also have impact for people working with this substance, please refer to the Patient Information Leaflet.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient	CAS #	Concentration % w/w
Baclofen USP (Milled)	1134-47-0	Proprietary
Lactose Monohydrate, NF (SuperTab 14SD)	10039-26-6	Proprietary
Microcrystalline Cellulose, NF (Avicel PH 102)	9004-34-6	Proprietary
Croscarmellose Sodium,NF (Vivasol)	74811-65-7	Proprietary
Zinc Stearate,USP	557-05-1	Proprietary

4. FIRST-AID MEASURES

DESCRIPTION OF FIRST AID MEASURES:

Inhalation: Remove the victim from danger zone, avoid further exposure.

Skin Contact: Remove contaminated clothing. Rinse contaminated skin immediately with plenty of water and soap and seek medical advice.

Eye Contact: Immediately rinse eyes thoroughly with running water as long as possible (approx. 15 min). Take injured quickly to medical center or call an ambulance.

Ingestion: If swallowed, seek medical advice immediately and show.

Notes to Physician: General measures to eliminate the substance and to reduce absorption.

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media: Water spray or fog, foam, dry chemical powder, CO2, dry sand

Unsuitable Extinguishing Media: No restrictions

Dangerous Combustion Products: hydrogen chloride, nitrogen oxides

Protective equipment for firefighters: Wear self-contained breathing apparatus and fire protective suite.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Avoid contact with skin, eyes and clothing.

Environmental precautions: Must not be released into sewers, drains or wells.

Methods for cleaning: Transfer large quantities into a container. Clean up the rest with absorbent material and discharge properly.

7. HANDLING AND STORAGE

No special handling requirements for normal use of this material. Store in a dry and cool place and observe special instructions from supplier.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Occupational Exposure Limit (OEL): no data available

Personnel Protection for open Handling: Safety Glasses (EN166) Lab Coat Disposable Gloves (EN374)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical Properties:

Physical State: Tablets (Solid Oral Dosage Form)

Appearance	10 mg:	White to off-white, round, flat tablets with bevel edge, debossed "I114" on one side and scored on the other side.
	20 mg:	White to off-white, round, flat tablets with bevel edge, debossed "I115" on one side and scored on the other side.
Odor	Data Not Available	
Taste	Data Not Available	
pH	Data Not Available	
Melting Point	Data Not Available	
Boiling Point	Data Not Available	
Decomposition	Data Not Available	

temperature	
Vapor pressure	Data Not Available
Density	Data Not Available
Solubility in water	Data Not Available
Specific Gravity	Data Not Available
Flashpoint	Data Not Available
Flammability limits	Data Not Available
Explosive properties	Data Not Available
Oxidizing Properties	Data Not Available

10. STABILITY AND REACTIVITY

Under the normal conditions of use, the product is stable.

11. TOXICOLOGICAL INFORMATION

Data of BACLOFEN drug substance is provided:

Acute Toxicity: LC50: > 2120 mg/m3 Route: inhalative Species: rat Exp. time: 4Hours
LD50: 145 mg/kg Route: oral Species: rat
LD50: 75 mg/kg Route: oral Species: mouse
LD50: 26 mg/kg Route: intravenous Species: mouse
LD50: 78 mg/kg Route: intravenous Species: rat

Irritation, Corrosion: Skin (Species: rabbit) mildly irritant
Eyes (Species: rabbit) mildly irritant

Sensitization: Skin (Species: guinea pig) not sensitizing

Mutagenicity: Negative with and without metabolic activation (AMES-Test (reverse mutation assay))
in vitroCell: Strains of salmonella typhimurium.
Negative with and without metabolic activation (Mammalian Cell Mutagenicity Test (HGPRT))
in vitroCell: Lymphoma cells L5178Y of the mouse
Negative (Micronucleus Test)
in vivo, Species: chinese hamster, Cell: Bone marrow
Negative (Sister Chromatid Exchange)
in vivo, Species: chinese hamster, Cell: Bone marrow

Chronic Effects: (Repeated Dose Toxicity)
NOAEL: 5 mg/kg/d Route: oral Species: rat Duration: 52 weeks
Pharmacological effects (Repeated Dose Toxicity)
NOAEL: 5 mg/kg/d Route: oral Species: rat, Organ: adrenal gland Duration: 104 weeks male
NOAEL: 12 mg/kg/d Route: oral Species: dog Duration: 56 weeks
Pharmacological effects (Repeated Dose Toxicity)
No evidence for carcinogenicity (Carcinogenesis)
NOAEL: 100 mg/kg/d Route: oral Species: rat Duration: 104 weeks

