SAFETY DATA SHEET

According to Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Third Revised Edition UNITED NATIONS New York and Geneva, 2023

Bumetanide Tablets USP 0.5 mg, 1 mg and 2 mg

1. IDENTIFICATION

GHS Product identifier: Bumetanide tablets USP

Product code:#

Chemical Description: 3-(butylamino)-4-phenoxy-5-sulfamoylbenzoic acid

Other means of identification:

Recommended use of the chemical: Pharmaceutical use -- Bumetanide is a diuretic, and is used for treatment of oedema associated with congestive heart failure, hepatic and renal disease.

Restrictions on use: The product should be used only for the above mentioned uses 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
Skin Irritation	3	Dermal
Reproductive toxicity	2	Oral

Labeling

Globally Harmonized System, UN (GHS)

Signal Word	**Danger**
Hazard Statements:	H361: Suspected of damaging the unborn child H316: Causes mild skin irritation
Precautionary Statements:	P260 Do not breathe dust. P264 Wash hands thoroughly after handling. P273Avoid release to the environment. P314 Get medical advice if you feel unwell. P403+P233 Store in a well-ventilated place. Keep container tightly closed. P405 Store locked up. P501Dispose of contents/container to local/national/international regulation.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical nature: Mixture containing Bumetanide

Hazardous ingredients	CAS	Content
Bumetanide	28395-03-1	0.58%
Sodium Lauryl Sulphate	151-21-3	ca. 1%
Lactose Monohydrate (Flowlac 90)	64044-51-5	<100%
Pregelatinized Starch	9005-25-8	<100%
Corn starch	9005-25-8	<100%
Magnesium Stearate	557-04-0	<100%
Light Magnesium oxide	1309-48-4	<100%
Microcrystalline cellulose	9004-34-6	<100%
Talc	14807-96-6	<100%

4. FIRST-AID MEASURES

Occupational exposure to Bumetanide may occur through inhalation and dermal contact with this compound at workplaces where this drug is produced or used. No limits for exposure have been established.

Inhalation

In case of irritation of the respiratory system or mucous membranes, seek medical attention. Move to fresh air. Seek medical attention if you feel unwell or if exposure prolonged.

Skin contact

Remove contaminated clothing. Wash affected skin with soap and plenty of water. If skin irritation or dermatitis commences or persists, seek medical attention. Cover skin burns with dry sterile dressings after decontamination.

Eye contact

Immediately flush contaminated eyes with gently flowing water.

Ingestion

Symptoms such as weakness, mental confusion, anorexia, lethargy, vomiting, and cramps may occur because of electrolyte depletion in case of over dosage. Seek medical attention.

5. FIRE-FIGHTING MEASURES

Fire extinguishing agents

Water spray, Foam, Carbon dioxide (CO_2), Dry powder.

Fire/explosion hazard

No data available

Specific hazards arising from the chemical

No data available

Personal protection

Self-contained breathing apparatus.

Special exposure hazards

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

6. ACCIDENTAL RELEASE MEASURES

Personal protection

Goggles, gloves, protective clothing, respiratory protection.
Remove ignition sources and provide sufficient ventilation.

Environmental precautions

Prevent contamination of soil, drains and surface waters.

Spillage procedure

Take up mechanically and collect in suitable container (adequately labelled) for disposal.

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.

Storage

Handling- Avoid inhalation. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure.

Fire precautions

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. Store at 25 °C

Segregation

Store locked up.

Storage conditions

Keep containers closed.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

Exposure limit values

Components with occupational exposure limits

CAS No	Name	TWA	STEL	Source
28395-03-1	Bumetide	Not established	-	-
9004-34-6	Microcrystalline Cellulose	10 mg/m^3 (skin)	-	ACGIH
557-04-0	Magnesium stearate	10 mg/m^3 (eye, skin, & URT irr)	-	ACGIH
151-21-3	Sodium Lauryl Sulphate	0.3 mg/m^3		Pfizer OEL

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

Breathing apparatus with filter required if occupational exposure limits may be exceeded.

Hand protection

Protective gloves.

Eye protection

Goggles.

Skin and body protection

Protective clothing.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Solid
Form: Tablets
Colour: white to off white
Odour: N.A.
pH: not tested
Melting point: not tested
Boiling point: not applicable
Flash point: not applicable
Flammability (solid): not tested
Vapour pressure: not tested
Auto-ignition temperature: not applicable
Decomposition temperature: not tested
Density: not tested
Solubility in water: Practically insoluble in water;

Solubility in solvents: Soluble in organic solvents such as ethanol, DMSO, and dimethyl formamide (DMF).
n-Octanol/Water Partition Coefficient:
Viscosity: Not tested
Oxidizing properties: not tested
Explosivity: Stable under ordinary conditions

10. STABILITY AND REACTIVITY

Conditions to avoid
Avoid moisture
Materials to avoid
Information not available
Hazardous decomposition products
Carbon dioxide, carbon monoxide, nitrogen oxides, sulfur oxides

11. TOXICOLOGICAL INFORMATION

Acute toxicity
Bumetanide

LD50 (oral, rat): >6 g/kg
LD50 (IV, rat): > 200 mg/kg

Sodium Lauryl Sulphate
LD50 (oral, rat): 1288 mg/kg
LD50 (dermal): > 400 mg/kg and < 2000 mg/kg

Based on toxicity data of Bumetanide and its excipients, it is not classified for acute toxicity.

Primary Irritation

Bumetanide
- Skin: category 2
- Eye: category 2A
-

(Sodium Lauryl Sulphate)
- Skin: Causes skin irritation - GHS classification category 2
- Eye: Causes serious eye irritation - GHS classification category 1

(Magnesium stearate)
Skin - category 2
Eye Irritation - category 2

GHS Classification of the mixture for skin irritation is category 3.

The mixture has been evaluated for eye irritation and based on available data, does not meet classification criteria.

Respiratory or Skin sensitization

- Respiratory: Not tested

GHS Classification is not possible.

CMR consideration:

Germ cell mutagenicity:

- Data unavailable

GHS Classification is not possible.

Carcinogenicity

·IARC (International Agency for Research on Cancer) Substance is not listed.
· NTP (National Toxicology Program) Substance is not listed.
· OSHA-Ca (Occupational Safety & Health Administration) Substance is not listed.

Reproductive toxicity

- Bumetanide – category 2

GHS classification for mixture is category 2 since Bumetanide is present at >0.1 %.

Specific target organ toxicity single exposure:

Bumetanide (active ingredient) - category 3
SLS may cause respiratory irritation – Category 3.

GHS classification for mixture is not applicable because of the low concentrations.

Specific target organ toxicity repeated exposure:
Ingredients are not classified for repeated exposure**.**

Aspiration hazard:
Due to lack of data GHS Classification is not possible.
Additional information:

12. ECOLOGICAL INFORMATION

Ecotoxicity data for Bumetanide is not available.

SLS and Magnesium stearate are classified as chronic 3 and chronic 4 respectively. Based on the GHS classification for environmental hazards, the mixture has been classified as chronic 4.

GHS Classification is not applicable for the mixture.

Persistence and degradability

Data not available. GHS Classification is not possible.

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
Incinerate in approved facility. Observe specific national regulation.
Contaminated packaging
Contaminated, empty containers must be disposed of as chemical waste.

14. TRANSPORT INFORMATION

The substance is not considered to be a dangerous good according to transport regulations

15. REGULATORY INFORMATION

CLASSIFICATION AND LABELLING
Compliance with following regulations:

- Globally Harmonized System of Classification and Labelling of Chemicals (GHS), UNECE 2003 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.

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