


SAFETY DATA SHEET

Cimetidine Hydrochloride Oral Solution, 300 mg/5 mL

1. IDENTIFICATION

Product Identifier:	Cimetidine Hydrochloride Oral Solution, 300 mg/5 mL
Synonyms:	<i>N</i> "-cyano- <i>N</i> -methyl- <i>N</i> '-[2-[[[5- methyl-1 <i>H</i> -imidazol-4-yl) methyl]thio]-ethyl]
National Drug Code (NDC):	50383-050-08 50383-050-16
Recommended Use:	Cimetidine Hydrochloride Oral Solution is indicated in: short-term treatment of active duodenal ulcer, maintenance therapy for duodenal ulcer patients at reduced dosage after healing of active ulcer, short-term treatment of active benign gastric ulcer, erosive gastroesophageal reflux disease (GERD), and the treatment of pathological hypersecretory conditions (i.e., Zollinger-Ellison Syndrome, systemic mastocytosis, multiple endocrine adenomas).
Company:	Akorn, Inc. 1925 West Field Court, Suite 300 Lake Forest, Illinois 60045
Contact Telephone:	1-800-932-5676
E mail:	customer.service@akorn.com
Emergency Phone Number:	CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. HAZARD(S) IDENTIFICATION

Physical Hazards:	Not classifiable.	
Health Hazards:	Skin Corrosion/Irritation	Category 2
	Serious Eye Damage/Eye Irritation	Category 2A
Symbol(s):		
Signal Word:	Warning.	
Hazard Statement(s):	H315 Causes skin irritation. H319 Causes serious eye irritation.	
Precautionary Statement(s):	P264 Wash hands and other exposed areas thoroughly after handling. P280 Wear protective gloves/protective clothing/eye protection/face protection.	

SAFETY DATA SHEET

Cimetidine Hydrochloride Oral Solution, 300 mg/5 mL

P303 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

+
P353

P305 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

+
P338

P332 If skin irritation occurs: Get medical advice/attention.

+
P313

P337 IF eye irritation persists: Get medical advice/attention.

+
P313

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazards Not Otherwise Classified:

None.

Supplementary Information:

None.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	Chemical Name	CAS Number	Chemical Formula	Molecular Weight	Percentage
Cimetidine	N"-cyano-N-methyl-N'-[2-[(5-methyl-1 H-imidazol-4-yl) methyl]thio]-ethyl]	51481-61-9	C ₁₀ H ₁₆ N ₆ •HCl	288.80	6%
Alcohol	Ethyl alcohol	64-17-5	C ₂ H ₅ OH	46.07	2.8%

The formula also contains FD&C Yellow No. 6, Hydrochloric Acid, Methylparaben, Natural Orange Flavor, Polyoxyethylene, Polyoxypropylene Glycol, Propylene Glycol, Propylparaben, Purified Water, Saccharin Sodium, Sodium Chloride, Dibasic Sodium Phosphate Anhydrous, and Sorbitol. The pH range is 5.1 to 5.7.

4. FIRST AID MEASURES

Ingestion:

If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

SAFETY DATA SHEET

Cimetidine Hydrochloride Oral Solution, 300 mg/5 mL

Eye Contact:	Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Skin Contact:	Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Inhalation:	Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Protection of First-Aiders:	Use personal protective equipment (see section 8).
Signs and Symptoms:	Solution is intended for human consumption under guidance of a physician. Solution is not considered hazardous under normal conditions.
Medical Conditions Aggravated by Exposure:	No data available.
Notes to Physician:	Treat supportively and symptomatically.

5. FIREFIGHTING MEASURES

Suitable Extinguishing Media:	Use water, carbon dioxide, dry chemical or alcohol-resistant foam as necessary.
Unsuitable Extinguishing Media:	Not determined.
<u>Specific Hazards Arising from the Chemical</u>	
Hazardous Combustion Products:	No data available.
Other Specific Hazards:	Closed containers may explode from the heat of fire.
Special Protective Equipment and Precautions for Firefighters:	Wear self-contained breathing apparatus and full and protective gear.

