

SAFETY DATA SHEET**1. Identification**

Product Identifier: Ranitidine Syrup (Ranitidine Oral Solution, USP)

Synonyms: 1,1-Ethenediamine, N-[2-[[[5-[(dimethylamino)methyl]-2-furanyl]methyl]thio]ethyl]-N'-methyl-2-nitro-, monohydrochloride

National Drug Code (NDC): 50383-051-11
50383-051-12
50383-051-16

Recommended Use: Pharmaceutical.

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: Flammable liquid and vapour Category 3

Health Hazards: Not classifiable.

Symbol(s):



Signal Word:

Warning.

Hazard Statement(s):

H226 Flammable liquid and vapour

Precautionary Statement(s):

P210 Keep away from heat/sparks/open flames/hot surfaces. No smoking.

P233 Keep container tightly closed.

P241 Use explosion-proof electrical/ventilating/lighting/.../equipment.

P242 Use only non-sparking tools.

P243 Take precautionary measures against static discharge.

P280 Wear protective gloves/eye protection/face protection.

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P303 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/
 + shower.
 P361
 +
 P353

P370 In case of fire: Use carbon dioxide, dry powder
 + or foam to extinguish.
 P378

P403 Store in a well-ventilated place. Keep cool.
 +
 P235

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

Hazards Not Otherwise Classified: Not classifiable.
Supplementary Information: None.

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Ranitidine HCl	66357-59-3	1,1-Ethenediamine, N-[2-[[[5-[(dimethylamino)methyl]-2-furanyl]methyl]thio]ethyl]-N'-methyl-2-nitro-, monohydrochloride	C ₁₃ H ₂₂ N ₄ O ₃ S•HCl	350.87	1.68%

*The formula also contains Alcohol, 7.5% w/v; Butylparaben, Dibasic Sodium Phosphate, Hypromellose, Monobasic Potassium Phosphate, Natural Peppermint Flavor, Propylparaben, Purified Water, Saccharin Sodium, Sodium Chloride, and Sorbitol.

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.

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

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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:

None.

Notes to Physician:

Treat supportively and symptomatically.

5. Firefighting Measures

Suitable Extinguishing Media:

Carbon dioxide, dry chemical or foam extinguishers are recommended. Do not use water extinguishers. Water jets may intensify the fire or be ineffective.

Unsuitable Extinguishing Media:

This product is flammable. Fire and explosions might result if vapors are allowed to accumulate in the vicinity of a source of ignition.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products:

Not determined.

Other Specific Hazards:

Not determined.

Special Protective Equipment/Precautions for Firefighters:

Wear self-contained breathing apparatus and full and protective gear.

6. Accidental Release Measures

Personal Precautions:

Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.

Personal Protective Equipment:

For personal protection see section 8.

Methods for Cleaning Up:

Stop leak and eliminate all sources of ignition (no smoking, sparks or flames). Fence or cordon the affected area and do not allow individuals to touch or walk through the spilled material unless wearing appropriate protective clothing. Wear protective clothing

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and equipment consistent with degree of hazard. Vapor-suppressing foam or water spray may be used to control vapors as appropriate.

Environmental Precautions: No data available.

Reference to Other Sections: Refer to Sections 8, 12 and 13 for further information.

7. Handling and Storage

Precautions for Safe Handling: This material contains flammable components. Ensure that any area in which this material is handled has sufficient ventilation to avoid the buildup of vapors and control employee potential exposure to volatiles below National Occupational Exposure Limits.

Conditions for Safe Storage, Including Any Incompatibilities: Avoid contact with ignition sources. The liquid might ignite in contrast with some types of ignition sources.

Specific End Use: Pharmaceuticals.

8. Exposure Controls/Personal Protection

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Ranitidine HCl	Not established.

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Respiratory Protection: 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: Not required for the normal use of this product. Safety glasses with side shields are recommended. 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: Not required for the normal use of this product. Chemically compatible gloves. 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: Not required for the normal use of this product. Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

9. Physical and Chemical Properties

Physical State/Color: Clear, pale yellow liquid.
Odor: Peppermint flavor.
Odor Threshold: No data available.
pH: No data available.
Melting Point: No data available.
Freezing Point: No data available.
Boiling Point: No data available.
Flash Point: 49°C – 50°C.
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: >1.
Relative Density: No data available.
Solubility(ies): Soluble in water.
Partition Coefficient (n-octanol/water): No data available.
Auto-Ignition Temperature: No data available.
Decomposition Temperature: No data available.
Viscosity: No data available.

10. Stability and Reactivity

Reactivity: No data available.

Chemical Stability: Stable under recommended storage conditions. Avoid direct sunlight, conditions that might generate heat and sources of ignition.

Possibility of Hazardous Reactions: No data available.

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

Incompatible Materials: Strong oxidizer. Avoid excessive heat.

Hazardous Decomposition Products: Does not undergo explosive decomposition.

11. Toxicological Information**Information on the Likely Routes of Exposure:**

Inhalation: May Causes irritation to the respiratory system.

Ingestion: No data available.

Skin Contact: May produce allergic skin reactions.

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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 – Oral:	No data available.
Acute Toxicity – Dermal:	No data available.
Acute Toxicity – Inhalation:	No data available.
Corrosivity:	No data available.
Dermal Irritation:	No data available.
Eye Irritation:	No data available.
Sensitization:	No data available.
Toxicokinetics/Metabolism:	No data available.
Target Organ Effects:	No data available.
Reproductive Effects:	No data available.
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.
Mutagenicity:	No data available.
Aspiration Hazard:	Based on available data, the classification criteria are not met.

12. **Ecological Information**

Ecotoxicity

Aquatic:	No data available.
Terrestrial:	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.

13. **Disposal Considerations**

Dispose of all waste in accordance with Federal, State and Local regulations.

14. Transport Information

UN Number:	Not applicable.
UN Proper Shipping Name:	Not applicable.
Transport Hazard Class(es):	Not applicable.
Packing Group:	Not applicable.
Department of Transportation:	Not regulated as a hazardous material.
International Air Transport Association (IATA):	Not regulated as a dangerous good.
International Maritime Dangerous Good (IMDG):	Not regulated as a dangerous good.

15. Regulatory Information**US Federal Regulations:**

Toxic Substance Control Act (TSCA):	Not listed.
CERCLA Hazardous Substance and Reportable Quantity:	Not listed.
SARA 313:	Not listed.
SARA 302:	Not listed.

State Regulations

California Proposition 65:	Not listed.
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16. Other Information

NFPA Rating:	
Health:	0
Flammability:	2
Reactivity:	0

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