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

Doxepin HCL capsules USP (10,25,50,75,100 mg)

1. IDENTIFICATION

GHS Product identifier: Doxepin HCL capsules

Product code: #

Chemical Description: (3*E*)-3-(6*H*-benzo[c][1]benzoxepin-11-ylidene)-*N*,*N*-dimethylpropan-1-amine;hydrochloride

Other means of identification:

Recommended use of the chemical: Used in treatment of depression. It has moderate antimuscarinic and marked sedative properties.

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
Acute Toxicity	4	Oral
STOT SE	1	
Reproductive toxicity	2	

Labeling

Globally Harmonized System, UN (GHS)

Classification	
Signal Word	**Danger**
Hazard Statements:	H302 Harmful if swallowed H370 Causes damage to organs H361 Suspected of damaging fertility or unborn child H362 May cause harm to breast-fed children
Precautionary Statements:	P273: Avoid release to the environment. P280: Wear protective gloves/protective clothing/eye protection/face 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 P311: Call a poison centre/physician P391: Collect spillage
Other hazards	Control formation and generating of dusts during use.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical nature: Mixture containing Doxepin HCl

Hazardous ingredients	CAS	Content
Doxepin Hydrochloride	1229-29-4	18.84%
Sodium Lauryl Sulphate (SLS)	151-21-3	-
Magnesium Stearate	557-04-0	-
Microcrystalline Cellulose	9004-34-6	-
Pregelatinized Starch	9005-25-8	-
Colloidal Silicon Dioxide	112945-52-5, 7631-86-9	-
Purified Water	-	-
This product is a mixture of chemical substances. The specific chemical % for other chemical ingredients of this product is being withheld as it is Propriety information.		

4. FIRST-AID MEASURES

Inhalation

Move the person into fresh air. In case of respiratory symptoms, place the person in a semi-seated position and administer oxygen. 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 15 minutes and consult a physician.

Ingestion

Never give anything by mouth to an unconscious person. DO not induce emesis. Rinse mouth with water. Consult a physician.

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

Carbon oxides, Nitrogen oxides (NOx)

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 of 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.

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. 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
. 1229-29-4	Doxepin HCl	600 µg/m^3 (8 hrs)	-	-
557-04-0	Magnesium Stearate	10 mg/m^3	-	-

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

Not required for the normal use of this product. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

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: Opaque capsules will colour coding for different strengths. Yellow – 10mg & 50 mg, Yellow/White – 25mg, Green – 75 mg. Green/White – 100 mg.
Form: Capsules
Colour: Yellow
Odour: Slight Amine like odour.
pH: Not available
Melting point: 185-191° C
Boiling point: Not applicable
Flash point: Not applicable
Flammability (solid): Doxepin HCl has a Minimum igniton energy value of 30mJ and is Non Electroconductive. It is susceptible to explosion by static discharge.
Vapour pressure: Not available
Auto-ignition temperature: Not available
Decomposition temperature: Not available
Density: Not available
Solubility in solvents: Freely soluble in water, alcohol, Methyelene chloride.
n-Octanol/Water Partition Coefficient: approx. 4.1 for doxepin
Viscosity: Not applicable
Oxidizing properties: Not applicable
Explosivity: Stable under ordinary conditions

10. STABILITY AND REACTIVITY

Conditions to avoid

Avoid moisture

Materials to avoid

Keep away from strong Oxidizing agents. Airborne particles/dust may fuel fire/explosion in presence of source of ignition.

Hazardous decomposition products

In event of thermal decomposition or fire, vapours potentially dangerous to health may be released.

Possible combustion products are Carbon oxides, nitrogen oxides, hydrochloric acid

11. TOXICOLOGICAL INFORMATION

Acute toxicity

Doxepin HCl active ingredient has been tested for acute toxicity.

Doxepin

LD_{50} (oral, rat): 147 mg/kg

100% Doxepin is classified in category 3 for acute toxicity.
Based on toxicity data of Doxepin HCl and its excipients, Doxepin mixture with 18.8% Doxepin HCl is classified into Category 4 for acute toxicity.

Primary Irritation

Skin: Doxepin HCl active ingredient is not classified for skin or eye irritation.

Respiratory or Skin sensitization
Doxepin mixture is not classifiable for respiratory or skin sensitization.

CMR consideration:

Germ cell mutagenicity:
- Data not sufficient for classification.

GHS Classification is not possible.

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.

GHS Classification for active ingredient is not possible due to lack of data.

Reproductive toxicity

Classified as Category 2 for reproductive toxicity since the mixture contains category 2 toxicant (doxepin HCl) ≥ 0.1%.

Specific target organ toxicity single exposure: (STOT SE)

Toxic effects to nervous, cardiovascular and autonomic system are related to doxepin overdose.
Doxepin HCl mixture, like the active ingredient would fall in Category 1.

Specific target organ toxicity repeated exposure:

- Data not available

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

Aspiration hazard:
GHS Classification is not possible.

Additional information: None

12. ECOLOGICAL INFORMATION

Ecotoxicity

Acute aquatic toxicity data
Doxepin – classified as acute 1

Doxepin tablet is not classified for long-term (chronic) hazard since the sum of concentrations of ingredients classified for chronic hazard is <25%.

Persistence and degradability
Biodegradation – 0% (biotic, 28 d)

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
Product residues should be considered as hazardous waste. Disposal must be done through authorised waste disposal firms in compliance with local regulations. Waste should not be released to sewers.

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

14. TRANSPORT INFORMATION

This substance is not classified as dangerous for transport.

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 2019

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 06/05/22