


# SAFETY DATA SHEET

## Ranitidine Syrup (Ranitidine Oral Solution, USP)

### 1. IDENTIFICATION

<b>Product Identifier:</b>	Ranitidine Syrup (Ranitidine Oral Solution, USP)	
<b>Synonyms:</b>	1,1-Ethenediamine, N-[2-[[[5-[(dimethylamino)methyl]-2-furanyl]methyl]thio]ethyl]-N'-methyl-2-nitro-, monohydrochloride	
<b>National Drug Code (NDC):</b>	50383-051-11 50383-051-12 50383-051-16	
<b>Recommended Use:</b>	Pharmaceutical. Ranitidine Syrup is indicated for treating heartburn or irritation of the esophagus caused by gastroesophageal reflux disease (GERD). It may be used to treat and maintain healing of severe irritation of the esophagus (erosive esophagitis). It may be used for short-term treatment of stomach or small intestinal ulcers. It may be used to maintain healing of stomach or small intestinal ulcers. It may be used to treat conditions that cause your body to make too much stomach acid (eg, Zollinger-Ellison syndrome).	
<b>Company:</b>	Akorn, Inc. 1925 West Field Court, Suite 300 Lake Forest, Illinois 60045	
<b>Contact Telephone:</b>	1-800-932-5676	
<b>E mail:</b>	customer.service@akorn.com	
<b>Emergency Phone Number:</b>	CHEMTREC 1-800-424-9300 (U.S. and Canada)	

### 2. HAZARD(S) IDENTIFICATION

<b>Physical Hazards:</b>	Flammable liquid and vapors	Category 3
<b>Health Hazards:</b>	Not classifiable.	
<b>Symbol(s):</b>		
<b>Signal Word:</b>	Warning.	
<b>Hazard Statement(s):</b>	H226 Flammable liquid and vapor.	
<b>Precautionary Statement(s):</b>	P210 Keep away from heat/sparks/open flames/hot surfaces. No smoking.	
	P233 Keep container tightly closed.	

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- 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/protective clothing/eye protection/face protection.
- P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower.
- P370 + P378 In case of fire: Use carbon dioxide, dry powder or foam to extinguish.
- P403 + P235 Store in a well-ventilated place. Keep cool.
- P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

**Hazards Not Otherwise Classified:**  
**Supplementary Information:**

Not classifiable.  
 None.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	Synonyms	CAS Number	Chemical Formula	Molecular Weight	Percentage
Ranitidine Hydrochloride	1,1-Ethenediamine, N-[2-[[[5-[(dimethylamino)methyl]-2-furanyl]methyl]thio]ethyl]-N'-methyl-2-nitro-, monohydrochloride	66357-59-3	C <sub>13</sub> H <sub>22</sub> N <sub>4</sub> O <sub>3</sub> S·HCl	350.87	1.68%
Alcohol	Ethyl alcohol	64-17-5	C <sub>2</sub> H <sub>5</sub> OH	46.07	7.5%

The formula also contains Butylparaben, Dibasic Sodium Phosphate, Hypromellose, Monobasic Potassium Phosphate, Natural Peppermint Flavor, Propylparaben, Purified Water, Saccharin Sodium, Sodium Chloride, and Sorbitol.

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### 4. FIRST AID MEASURES

<b>Ingestion:</b>	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.
<b>Eye Contact:</b>	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.
<b>Skin Contact:</b>	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.
<b>Inhalation:</b>	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.
<b>Protection of First-Aiders:</b>	Use personal protective equipment (see section 8).
<b>Signs and Symptoms:</b>	Aphthous ulcer, grossly obvious gingivitis, trauma, mucocele, short frenum, stomatitis, glossitis, dry mouth, hypesthesia, glossal edema, paresthesia.
<b>Medical Conditions Aggravated by Exposure:</b>	Not determined.
<b>Notes to Physician:</b>	Treat supportively and symptomatically.

### 5. FIREFIGHTING MEASURES

<b>Suitable Extinguishing Media:</b>	Use water, carbon dioxide, dry chemical or foam as necessary.
<b>Unsuitable Extinguishing Media:</b>	Not determined.

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### Specific Hazards Arising from the Chemical

<b>Hazardous Combustion Products:</b>	Keep ignition sources away. Protect against electrostatic charges. Toxic gases and vapors may be released if involved in a fire.
<b>Other Specific Hazards:</b>	Closed containers may explode from the heat of fire.
<b>Special Protective Equipment and Precautions for Firefighters:</b>	Wear self-contained breathing apparatus and full and protective gear.

### 6. ACCIDENTAL RELEASE MEASURES

<b>Personal Precautions:</b>	Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.
<b>Personal Protective Equipment:</b>	For personal protection see section 8.
<b>Methods for Cleaning Up:</b>	Absorb with inert material. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations.
<b>Environmental Precautions:</b>	Contain material and prevent release to basements, confined spaces, waterways or soil.
<b>Reference to Other Sections:</b>	Refer to Sections 8, 12 and 13 for further information.

