

Safety Data Sheet

Issuing date: 06AUG2020

Revision date: 02MAY2022

Revision number: 02

1. Identification of the substance/preparation and the company/undertaking

GHS product identifier

Product name: Cimetidine Hydrochloride Oral Solution

Other means of identification

Product code(s): 0121-0649-08; 0121-0649-16; 0121-0649-05; 0121-0649-40; 0121-1298-93; 0121-1298-40
UN-Number: NA
Synonyms: NA

Recommended use of the chemical and restrictions on use

Recommended use: Pharmaceutical product used for gastrointestinal conditions as an acid reducer to treat peptic ulcer, gastroesophageal reflux disease (GERD), heartburn and upset stomach
Uses advised against: Do not use except as prescribed.

Supplier address/information

Pharmaceutical Associates, Inc.
201 Delaware Street
Greenville, SC 29605 (864) 277 -7282

Emergency telephone number: CHEMTREC 800.424.9300

2. Hazards Identification

Classification This product is a mixture and is a pharmaceutical product. It is considered non-Hazardous according to the OSHA Hazard Communication Standard 2012 (29 CFR 1910.1200).

Chemical family: Mixture

Statement of Hazard: Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

Additional Hazard Information:

Short term: The most common effects may include diarrhea, headaches, dizziness, somnolence, reversible confusions states, gynecomastia, reversible impotence, decreased white blood cell counts, increases in serum transaminase, hypersensitivity

Long term: Not available.

Known Clinical Effects: Not available

EU Indication of danger: Not classified.

Emergency overview

Seek medical attention in case of accidental exposure or overdose. The product is generally safe when used as prescribed.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential of exposure in your workplace.

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Precautionary statements

General advice: Seek medical attention in case of accidental exposure or overdose.

Eyes: Avoid contact with eyes.

Skin Contact: Avoid skin contact.

Inhalation: Not intended for inhalation.

Ingestion: Generally safe at recommended doses. Dilute before use. In case of overdose, seek medical attention immediately.

Storage: There are no special storage conditions for safety. For product integrity, store under conditions specified on the label.

Disposal: Dispose of in accordance with applicable laws and regulations.

3. Composition/Information on ingredients

Chemical name	CAS-No	Weight mg	Trade Secret
Cimetidine	51481-61-9	300	
Ethanol, USP	64-17-5		X
Hydrochloric Acid	7647-01-0		
Methylparaben	99-76-3		X
Propylparaben	94-13-3		X
Propylene Glycol	57-55-6		X
Sodium Saccharin	6155-57-3		X
Sodium Chloride	7647-14-5		X
Sodium Hydroxide	1310-73-2		X
Sodium Phosphate Dibasic	7558-79-4		X
Sorbitol Solution	Mixture		X
PFC Berry Citrus Sweet Blend	Mixture		X
FD&C Yellow No. 6	2783-94-0		X

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4. First aid measures

Description of necessary first-aid measures

Eye contact:

Flush with running water for 15 minutes holding eyelids open. Contact medical personnel if irritation persists.

Skin contact:

Wash contaminated area thoroughly. If irritation persists, contact medical personnel.

Inhalation:

Remove to fresh air and contact medical personnel.

Ingestion:

The product is intended for ingestion. In the case of accidental ingestion or overdose, contact medical personnel.

Most important symptoms/effects, acute and delayed

The most common effects may include diarrhea, headaches, dizziness, somnolence, reversible confusions states, gynecomastia, reversible impotence, decreased white blood cell counts, increases in serum transaminase, hypersensitivity

Indication of immediate medical attention and special treatment needed, if necessary

Immediate medical attention is required if overdose is suspected.

Notes to Physician: NA

5. Fire-fighting measures

Suitable extinguishing media:

Use carbon dioxide, dry chemical or water spray.

Specific hazards arising from the chemical

Not applicable.

Explosion data:

Not applicable

Protective equipment and precautions for firefighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (See Section 8). Minimize exposure.

Environmental precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and materials for containment and cleaning up

- Methods for containment:
- Methods for cleaning up:

Isolate area around spill as specified by site procedures. Absorb the liquid with suitable material. Dispose of spill material in accordance with applicable federal, state or local regulations.

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7. Handling and storage

Precautions for safe handling

Handling:

No special handling required for hazard control under conditions of normal product use.

Conditions for safe storage, including any incompatibilities

Storage:

No special storage required for hazard control. For product protection, follow storage recommendations on the case label, primary product label and insert.

Incompatible products:

As a precautionary measure, keep away from strong oxidizers.

8. Exposure controls/personal protection

Control parameters

Exposure guidelines: The exposure guidelines listed below are for the individual components and not the product itself.