SAFETY DATA SHEET

Cimetidine Hydrochloride Oral Solution, 300 mg/5 mL

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions:	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate personal protective equipment and clothing.
Personal Protective Equipment:	For personal protection see section 8.
Methods for Cleaning Up:	Absorb with inert material. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations.
Environmental Precautions:	Contain material and prevent release to basements, confined spaces, waterways or soil.
Reference to Other Sections:	Refer to Sections 8, 12 and 13 for further information.

7. HANDLING AND STORAGE

Precautions for Safe Handling:	Handle in accordance with product label and/or product insert information and in accordance with good industrial hygiene and safety practices.
Conditions for Safe Storage, Including Any Incompatibilities:	Store at 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature]. Dispense in light-resistant, tight container.
Specific End Use:	Pharmaceutical drug product.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Occupational Exposure Guidelines:

Ingredient	Type	Value
Cimetidine	TWA	500 mcg/m ³
Alcohol	OSHA PEL	1,000 ppm; 1,900 mg/m ³
	NIOSH IDLH	3,300 ppm
	NIOSH REL	1,900 mg/m ³
	ACGIH TWA	1,000 ppm
	ACGIH TLV STEL	1,000 ppm

OSHA: Occupational Safety and Health Administration; PEL: Permissible Exposure Limits; NIOSH: National Institute for Occupational Safety and Health; IDLH: Immediately Dangerous to Life or Health; REL: Recommended Exposure Limits. ACGIH: American Conference of Governmental Industrial Hygienists; TLV: Threshold Limit Value; STEL: Short Term Exposure Limit; TWA: Time Weighted Average.

Engineering Controls:	None required for the normal use of this product. Engineering controls should be used as the primary means to control exposures.
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SAFETY DATA SHEET

Cimetidine Hydrochloride Oral Solution, 300 mg/5 mL

Respiratory Protection:	None required for the normal use of this product. Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
Eyes Protection:	None required for the normal use of this product. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
Hand Protection:	None required for the normal use of this product. Chemically compatible gloves should be worn when working with large quantities. For handling solutions ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
Skin Protection:	None required for the normal use of this product. Wear protective laboratory coat, apron, or disposable garment when working with large quantities.
General Hygiene Considerations:	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State/Color:	Yellow liquid.
Odor:	Orange odor.
Odor Threshold:	No data available.
pH:	5.1 to 5.7.
Melting Point:	No data available.
Freezing Point:	No data available.
Boiling Point:	No data available.
Flash Point:	No data available.
Evaporation Rate:	Same as water.
Flammability (solid, gas):	No data available.
Flammability Limit - Lower:	No data available.
Flammability Limit - Upper:	No data available.
Vapor Pressure:	No data available.
Vapor Density:	No data available.
Relative Density:	No data available.
Solubility(ies):	Soluble in water.
Partition Coefficient (n-octanol/water):	No data available.
Auto-Ignition Temperature:	No data available.

SAFETY DATA SHEET

Cimetidine Hydrochloride Oral Solution, 300 mg/5 mL

Decomposition Temperature: No data available.
Viscosity: No data available.

10. STABILITY AND REACTIVITY

Reactivity: The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical Stability: Stable under recommended storage conditions.

Possibility of Hazardous Reactions: No data available.

Conditions to Avoid (e.g., static discharge, shock, or vibration): No data available.

Incompatible Materials: Strong oxidizing agents.

Hazardous Decomposition Products: No data available.

11. TOXICOLOGICAL INFORMATION

Information on the Likely Routes of Exposure

Inhalation: No data available.
Ingestion: No data available.

Skin Contact: Causes skin irritation.

Eye Contact: Causes eye irritation.

Symptoms Related to the Physical, Chemical and Toxicological Characteristics: See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

Delayed and Immediate Effects of Exposure: No data available.

