


### Section 1: Identification

<b>Common Name/Trade Name</b>	RANITIDINE HCL USP	
<b>Supplier Information</b>	Letco Medical, LLC 1316 Commerce Drive NW Decatur, AL 35601 1 (800) 239-5288 +1 (734) 843-4693	<b>IN CASE OF EMERGENCY:</b> Chemtrec 1 (800) 424-9300 (24 hours)
<b>Product Synonym(s)</b>	N/A	
<b>Relevant Use(s) of Product</b>	Manufacture or Compounding of Substances	

### Section 2: Hazards Identification

<b>Classification of Substance or Mixture</b>	Acute toxicity (Category 4), Eye irritation (Category 2), Specific target organ toxicity - single, Skin irritation (Category 2)	
<b>Signal Word</b>	Warning	
<b>Hazard Statement(s)</b>	H315 Causes skin irritation H317 May cause an allergic skin reaction H319 Causes serious eye irritation H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled H335 May cause respiratory irritation	
<b>Pictogram(s)</b>		
<b>Precautionary Statement(s)</b>	P280 Wear protective gloves/protective clothing/eye protection/face protection. P285 In case of inadequate ventilation wear respiratory protection. P302+P352 IF ON SKIN Wash with soap and water. P304+P340 IF INHALED Remove victim to fresh air and keep at rest in a position comfortable for breathing. P305+P351+P338 IF IN EYES Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. continue rinsing. P312 Call a POISON CENTER or doctor/physician if you feel unwell.	
<b>Hazards Not Otherwise Classified</b>	No data available	
<b>Ingredient(s) with Unknown Toxicity</b>	No data available	

### Section 3: Composition/Information on Ingredients

<b>Chemical Name</b>	N/A
<b>Common Name</b>	Ranitidine hydrochloride
<b>CAS Number</b>	66357-59-3
<b>Impurities and/or Stabilizing Additives</b>	No data available

## Section 4: First Aid Measures

<b>General Advice</b>	Personnel protection for the first Aider. Immediately remove any clothing soiled by the product. Remove breathing equipment only after contaminated clothing have been completely removed. In case of irregular breathing or respiratory arrest provide artificial respiration.
<b>If Inhaled</b>	If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
<b>In Case of Skin Contact</b>	In case of contact, immediately flush skin with plenty of water. Cover the irritated skin with an emollient. Remove contaminated clothing and shoes. Cold water may be used. Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention. Serious Skin Contact: Wash with a disinfectant soap and cover the contaminated skin with an anti-bacterial cream. Seek medical attention.
<b>In Case of Eye Contact</b>	Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used. Get medical attention.
<b>If Swallowed</b>	Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Loosen tight clothing such as a collar, tie, belt or waistband. Get medical attention if symptoms appear.
<b>Most Important Symptoms and Effects</b>	Adverse effects may include bitter taste, headache, blurred vision, constipation or diarrhea, nausea, vomiting, abdominal pain, muscle pain, dizziness, drowsiness, loss of appetite, trouble sleeping, yellow skin or eyes, skin rash, hair loss, and unusual bleeding or bruising. Possible allergic reaction to material if inhaled, ingested, or in contact with skin. Overdose effects may include the above adverse effects and abnormal gait, low blood pressure, lethargy, confusion, delirium, and hallucinations. Acute : Eye, skin, gastrointestinal and/or respiratory tract irritation. Chronic : Possible hypersensitization. Medical Conditions Aggravated by Exposure : Hypersensitivity to material, compromised immune system, active alcoholism, cardiac rhythm disturbances, porphyria, and impaired liver or kidney function. Cross Sensitivity : Persons sensitive to one of the histamine H2-receptor antagonists may be sensitive to this material as well. Target Organs : Gastrointestinal system

## Section 5: Fire Fighting Measures

<b>Suitable Extinguishing Media</b>	Suitable extinguishing Media : Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials. For safety reason unsuitable extinguishing agents Water with full jet.
<b>Special Hazards Arising From the Substance/Mixture</b>	This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.
<b>Special PPE and/or Precautions for Firefighters</b>	Specific hazards in case of fire : SMALL FIRE: Use DRY chemical powder. LARGE FIRE: Use water spray, fog or foam. Do not use water jet. Special protective equipment and precaution for fire fighters : As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

## Section 6: Accidental Release Measures

<b>Personal Precautions, Protective Equipment and Emergency Procedures</b>	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 and equipment consistent with the degree of hazard. Vapour-suppressing foam or water spray may be used to control vapours as appropriate.
<b>Methods and Materials Used for Containment</b>	Prevent entry into waterways, sewers, surface drainage systems and poorly ventilated areas.
<b>Cleanup Procedures</b>	Small Spill: Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements. Large Spill: Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.