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Cimetidine	Not available	Not available	Not Available
Ethanol, USP	Not Available	1900 mg/m ³ TWA (200 Proof)	1000 ppm TWA
Hydrochloric Acid	2 ppm Ceiling	Not Available	5 ppm Ceiling
Methylparaben	Not Available	Not Available	Not Available
Propylparaben	Not Available	Not Available	Not Available
Propylene Glycol	Not Available	10 mg/m ³ TWA (WEEL)	Not Available
Sodium Saccharin	Not Available	Not Available	Not Available
Sodium Chloride	Not Applicable	Not Applicable	Not Applicable
Sodium Hydroxide	2 mg/m ³	2 mg/m ³ TWA	Not Available
Sodium Phosphate Dibasic	Not Available	Not Available	Not Available
Sorbitol Solution	Not Available	Not Available	Not Available
PFC Berry Citrus Sweet Blend	Not Available	Not Available	Not Available
FD&C Yellow No. 6	Not Available	Not Available	Not Available

Appropriate engineering controls

Engineering measures:

Engineering controls should be used to limit exposure.

Individual protection measures, such as personal protective equipment

Eye/face protection:

Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

Skin and body protection:

Not required under normal conditions of use. Wear protective clothing when working with large quantities.

Respiratory protection:

Not required under normal use of the product.

Hygiene measures:

Wash hands thoroughly after use.

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9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state: Solution
Odor: Slight Fruity/Berry
Appearance: Clear, light orange liquid
Odor threshold: Not available

Property	Values	Remarks/Method
pH	Not available	
Melting point/range	Not applicable	
Boiling point/boiling range	Not available	
Flash point	Not applicable	
Evaporation rate	Not applicable	
Flammability (solid, gas)	Not applicable	
Flammability limits in air	Not applicable	
-upper flammability limit	Not applicable	
-lower flammability limit	Not applicable	
Vapor pressure	Not applicable	
Vapor density	Not applicable	
Specific gravity	Not applicable	
Water solubility	Not applicable	
Solubility in other solvents	Not applicable	
Partition coefficient: n-octanol/water	Not applicable	
Autoignition temperature	Not applicable	
Decomposition temperature	Not applicable	
Viscosity	Not available	
Flammable properties	Not applicable	
Explosive properties	Not applicable	
Oxidizing properties	Not applicable	

Other information VOC content (%)

2.8% Alcohol

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10. Stability and reactivity

Reactivity	Stable at normal conditions
Chemical stability	Stable at normal conditions
Possibility of hazardous reactions	Stable at normal conditions
Conditions to avoid	None known
Incompatible materials	As a precautionary measure, keep away from strong oxidizers.
Hazardous decomposition products	None known

11. Toxicological information

Information on likely routes of exposure

Product information:

- Inhalation: Not Available
- Eye contact: Not Available
- Skin contact: Not Available
- Ingestion: Not Available

The information in the table below is for the individual components and not the product.

Chemical name	LD50 oral	LD50 dermal	LC50 inhalation
Cimetidine	5 mg/kg Rat	Not Available	Not Available
Ethanol, USP	3632 mg/kg Mouse	Not Available	20000 ppm 10hr. Rat
Hydrochloric Acid	238-277 mg/kg Rat	>5101 mg/kg Rabbit	3124 ppm/hour Rat
Methylparaben	2100 mg/kg Rat	No skin irritation 24 hr. Rabbit	Not Available
Propylparaben	7500 mg/kg Mouse	Not Available	Not Available
Propylene Glycol	20000 mg/kg Rat	20800 mg/kg Rabbit	Not Available
Sodium Saccharin	14200 mg/kg Rat	Not Available	Not Available
Sodium Chloride	3 g/kg Rat	>10 g/kg Rabbit	>42 g/m ³ Rat
Sodium Hydroxide	Not Available	Severe burns 24 hr Rabbit	Not Available
Sodium Phosphate Dibasic	17 g/kg Rat	Not Available	Not Available
Sorbitol Solution	Not Available	Not Available	Not Available
PFC Berry Citrus Sweet Blend	Not Available	Not Available	Not Available
FD&C Yellow No. 6	Not Available	Not Available	Not Available

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Symptoms related to the physical, chemical and toxicological characteristics

None

Delayed and immediate effects and also chronic effects from short and long term exposure

- Sensitization: No data available
- Mutagenic effects: No data available
- Carcinogenicity: Not carcinogenic
- Reproductive toxicity: No data available
- STOT – single exposure: No data available
- STOT – repeated exposure: No data available
- Aspiration hazard: No data available

Numerical measures of toxicity – product

- No data available

12. Ecological information

Ecotoxicity:

Environmental properties have not been thoroughly evaluated. Releases to the environment should be avoided.

Persistence and Degradability

No data available

Bioaccumulation

No data available

Other adverse effects:

No data available.

The following table lists the data for the individual components, if available.