Acute Toxicity

Not fully established. This product is a mixture that has not been fully tested as a whole. Information provided herein is derived from the approved product insert and/or supplier SDS for active ingredients.

Ingredient	Species	Route	Test Type	Dosage
Cimetidine	Rat	Oral	LD ₅₀	5,000 mg/kg
Alcohol	Rat	Oral	LD ₅₀	7,060 mg/kg
	Mouse	Oral	LD ₅₀	3,450 mg/kg

Irritation / Sensitization

Ingredient	Study Type	Species	Severity
No data available	No data available	No data available	No data available

SAFETY DATA SHEET

Cimetidine Hydrochloride Oral Solution, 300 mg/5 mL

Repeated Dose Toxicity

Ingredient	Duration	Species	Route	Dosage	Test Type	Target Organ
No data available	No data available	No data available	No data available	No data available	No data available	No data available

Reproduction and Developmental Toxicity

Ingredient	Study Type	Species	Route	Dosage	Test Type	Effect(s)
No data available	No data available	No data available	No data available	No data available	No data available	No data available

Genetic Toxicity

Ingredient	Study Type	Cell Type / Organism	Result
No data available	No data available	No data available	No data available

Aspiration Hazard:

No data available.

Toxicokinetics/Metabolism:

No data available.

Target Organ Effects:

No data available.

Systemic Effects:

No data available.

Reproductive Effects:

Pregnancy Category B. There are no adequate and well-controlled studies in pregnant women. Because animal reproductive studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Carcinogenicity:

No data available.

National Toxicology Program (NTP):

Not considered to be a carcinogen.

International Agency for Research on Cancer (IARC):

Not considered to be a carcinogen.

Occupational Safety and Health Administration (OSHA):

Not considered to be a carcinogen.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity

Ingredient	Species	Test Type	Dosage	Duration
Alcohol	Water flea (Daphnia magna)	EC ₅₀	7.7-11.2 mg/l	48 hours
	Fathead minnow (Pimephales promelas)	LC ₅₀	>100 mg/l	96 hours

Terrestrial Toxicity:

No data available.

Persistence and Degradability:

No data available.

Bioaccumulative Potential:

No data available.

Mobility in Soil:

No data available.

Mobility in Environment:

No data available.

Other Adverse Effects:

No data available.



SAFETY DATA SHEET

Cimetidine Hydrochloride Oral Solution, 300 mg/5 mL

13. DISPOSAL CONSIDERATIONS

Do not empty into drains; dispose of this material and its container in a safe way. Dispose of all waste in accordance with Federal, State and Local regulations.

14. TRANSPORT INFORMATION

Department of Transportation (DOT): Not regulated as a hazardous material.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
No applicable	No applicable	No applicable	No applicable

International Air Transport Association (IATA): Not regulated as a dangerous good.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
No applicable	No applicable	No applicable	No applicable

International Maritime Dangerous Good (IMDG): Not regulated as a dangerous good.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
No applicable	No applicable	No applicable	No applicable

15. REGULATORY INFORMATION

US FEDERAL REGULATIONS

Toxic Substance Control Act (TSCA):

Ingredient	Inventory
Cimetidine	No
Alcohol	Yes

CERCLA Hazardous Substance:

Ingredient	Reportable Quantity
Not applicable	Not applicable

EPCRA Extremely Hazardous Substances and Toxic Chemicals:

Ingredient	Section 302	Section 313
Not applicable	Not applicable	Not applicable

U.S. STATE RIGHT-TO-KNOW REGULATIONS

Ingredient	New Jersey	Pennsylvania	Massachusetts
Cimetidine	Listed	Listed	Not listed
Alcohol	Listed	Listed	Listed

California Proposition 65: Alcohol is listed to cause cancer, birth defects and other reproductive harm.

SAFETY DATA SHEET

Cimetidine Hydrochloride Oral Solution, 300 mg/5 mL

16. OTHER INFORMATION

See footer of this document for Revision Date and Revision Number.

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