### 7. HANDLING AND STORAGE

<b>Precautions for Safe Handling:</b>	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.
<b>Conditions for Safe Storage, Including Any Incompatibilities:</b>	Store between 4° and 25°C (39° and 77°F). Do not freeze. Dispense in tight, light-resistant containers as defined in the USP/NF. Store away from oxidizing agents and acids.
<b>Specific End Use:</b>	Pharmaceutical drug product.

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Occupational Exposure Guidelines:**

Ingredient	Type	Value
Ranitidine Hydrochloride	STEL	50 mcg/m <sup>3</sup>
	TWA	500 mcg/m <sup>3</sup>
Alcohol	OSHA PEL	1,000 ppm; 1,900 mg/m <sup>3</sup>
	NIOSH IDLH	3,300 ppm
	NIOSH REL	1,900 mg/m <sup>3</sup>
	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:**

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

**Respiratory Protection:**

Not 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:**

Not 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:**

Not required for the normal use of this product. Wear chemically compatible gloves for handling solutions and 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.

**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.

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**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° to 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:	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):	Keep away from heat, spark, flames, and other sources of ignition.
Incompatible Materials:	Oxidizing substances.
Hazardous Decomposition Products:	Toxic gases and vapors may be released if involved in a fire.

**11. TOXICOLOGICAL INFORMATION****Information on the Likely Routes of Exposure**

Inhalation:	May cause irritation to the respiratory system.
Ingestion:	No data available.
Skin Contact:	May produce allergic skin reactions.
Eye Contact:	Causes eye irritation.

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**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
Ranitidine Hydrochloride	Rat	Oral	LD <sub>50</sub>	4,190 mg/kg
	Mouse	Oral	LD <sub>50</sub>	1,100 mg/kg
	Guinea Pig	Oral	LD <sub>50</sub>	2,500 mg/kg
	Mouse	Oral	LD <sub>50</sub>	2,000 mg/kg
Alcohol	Rat	Oral	LD <sub>50</sub>	2,404 mg/kg

**Irritation / Sensitization**

Ingredient	Study Type	Species	Severity
Ranitidine Hydrochloride	Irritancy Test (Eye)	Rabbit	Minimal
	Optimization Test (Skin)	Guinea Pig	Weak
	Sensitization Test (Skin)	Guinea Pig	Non-sensitizing

**Repeated Doses 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.

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<b>Reproductive Effects:</b>	Pregnancy Category B. Reproduction studies have been performed in rats and rabbits at doses up to 160 times the human dose and have not revealed evidence of harm to fetus.
<b>Carcinogenicity:</b>	There was no indication of tumorigenic or carcinogenic effects in life span studies in mice and rats at dosages up to 2,000 mg/kg/day.
<b>National Toxicology Program (NTP):</b>	Not considered to be a carcinogen.
<b>International Agency for Research on Cancer (IARC):</b>	Not considered to be a carcinogen.
<b>Occupational Safety and Health Administration (OSHA):</b>	Not considered to be a carcinogen.

### 12. ECOLOGICAL INFORMATION

#### Aquatic Toxicity

Ingredient	Species	Test Type	Dosage	Duration
Ranitidine Hydrochloride	No data available.	No data available.	No data available.	No data available.
Alcohol	Water flea ( <i>Daphnia magna</i> )	EC <sub>50</sub>	7.7-11.2 mg/l	48 hours
	Fathead minnow ( <i>Pimephales promelas</i> )	LC <sub>50</sub>	>100 mg/l	96 hours

<b>Terrestrial Toxicity:</b>	No data available.
<b>Persistence and Degradability:</b>	No data available.
<b>Bioaccumulative Potential:</b>	No data available.
<b>Mobility in Soil:</b>	No data available.
<b>Mobility in Environment:</b>	No data available.
<b>Other Adverse Effects:</b>	No data available.

### 13. DISPOSAL CONSIDERATIONS

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

### 14. TRANSPORT INFORMATION

#### Department of Transportation (DOT):

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Ethanol Solution	UN1170	Class 3	III





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### International Air Transport Association (IATA):

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Ethanol Solution	UN1170	Class 3	III

### International Maritime Dangerous Good (IMDG):

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Ethanol Solution	UN1170	Class 3	III

## 15. REGULATORY INFORMATION

### US FEDERAL REGULATIONS

#### Toxic Substance Control Act (TSCA):

Ingredient	Inventory
Ranitidine Hydrochloride	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
Ranitidine Hydrochloride	Listed	Listed	Not Listed
Alcohol	Listed	Listed	Listed

#### California Proposition 65:

Alcohol is listed to cause cancer, birth defects and other reproductive harm.

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### 16. OTHER INFORMATION

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

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