



GLENMARK PHARMACEUTICALS LIMITED

SAFETY DATA SHEET

**PRODUCT: CETRIZINE HYDROCHLORIDE
TABLETS USP**

SDS NO. : SDS/GHS/GPL/486.00

EFFECTIVE DATE : 25/04/2024

PAGE No. : 1 of 14

Section 1. Identification

1.1 Product Name: Cetirizine Hydrochloride Tablets USP

1.2 Synonyms: Not Known

1.3 Recommended use of the chemical and restrictions on use:

Anti-histamine

1.4 Company Identification: Glenmark Pharmaceuticals Inc., USA

750 Corporate Drive

Mahwah, NJ 07430


1.5 Emergency Contact details: (201) 684-8000

Section 2. Hazard Identification

2.1 Classification of the substance or mixture

Not considered a Hazardous Substance by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200). Not classified as Dangerous Goods for transport purposes.

CHEMWATCH HAZARD RATINGS

	Min	Max
Flammability	0	
Toxicity	0	
Body Contact	0	
Reactivity	1 	
Chronic	0	

0 = Minimum

1 = Low

2 = Moderate

3 = High

4 = Extreme



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NFPA 704 diamond



Note: The hazard category numbers found in GHS classification in section 2 of this SDSs are NOT to be used to fill in the NFPA 704 diamond. Blue = Health Red = Fire Yellow = Reactivity White = Special (Oxidizer or water reactive substances)

Classification	Acute Toxicity (Oral) Category 4 *LIMITED EVIDENCE
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2.2 Label elements:

Hazard pictogram(s)	
Signal word	Warning

2.3 Hazard statement:

H302	Harmful if swallowed.
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2.4 Precautionary statement:

P101	If medical advice is needed, have product container or label at hand.
P102	Keep out of reach of children.
P103	Read label before use.
P501	Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation.

2.5 Other hazards: Not Known

Section 3- Composition/Information on Ingredients

3.1 Mixture:

CHEMICAL NAME	CAS #	%
Cetirizine Hydrochloride	83881-52-1	Proprietary



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Magnesium Stearate.	83881-51-0	Proprietary
Ingredients determined not to be hazardous [Mfr]	-	Proprietary

Section 4. First aid Measures

4.1 Eye Contact: Generally, not applicable.

4.2 Skin Contact: If skin contact occurs:

- Immediately remove all contaminated clothing, including footwear.
- Flush skin and hair with running water (and soap if available).
- Seek medical attention in event of irritation.

4.3 Inhalation:

- If fumes, aerosols or combustion products are inhaled remove from contaminated area.
- Other measures are usually unnecessary

4.4 Ingestion:

- Immediately give a glass of water.
- First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.

4.5 Most important symptoms and effects, both acute and delayed

Treat symptomatically

Section 5. Fire-fighting Measures

5.1 Extinguishing Media:

- There is no restriction on the type of extinguisher which may be used.
- Use extinguishing media suitable for surrounding area.

5.2 Fire Incompatibility: Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result

5.3 Fire Fighting:

- Alert Fire Brigade and tell them location and nature of hazard.
- Wear breathing apparatus plus protective gloves in the event of a fire.
- Prevent, by any means available, spillage from entering drains or water courses.



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- Use firefighting procedures suitable for surrounding area.
- Slight hazard when exposed to heat, flame and oxidisers.

5.4 Fire/Explosion Hazard:

- The material is not readily combustible under normal conditions.
- However, it will break down under fire conditions and the organic component may burn.
- Not considered to be a significant fire risk.
- Heat may cause expansion or decomposition with violent rupture of containers.
- Decomposition may produce toxic fumes of: carbon dioxide (CO₂), hydrogen chloride, phosgene, nitrogen oxides (NO_x), other pyrolysis products typical of burning organic material.

Section 6. Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures:

Personal Protective Equipment advice is contained in Section 8 of the SDS.

6.2 Minor Spills:

- Clean up all spills immediately.
- Secure load if safe to do so.
- Bundle/collect recoverable product.
- Collect remaining material in containers with covers for disposal.

