

SAFETY DATA SHEET

**According to Globally Harmonized System of Classification and Labelling of Chemicals (GHS),
Third Revised Edition UNITED NATIONS
New York and Geneva, 2019**

Baclofen Tablet (5 mg, 10 mg, 15 mg)

1. IDENTIFICATION

GHS Product identifier: Baclofen Tablets

Product code: #

Chemical Description: 4-amino-3-(4- chlorophenyl)-butanoic acid

Other means of identification: -

Recommended use of the tablet: Pharmaceutical use as muscle relaxant

Restrictions on use: The product should be used only for the above mentioned use and may not be used for any other purpose than stated above.

Manufactured by:

Mankind Pharma Ltd.,
Unit III, Opp. Dental College, Rampur Ghat,
Teh. -Paonta Sahib (HP-173025), India.
CIN No.: U74899DL1991PLC044843

Emergency phone number: +91 1704227600

2. HAZARDS IDENTIFICATION

Classification

Globally Harmonized System, UN (GHS)

Classification	Category	Exposure Route
Acute toxicity	4	Oral
Skin Irritation	2	Dermal
Eye Irritation	2	-
Reproductive toxicity	1B	-
Respiratory sensitization	1	Inhalation
Skin sensitization	1	

Labelling

Globally Harmonized System, UN GHS



Classification	
Signal Word	None
Hazard Statements:	<p>H302 Harmful if swallowed</p> <p>H315 Causes skin irritation</p> <p>H317 May cause allergic skin reaction</p> <p>H319 Causes serious eye irritation</p> <p>H360 Suspected of damaging fertility or the unborn child.</p> <p>H334 May cause allergy or asthma symptoms or breathing difficulties if Inhaled.</p>
Precautionary Statements:	<p>P264: Wash hands thoroughly after handling.</p> <p>P272: Contaminated work clothing should not be allowed out of the Workplace.</p> <p>P273: Avoid release to the environment.</p> <p>P280: Wear protective gloves/protective clothing/eye protection/face Protection.</p> <p>P284: Wear respiratory protection.</p> <p>P305 + P351 + P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing</p> <p>P332+P313 If skin irritation occurs: Get medical advice/attention.</p> <p>P337+P313: If eye irritation persists: Get medical advice/attention.</p> <p>P362: Take off contaminated clothing.</p> <p>P405: Store locked up.</p>
Other hazards	Under fire conditons, toxic vapours can be emitted.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical nature: Mixture containing Baclofen

Composition	CAS	Content
Baclofen	1134-47-0	5.0%
Lactose Anhydrous	63-42-3	Proprietary Information.
Dibasic Calcium Phosphate	7789-77-7	
Microcrystalline Cellulose	9004-34-6	
Sodium Starch Glycolate	9063-38-1	
Colloidal Silicon dioxide	112945-52-5	
Magnesium Stearate	557-04-0	

4. FIRST-AID MEASURES

Inhalation

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

Skin contact

Wash off with soap and plenty of water. Take victim immediately to hospital. Consult a physician.

Eye contact

Rinse thoroughly with plenty of water for at least 20 minutes and consult a physician

Ingestion

If this product is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTRE. Rinse mouth with water
Never give anything by mouth to an unconscious person.

5. FIRE-FIGHTING MEASURES

Fire extinguishing agents

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Fire/explosion hazard

No data available

Specific hazards arising from the chemical

When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including calcium, carbon, magnesium, silicon, sodium and nitrogen oxides)

Personal protection

Self-contained breathing apparatus. Fire-fighters must wear self-contained breathing apparatus for firefighting if necessary

Special exposure hazards

Do not release chemically contaminated water into drains, soil, or surface water. Dispose contaminated water and soil according to local regulations.

6. ACCIDENTAL RELEASE MEASURES

Personal protection

Personnel wearing nitrile or other appropriate gloves, lab coat or other protective clothing and eye protection should immediately clean incidental spills. When there is any danger of airborne dusts being generated, use a full-face respirator equipped with a High Efficiency Particulate (HEPA) filter

Environmental precautions

Prevent product from entering sewer or confined spaces, waterways, soil or public waters. Do not flush to sewer. For spills on water, contain, minimize dispersion and collect.

7. HANDLING AND STORAGE

Handling

Occupational hygiene

Avoid ingestion, inhalation, skin and eye contact. Handle in accordance with good industrial hygiene practice and any legal requirements.

Conditions for safe storage

Avoid dust formation and ignition sources. Ensure good local exhaust ventilation.

Keep away from heat/sparks/open flames/hot surfaces – No smoking.

Storage facilities

Store in a cool, dry area with adequate ventilation. Keep tightly closed.

Segregation

Store locked up.

Storage conditions

Keep containers closed. Store at 25 °C

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

Exposure limit values

Components with occupational exposure limits

CAS No	Name	TWA	STEL	Other
1134-47-0	Baclofen	Not known	-	Teva OEL Range µg/m ³ > 10 - < 100
557-04-0	Magnesium stearate	10 mg/m ³ (eye, skin, & URT irr)	-	ACGIH
112926-00-8	Colloidal Silicon Dioxide		80 mg/m ³	
9004-34-6	Microcrystalline Cellulose	10 (total dust), 5 (resp. fract.)		