Reproduction Toxicity: Not teratogenic / not embryotoxic (Embryo-Fetal Development)
Not teratogenic / not embryotoxic (Embryo-Fetal Development)
NOAEL: 40 mg/kg/d Route: oral Species: mouse
NOAEL: 5 mg/kg/d Route: oral Species: rat

Negative (Combined Fertility and Embryo-Fetal Development)
NOAEL: 5 mg/kg/d Route: oral Species: rat

Human Pharmacokinetics: Half Life (T½ß): 3 - 4 hours
Availability: approx. 100 % Route: oral Species: human

Toxicological Hazard Classification:

Acute Toxicity (oral): Cat.4
Acute Toxicity (dermal): Cat.5
Acute Toxicity (inhalation): not classified
Eye Corrosion / Irritation: not classified
Skin Corrosion / Irritation: not classified
Respiratory sensitizer: not classifiable
Skin sensitizer: not classified
Germ cell mutation: not classified
Carcinogenicity: not classified
Reproductive toxicity: not classified
Specific organ toxicity (single dose), not lethal: not classifiable
Specific organ toxicity (repeated exposure): not classified
Aspiration Hazard: not applicable

Carcinogenicity listing International Lists: Not Listed

12. ECOLOGICAL INFORMATION

Fish acute toxicity: LC50: > 580 mg/l Species: zebra fish (danio rerio) Exp. time: 96 hours
Method: OECD 203 * 1984 *

Aquatic invertebrate acute toxicity: no data available

Algae Toxicity: no data available

Bacterial Respiration Inhibition: no data available

Biological Elimination: Degradation: 11.1 % (aerobic: Temperature: 20 °C BOD/ThODX100)
Not readily degradable
Initial conc.: 2 mg/l, Duration: 28 days
Method: OECD 301D * 1981

Partition Coefficient: log Pow: 0.11 (Temperature: 23 °C)

Biological accumulation: no data available

Soil and Sludge Sorption/Desorption: no data available

PBT assessment: no data available

Other adverse effects: no data available

13. DISPOSAL CONSIDERATIONS

Disposal Requirements: Fill into suitable waste receptacles, seal and label them properly. Incineration in an approved, controlled furnace with combustion gas scrubbing and emission gas control. Local regulations should be adhered to.

14. TRANSPORT INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION: This product is NOT classified as dangerous goods, per U.S. DOT regulations, under 49 CFR 172.101.

TRANSPORT CANADA TRANSPORTATION OF DANGEROUS GOODS REGULATIONS: This product does not meet the criteria of classification of Dangerous Goods, per regulations of Transport Canada.

INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA): This product does not meet the criteria as Dangerous Goods, per rules of IATA.

INTERNATIONAL MARITIME ORGANIZATION (IMO) DESIGNATION: This product is NOT classified as Dangerous Goods by the International Maritime Organization.

EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY

ROAD (ADR): This product does not meet the criteria as Dangerous Goods of the United Nations Economic Commission for Europe**.**

TRANSPORT IN BULK ACCORDING TO THE IBC CODE: Not applicable.

ENVIRONMENTAL HAZARDS: This product does not meet the criteria of environmentally hazardous according to the criteria of the UN Model Regulations (as reflected in the IMDG Code, ADR, RID, and ADN) and is not specifically listed in Annex III under MARPOL 73/78

15. REGULATORY INFORMATION

Chemical characterization of the substance / preparation:

Chemical Name	Contains:	CAS Number	Signal Word	Classification
BACLOFEN	0 - 15 %	1134-47-0	W	H302, H313

SEE CURRENT PRODUCT PACKAGE INSERT FOR DETAILED INFORMATION

16. OTHER INFORMATION

Abbreviations used

H302: Harmful if swallowed.
H313: May be harmful in contact with skin. (in EU not leading to classification as hazardous**)**

This document is prepared by Innogenix, LLC. in good faith to provide relevant available information about handling of this drug product distributed into interstate commerce and in the workplace. The information provided is based on references from Novartis safety data sheet and approved labeling for Baclofen Tablets, USP.

THIS SAFETY DATA SHEET IS WITHOUT WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE).

In the event of an adverse incident associated with this product, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute or product literature which may accompany the finished product.

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End of Safety Data Sheet