6.3 Major Spills:

- Clean up all spills immediately.
- Wear protective clothing, safety glasses, dust mask, gloves.
- Secure load if safe to do so. Bundle/collect recoverable product.

Section 7. Handling and Storage

7.1 Safe Handling:

- Avoid all personal contact, including inhalation.
- Wear protective clothing when risk of exposure occurs.
- Use in a well-ventilated area.
- Prevent concentration in hollows and sumps.



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7.2 Other Information (Storage):

- Store away from incompatible materials.
- Store between 20⁰C to 25⁰C (68 ⁰Fto 77⁰F)

7.3 Suitable Container:

- Alu Alu blister pack
- HDPE Bottle
- Polyethylene or polypropylene container.
- Packing as recommended by manufacturer.
- Check all containers are clearly labelled and free from leaks.

7.4 Storage Incompatibility: Avoid reaction with oxidising agents

Section 8. Exposure Controls/Personal Protection

8.1 Occupational Exposure Limits (OEL):

EMERGENCY LIMITS

Ingredient	TEEL-1	TEEL-2	TEEL-3
cetirizine Hydrochloride	Not Available	Not Available	Not Available
Ingredient	Original IDLH	Revised IDLH	
cetirizine hydrochloride	Not Available	Not Available	

OCCUPATIONAL EXPOSURE BANDING

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
cetirizine hydrochloride	E	≤ 0.01 mg/m ³
Notes:	Occupational exposure banding is a process of assigning chemicals into specific categories or bands based on a chemical's potency and the adverse health outcomes associated with exposure. The output of this process is an occupational exposure band (OEB), which corresponds to a range of exposure concentrations that are expected to protect worker health.	

8.2 Exposure Controls:

Appropriate engineering controls	Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection.
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	<p>The basic types of engineering controls are: Process controls which involve changing the way a job activity or process is done to reduce the risk. Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment.</p>
<p>Individual protection measures, such as personal protective equipment</p>	
<p>Eye and face protection</p>	<p>No special equipment for minor exposure i.e. when handling small quantities. OTHERWISE: Safety glasses with side shields. Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task.</p>
<p>Skin protection</p>	<p>See Hand protection below</p>
<p>Hands/feet protection</p>	<p>Wear general protective gloves, eg. light weight rubber gloves.</p>
<p>Body protection</p>	<p>See Other protection below</p>
<p>Other protection</p>	<p>Overalls. P.V.C apron. Barrier cream. Skin cleansing cream.</p>

Respiratory protection

- Respirators may be necessary when engineering and administrative controls do not adequately prevent exposures.
- The decision to use respiratory protection should be based on professional judgment that takes into account toxicity information, exposure measurement data, and frequency and likelihood of the worker's exposure - ensure users are not subject to high thermal loads which may result in



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heat stress or distress due to personal protective equipment (powered, positive flow, full face apparatus may be an option).

- Published occupational exposure limits, where they exist, will assist in determining the adequacy of the selected respiratory protection. These may be government mandated or vendor recommended.
- Certified respirators will be useful for protecting workers from inhalation of particulates when properly selected and fit tested as part of a complete respiratory protection program.
- Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU)
- Use approved positive flow mask if significant quantities of dust becomes airborne.
- Try to avoid creating dust conditions.

Section 9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	:	Solid
Appearance	:	Coated Tablet
Colour	:	White
pH Value	:	Not Known
Vapor Pressure	:	Not Known
Vapor Density	:	Not Known
Evaporation Rate	:	Not Known
Flash point	:	Not Known
Molecular Weight	:	Not Known
Melting point/range	:	Not Known
Boiling point/boiling range	:	Not Known
Density	:	Not Known
Viscosity	:	Not Known
Water solubility	:	Not Known
Solubility in other solvents	:	Not Known
Minimum ignition energy (MIE)	:	Not Known
Minimum ignition temperature (MIT)	:	Not Known



