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

Chlorthalidone Tablets 25 and 50 mg

1. IDENTIFICATION

GHS Product identifier: Chlorthalidone Tablets 25 and 50 mg
Product code: #
Chemical Description: 2-Chloro-5(1-hydroxy-3-oxo-1-isoindolinyl)benzenesulfonamide
Other means of identification: -
Recommended use: It is used to treat high blood pressure and fluid retention caused by various conditions, including heart disease.
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
Skin irritation	2	
Eye irritation	2	-
Target organ toxicity (single exposure)	3	-

Labelling

Warning

Classification	
Signal Word	**Warning**
Hazard Statements:	H315: Causes skin irritation. H319: Causes serious eye irritation. H335: May cause respiratory irritation.
Precautionary Statements:	P264: Wash hands thoroughly after handling. P272: Contaminated work clothing should not be allowed out of the Workplace. P273: Avoid release to the environment. P280: Wear protective gloves/protective clothing/eye protection/face Protection. P284: Wear respiratory protection. P305 + P351 + P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P332+P313 If skin irritation occurs: Get medical advice/attention. P337+P313: If eye irritation persists: Get medical advice/attention. P362: Take off contaminated clothing. P405: Store locked up
Other hazards	None

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical nature: Mixture containing Chlorthalidone

Hazardous ingredients	**CAS**	**Content**
Chlorthalidone	77-36-1	35.7%
Other ingredients		
Microcrystalline cellulose	9004-34-6	-
Sodium starch glycolate (Type A)	9063-38-1	-
Pregelatinized starch (Type B)	9005-25-8	-
Colloidal silicon dioxide	112945-52-5	-
Stearic acid	NA	-

4. FIRST-AID MEASURES

Inhalation

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

Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention

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, dry chemical or carbon dioxide.

Fire/explosion hazard

Fine particles (such as dust and mists) may fuel fires/explosions

Specific hazards arising from the chemical

During combustion may emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.

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

Wear respiratory protection.

Environmental precautions

Prevent product from entering sewer or confined spaces, waterways, soil or public waters. Do not flush to sewer.

7. HANDLING AND STORAGE

Handling

Occupational hygiene

Follow recommendations for handling pharmaceutical agents (i.e., use of engineering controls and/or other personal protective equipment if needed).

Conditions for safe storage

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

Storage facilities

Store away from light, in a cool, dry area. Keep tightly closed.

Segregation

Store locked up.

Storage conditions

Store in tight light resistant containers. Store at 20°C to 25°C temperature.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

Exposure limit values

Components with occupational exposure limits

CAS No	Name	ACGIH TLV	OSHA PEL	NIOSH
. 9004-34-6	Cellulose	TWA 10 mg/m^3	TWA: 10mg/m^3 (total) TWA: 5 mg/m^3 (resp fraction)	TWA: 10 mg/m^3 (total) TWA: 5 mg/m3 (resp)

Chlorthalidone – 8-hr TWA : Not established

Occupational exposure controls

Appropriate engineering controls

Ensure adequate ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits.If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels,and processing equipment) are designed in a manner to prevent the escape of dust into the work area(i.e. there is no leakage from the equipment). It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in the handling of this product contain explosion relief vents or an explosion suppression system or an oxygen-deficient environment.

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, round shaped, Compressed Tablet
Form: solid
Colour: white to off white
Odour: Odourless
pH: Not determined
Melting point: 239 °C (Drug bank)
Boiling point: Not applicable.
Flash point: Not determined. It is expected to be combustible.
Flammability (solid): Not available
Vapour density: >1 (Air =1), <1 mg/ml (water = 1)
Auto-ignition temperature: Not tested
Decomposition temperature: Not tested
Relative Density: 1.6±0.1 g/cm3
Solubility in water: 20 mg/L (at 20 °C) (MERCK INDEX (1996)) Chlorthalidone is practically insoluble in water, in ether and in chloroform; soluble in methanol; slightly soluble in alcohol (HSDB) 5.28e-02 g/L (HMDB)
n-Octanol/Water Partition Coefficient: 0.85(Drug bank) log K o/w = 0.85 (HSDB) 1.3 (HMDB)
Viscosity: Not applicable

10. STABILITY AND REACTIVITY

Chemical stability

Stable under recommended storage conditions

Conditions to avoid

Heat. Avoid dust formation. Dust may form explosive mixture in air. Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

Materials to avoid

Microcrystalline cellulose present in the mixture is combustible and incompatible with strong oxidizing agents including bromine pentafluoride, sodium nitrate, fluorine, perchlorates, perchloric acid, sodium chlorate, magnesium perchlorate, F2, zinc permanganate, sodium nitrite, sodium nitrate, sodium peroxide. Nitration with a mixture of nitric and sulfuric acids produces cellulose nitrates (celluloid pyroxylin, soluble pyroxyline, guncotton) which are flammable or explosive.

Hazardous decomposition products

Carbon Dioxide, Carbon Monoxide, Nitrogen Oxides, Sulfur oxide, Hydrogen Chloride gas

11. TOXICOLOGICAL INFORMATION

Acute toxicity

Chlorthalidone - Toxicity Data:
Oral LD50 (rat): >5 gm/kg; Subcutaneous LD_{50} (rat): >5 gm/kg; Oral LD_{50} (mouse): >5 gm/kg; SubcutaneousLD$_{50}$ (mouse): >5 gm/kg

Primary Irritation:

Skin/eye irritation - Chlorthalidone – Category 2 for skin and eye irritation
Mixture falls under category 2 for skin and eye irritation.

Skin contact may result in inflammation characterized by itching, scaling, reddening, blistering, pain or dryness. Eye contact may result in redness, pain or severe eye damage. Inhalation may cause irritation of the lungs and respiratory system.

Respiratory or Skin sensitization- Data not available
CMR consideration:

Germ cell mutagenicity:
Not mutagenic. Mixture not classifiable.

Carcinogenicity
No data available. Not classifiable as human carcinogen.

Reproductive toxicity: Data not available

Specific target organ toxicity single exposure: Chlorthalidone is classified as category 3. (target organ – respiratory system)

Mixture is therefore classified as category 3.

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- Unknown

Mixture is not classifiable owing to lack of studies.

Persistence and degradability
High Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.
Bio accumulative potential
Low
Additional information
Do not discharge product uncontrolled into the environment.

13. DISPOSAL CONSIDERATIONS

Product disposal

All wastes containing the material should be properly labeled. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner, e.g., appropriately permitted municipal or onsite wastewater treatment facility.

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 28/08/2022