Occupational exposure controls

Appropriate engineering controls

Maintain air concentrations below occupational exposure standards. Prevent dust formation.

General Personal Protection

Goggles, gloves, protective clothing.

Respiratory protection

Where the neat test chemical is weighed and diluted, wear a NIOSH-approved half face respirator equipped with an organic vapor/acid gas cartridge (specific for organic vapors, HCl, acid gas and SO₂) with a dust/mist filter. (NTP, 1992).

Hand protection

Protective gloves.

Eye protection

Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin and body protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Solid

Form: Tablets

Colour: White to off white

Odour: Odourless

pH: Not available

Melting point: 207°C

Boiling point: Not applicable

Flash point: Not applicable

Flammability (solid): Not available

Vapour pressure: Not applicable

Auto-ignition temperature: Not available

Decomposition temperature: Not available

Density: : 1.3±0.1 g/cm³

Solubility in water: slightly soluble in water and methanol.

Solubility in solvents: Not available

n-Octanol/Water Partition Coefficient: - 0.62

Dust Explosion Details:

Baclofen API has dust explosive potential with MIE between 30 and 100 mJ and Dust Explosion class St1. However, the dust of the formulation with the presence of excipients is not expected to be a dust explosion hazard.

10. STABILITY AND REACTIVITY

Conditions to avoid

Exposure to or contact with extreme temperatures, incompatible chemicals

Materials to avoid

Incompatible with strong oxidizing agents, and strong acids

Hazardous decomposition products

Products of thermal decomposition may include calcium, carbon, magnesium, silicon, sodium, and nitrogen oxides

11. TOXICOLOGICAL INFORMATION

Acute toxicity

Baclofen active ingredient has been tested for acute toxicity.

LC₅₀: > 2120 mg/m³ Route: inhalation 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

100% Baclofen is classified in category 3 for acute toxicity.

Based on toxicity data of Baclofen and its excipients, Baclofen tablet with 5% active ingredient may be classified as category 4.

Primary Irritation

a. Skin irritation

Active ingredient (Baclofen) classified in category 2.

Magnesium stearate - GHS classification category 2.

Sodium starch glycolate- GHS classification category 2.

Dibasic calcium phosphate dihydrate – category 2

Sum of ingredients in cat 2 >10%, hence mixture classified as skin category 2

b. Eye Irritation

Active ingredient classified in category 2.

Dibasic calcium phosphate dihydrate – cat 2A

Magnesium stearate - GHS classification category 2.

Based on the 'Decision logic 3.3.2 for serious eye damage/irritation" of GHS classification, mixture is classified as category 2 for eye irritation

c. Respiratory or Skin sensitization

Respiratory Sensitization, Category 1

Skin Sensitization, Category 1

d. CMR consideration:

Germ cell mutagenicity:

- Data not available

Carcinogenicity

Not classifiable as human carcinogen.

No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

e. Reproductive toxicity

- Category 1B

Specific target organ toxicity single exposure:

- Specific Target Organ Toxicity (single exposure)

Substance falls under Category 3 but based on evidence approach, mixture may be exempted from classification. (Decision logic 3.8.1)

Specific target organ toxicity repeated exposure:

Due to lack of data the GHS classification is not possible.

Aspiration hazard:

GHS Classification is not possible.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Data unavailable for baclofen. None of the other ingredients present in Baclofen Tablets present any notable aquatic toxicity.

Persistence and degradability

Data not available.

Behaviour in treatment plants

Data not available. GHS Classification is not possible.

Additional information

Do not discharge product uncontrolled into the environment.

13. DISPOSAL CONSIDERATIONS

Product disposal

Waste disposal must be in accordance with appropriate State, and local regulations. This product, if unaltered by use, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. All protective clothing, gloves, and disposable materials used in the preparation or handling of this drug should be disposed of in accordance with established hazardous waste disposal procedures. It is the responsibility of the generator to determine at the time of disposal whether the product meets the criteria of a hazardous waste per regulations of the area in which the waste is generated and/or disposed. Incineration is recommended for the product and disposable equipment. Shipment of wastes must be done with appropriately permitted and registered transporters. Reusable equipment should be cleaned with soap and water and thoroughly rinsed.

Contaminated packaging

Contaminated, empty containers must be disposed of as chemical waste.

14. TRANSPORT INFORMATION

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

15. REGULATORY INFORMATION

CLASSIFICATION AND LABELLING

Compliance with following regulations:

- Globally Harmonized System of Classification and Labelling of Chemicals (GHS), UNECE 2019 as amended
- UN Recommendations on the Transport of Dangerous Goods, UNECE 2009

16. OTHER INFORMATION

Recommended restrictions on use

This product should be stored, handled and used in accordance with good industrial hygiene practices and in conformity with any legal regulation. The information contained herein is based on the present state of our knowledge and is intended to describe our products from the point of view of safety requirements. It should not therefore be construed as guaranteeing specific properties.

MSDS Changes

Prepared on 18/02/2022