Chemical name	Toxicity to algae	Toxicity to fish	Toxicity to micro-organisms	Daphnia Magna (water flea)
Cimetidine	Not Available	Not Available	Not Available	Not Available
Ethanol, USP	Not Available	Not Available	Not Available	Not Available
Hydrochloric Acid	Not Available	282 mg/l – 96h Gambusia affinis (Mosquito fish)	Not Available	Not Available
Methylparaben	91 mg/L 72 hr. Pseudokirchneriella subcapitata	59.5 mg/L 89 hr. Oryzias latipes	Not Available	41.1 mg/L 48 hr.
Propylparaben	7.6 mg/L 72 hr. Pseudokirchneriella subcapitata	6.4 mg/L 96 hr. Danio rerio	Not Available	15.4 mg/L 72hr.
Propylene Glycol	Not Available	52930 mg/L 96 hr Pimephales Promelas	Not Available	13020 mg/L 48 hr.

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Chemical name	Toxicity to algae	Toxicity to fish	Toxicity to micro-organisms	Daphnia Magna (water flea)
Sodium Saccharin	Not Available	Not Available	Not Available	Not Available
Sodium Chloride	Not Available	7650 mg/l 96h Pimephals prome	Not Available	1000 mg/l 48 h
Sodium Hydroxide	Not Available	125 mg/l 96 h Gambusia affinis (Mosquito fish)	Not Available	34.59 mg/l 96 h
Sodium Phosphate Dibasic	Not Available	Not Available	Not Available	Not Available
Sorbitol Solution	Not Available	Not Available	Not Available	Not Available
PFC Berry Citrus Sweet Blend	Not Available	Not Available	Not Available	Not Available
FD&C Yellow No. 6	Not Available	Not Available	Not Available	Not Available

13. Disposal considerations

Waste disposal methods

Dispose of waste in accordance with all federal, state and local regulations.

Contaminated packaging

Dispose of waste in accordance with all federal, state and local regulations.

14. Transport information

Notes:

Not regulated for transport under USDOT, IATA, TDG, IMDG or other regulations.

15. Regulatory information

International inventories

Legend

U.S. Federal regulations;

Not applicable

Chemical name	California Listed	TSCA Listed (8b)	EINECS	Sara 311/312
Cimetidine	No	No	No	Not Applicable
Ethanol, USP	No	Listed	Listed	Not Applicable
Hydrochloric Acid	No	Listed	Listed	Not Applicable
Methylparaben	No	Listed	Listed	Not Applicable
Propylparaben	No	Listed	Listed	Not Applicable
Propylene Glycol	No	Listed	Listed	Not Applicable
Sodium Saccharin	No	Listed	Listed	Not Applicable

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Chemical name	California Listed	TSCA Listed (8b)	EINECS	Sara 311/312
Sodium Chloride	No	Listed	Listed	Not Applicable
Sodium Hydroxide	No	Listed	Listed	Not Applicable
Sodium Phosphate Dibasic	No	Listed	Listed	Not Applicable
Sorbitol Solution	No	Not Listed	Not Listed	Not Applicable
PFC Berry Citrus Sweet Blend	No	Not Listed	Not Listed	Not Applicable
FD&C Yellow No. 6	No	Not Listed	Not Listed	Not Applicable

SARA 311/312 Hazard categories:

Not Applicable

Clean Water Act

This product **does not** contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

CERCLA No components are listed under CERCLA.

California Proposition 65:

This product does not contain any ingredients listed in Proposition 65 chemicals.

U.S. state Right-to-Know regulations

“X” designates that the ingredients are listed on the state Right-to-Know list

Chemical name	New Jersey	Massachusetts	Pennsylvania	Illinois	Rhode Island
Cimetidine					
Ethanol, USP	X	X	X	X	X
Hydrochloric Acid					
Methylparaben	X		X		
Propylparaben	X		X		
Propylene Glycol	X		X		
Sodium Saccharin	X	X	X		
Sodium Chloride					
Sodium Hydroxide	X	X	X	X	X
Sodium Phosphate Dibasic	X	X	X		
Sorbitol Solution	X		X		
PFC Berry Citrus Sweet Blend					
FD&C Yellow No. 6					

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U.S. EPA label information:
Not applicable

16. Other information

Prepared by: Pharmaceutical Associates Inc.
Issuing date: 06AUG2020

Revision 00
Revision date: 06AUG2020
Revision note: New SDS

Revision 01
Revision date: 10MAY2021
Revision note: Added NDCs 0121-0649-05; 0121-0649-40; 0121-1298-93; 0121-1298-40

Revision 02
Revision date: 02MAY2022
Revision note: Corrected clinical uses, corrected Ethanol reference from 200 Proof to USP grade Ethanol and corrected typos.

General Disclaimer

The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as 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 material or in any process, unless specified in the text.

End of Safety Data Sheet