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Layer ignition temperature (LIT)	:	Not Known
Flammability/explosivity	:	Not Known
Reactivity/exotherms	:	Not Known
Electrostatic nature	:	Not Known
Highly dusty material	:	Not Known
Any other properties which cause handling or processing difficulties	:	Not Known
Average PSD (particle size distribution (micron))	:	Not Known

Section 10. Stability and Reactivity

10.1 Reactivity: Not Known

10.2 Chemical Stability: Product is considered stable

10.3 Possibility of hazardous reactions: Will not occur.

10.4 Conditions to Avoid: Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result

10.5 Incompatibilities Materials: Avoid reaction with oxidising agents

10.6 Hazardous Decomposition Products: Decomposition may produce toxic fumes of: carbon dioxide (CO₂), hydrogen chloride, phosgene, nitrogen oxides (NO_x) other pyrolysis products typical of burning organic material.

Section 11. Toxicological Information

11.1 Information on toxicological effects

Inhaled	The material is not thought to produce adverse health effects or irritation of the respiratory tract (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.
Ingestion	Not considered to cause discomfort through normal use.



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Skin Contact	Generally not applicable.	
Eye	Generally not applicable.	
Chronic	<p>There exists limited evidence that shows that skin contact with the material is capable either of inducing a sensitisation reaction in a significant number of individuals, and/or of producing positive response in experimental animals.</p> <p>There is some evidence that human exposure to the material may result in developmental toxicity. This evidence is based on animal studies where effects have been observed in the absence of marked maternal toxicity, or at around the same dose levels as other toxic effects but which are not secondary non-specific consequences of the other toxic effects.</p> <p>Long-term therapeutic use of antihistamines has been associated with glycosuria, obstructive jaundice, thrombocytopenic purpura, early menses, induced lactation, gynecomastia, decreased libido, impotence and inhibition of lactation. Haematological complications although rare, may include hypoplastic or aplastic anaemia, leukopenia, agranulocytosis, pancytopenia, thrombocytopenia and haemolytic anaemia. Allergic hypersensitivities are characterised by drug fever, eczematous dermatitis and urticaria, morbili-form and scarlatiniform eruptions (both rare), erythema multiforme, photo-sensitivity, peripheral, angioneurotic, and laryngeal oedema, asthma, lupus-like syndrome and anaphylaxis.</p> <p>Long-term use of antihistamines may result in extrapyramidal symptoms such as facial dyskinesia (difficulty in movement).</p> <p>Topical application of antihistamines to large areas may result in systemic side-effects and may, in addition, carry the risk of sensitisation producing allergic contact dermatitis characterised by eczematous eruptions.</p>	
cetirizine hydrochloride	TOXICITY Oral (Dog) LD50; >320 mg/kg ^[2]	IRRITATION Not Available
Legend:	1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2. Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances	

Section 12. Ecological Information

12.1 Toxicity:

cetirizine hydrochloride	Endpoint	Test Duration (hr)	Species	Value	Source
	Not	Not Available	Not Available	Not	Not Available



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	Available		Available
Legend:	Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data		

DO NOT discharge into sewer or waterways.

12.2 Persistence and degradability:

Ingredient	Persistence: Water/Soil	Persistence: Air
cetirizine hydrochloride	No Data available for all ingredients	No Data available for all ingredients

12.3 Bio accumulative potential:

Ingredient	Bioaccumulation
cetirizine hydrochloride	No Data available for all ingredients

12.4 Mobility in soil:

Ingredient	Mobility
cetirizine hydrochloride	No Data available for all ingredients

Section 13. Disposal Considerations

13.1 Waste treatment methods

Product / Packaging disposal	Recycle wherever possible or consult manufacturer for recycling options. Consult State Land Waste Authority for disposal. Bury or incinerate residue at an approved site. Recycle containers if possible, or dispose of in an authorised landfill.
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Section 14. Transport Information

Labels Required

Marine Pollutant	NO
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**Land transport (DOT): NOT REGULATED FOR TRANSPORT OF DANGEROUS
GOODS**

**Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF
DANGEROUS GOODS**

**Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF
DANGEROUS GOODS**

Transport in bulk according to Annex II of MARPOL and the IBC code

Not Applicable

Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code

Product name	Group
cetirizine hydrochloride	Not Available

Transport in bulk in accordance with the IGC Code

Product name	Ship Type
cetirizine hydrochloride	Not Available

Section 15. Regulatory Information

**15.1 Safety, health and environmental regulations/legislation specific for the substance or
mixture:**

**CETRIZINE HYDROCHLORIDE IS FOUND ON THE FOLLOWING REGULATORY
LISTS**

- Not Applicable

Additional Regulatory Information

Not Applicable

Federal Regulations

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SECTION 311/312 HAZARD CATEGORIES

Flammable (Gases, Aerosols, Liquids, or Solids)	No
Gas under pressure	No
Explosive	No
Self-heating	No
Pyrophoric (Liquid or Solid)	No
Pyrophoric Gas	No



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Corrosive to metal	No
Oxidizer (Liquid, Solid or Gas)	No
Organic Peroxide	No
Self-reactive	No
In contact with water emits flammable gas	No
Combustible Dust	No
Carcinogenicity	No
Acute toxicity (any route of exposure)	No
Reproductive toxicity	No
Skin Corrosion or Irritation	No
Respiratory or Skin Sensitization	No
Serious eye damage or eye irritation	No
Specific target organ toxicity (single or repeated exposure)	No
Aspiration Hazard	No
Germ cell mutagenicity	No
Simple Asphyxiant	No
Hazards Not Otherwise Classified	No

US. EPA CERCLA HAZARDOUS SUBSTANCES AND REPORTABLE QUANTITIES

(40 CFR 302.4)

None Reported

US. EPCRA SECTION 313 TOXIC RELEASE INVENTORY (TRI) (40 CFR 372)

None Reported

Additional Federal Regulatory Information

Not Applicable

State Regulations

US. CALIFORNIA PROPOSITION 65

None Reported

Additional State Regulatory Information

Not Applicable

National Inventory Status

National Inventory	Status
Australia - AIIC / Australia Non-Industrial Use	No (cetirizine hydrochloride)



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National Inventory	Status
Canada - DSL	No (cetirizine hydrochloride)
Canada - NDSL	No (cetirizine hydrochloride)
China - IECSC	No (cetirizine hydrochloride)
Europe - EINEC / ELINCS / NLP	No (cetirizine hydrochloride)
Japan - ENCS	No (cetirizine hydrochloride)
Korea - KECI	No (cetirizine hydrochloride)
New Zealand - NZIoC	No (cetirizine hydrochloride)
Philippines - PICCS	No (cetirizine hydrochloride)
USA - TSCA	No (cetirizine hydrochloride)
Taiwan - TCSI	Yes
Mexico - INSQ	Yes
Vietnam - NCI	Yes
Russia - FBEPH	No (cetirizine hydrochloride)
Legend:	Yes = All CAS declared ingredients are on the inventory No = One or more of the CAS listed ingredients are not on the inventory. These ingredients may be exempt or will require registration.

Section 16. Additional Information

Disclaimer:

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

Definitions and abbreviations

PC – TWA: Permissible Concentration-Time Weighted Average



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PC – STEL: Permissible Concentration-Short Term Exposure Limit

IARC: International Agency for Research on Cancer

ACGIH: American Conference of Governmental Industrial Hygienists

STEL: Short Term Exposure Limit

TEEL: Temporary Emergency Exposure Limit

IDLH: Immediately Dangerous to Life or Health Concentrations

OSF: Odour Safety Factor

NOAEL: No Observed Adverse Effect Level

LOAEL: Lowest Observed Adverse Effect Level

TLV: Threshold Limit Value

LOD: Limit of Detection

OTV: Odour Threshold Value

BCF: Bio Concentration Factors

BEI: Biological Exposure Index

NFPA: National Fire Protection Association

LDLo: Lethal dose low

TDLo: Toxic dose low

Compiled By (R & D)

Approved by (EHS Head)

Lysa
25/04/2024

[Signature]
25/04/2024

Signature /Date

Signature /Date