## Section 7: Handling and Storage

<b>Precautions for Safe Handling</b>	Keep away from heat. Keep away from sources of ignition. Empty containers pose a fire risk, evaporate the residue under a fume hood. Ground all equipment containing material. Do not ingest. Do not breathe dust. Wear suitable protective clothing. In case of insufficient ventilation, wear suitable respiratory equipment. If ingested, seek medical advice immediately and show the container or the label. Avoid contact with skin and eyes.
<b>Conditions for Safe Storage</b>	Keep container tightly closed. Keep container in a cool, well-ventilated area. Do not store above 25°C (78.3°F). Store in tight, light-resistant container and keep the temperature not exceeding 26°C. This material should be handled and stored per label instructions to ensure product integrity.

## Section 8: Exposure Controls/Personal Protection

<b>Components with Workplace Control Parameters</b>	Industry : 15-minute *STEL: 50 micrograms/m <sup>3</sup> .
<b>Appropriate Engineering Controls</b>	Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit. Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures. The usual precautionary measures are to be adhered to when handling chemicals. Do not drink, eat and smoke while working. Avoid contact with the eye and skin. Keep away from food stuffs, feed and beverages.
<b>PPE - Eye/Face Protection</b>	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 is preferred. Maintain eyewash facilities in the work area.
<b>PPE - Skin Protection</b>	Protective coveralls should be worn. The sleeves should either be taped or have gloves worn over them to prevent material from contacting the skin.
<b>PPE - Body Protection</b>	Protective coveralls should be worn. The sleeves should either be taped or have gloves worn over them to prevent material from contacting the skin.
<b>PPE - Respiratory Protection</b>	Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist before handling this product. *NOISH / *MSHAApproved Respirator.

## Section 9: Physical and Chemical Properties

<b>Appearance</b>	Physical state: Crystalline powder. Color: Pale yellow color
<b>Upper/Lower Flammability or Explosive Limits</b>	No data available
<b>Odor</b>	Practically odorless or sulfur-like odor.
<b>Vapor Pressure</b>	Not found
<b>Odor Threshold</b>	Not found
<b>Vapor Density</b>	No data available
<b>pH</b>	4.5 – 6.0 (1% in water)
<b>Relative Density</b>	Not found
<b>Melting Point/Freezing Point</b>	133 - 134° C
<b>Solubility</b>	Very soluble in water, sparingly soluble in Alcohol.
<b>Initial Boiling Point and Boiling Range</b>	Not found
<b>Flash Point</b>	Not found
<b>Evaporation Rate</b>	Not found
<b>Flammability (Solid, Gas)</b>	Not found
<b>Partition Coefficient</b>	Not found
<b>Auto-Ignition Temperature</b>	Not found
<b>Decomposition Temperature</b>	140°C with decomposition
<b>Viscosity</b>	No data available

## Section 10: Stability and Reactivity

<b>Reactivity</b>	No data available
<b>Chemical Stability</b>	This product is expected to be stable.
<b>Possibility of Hazardous Reactions</b>	Avoid excessive heat. (Temperatures above 70°C may result in exothermic decomposition.)
<b>Conditions to Avoid</b>	Avoid direct sunlight, conditions that might generate heat and sources of ignition.
<b>Incompatible Materials</b>	Excess, incompatible materials.
<b>Hazardous Decomposition Products</b>	This material is combustible. When heated to decomposition, material emits toxic fumes of sox, nox and HCl. Emits toxic fumes under fire conditions.

## Section 11: Toxicological Information

<b>Acute Toxicity - LD50 Oral</b>	Acute ORAL (LD50) 4 190 mg/kg [Rat] 1 100 mg/kg [Mouse] 2500 mg/kg [Rabbit]. Chronic Toxicity : Repeated oral administration of ranitidine to rats has resulted in hyperplastic changes in the stomach, leading to adenoma and carcinoid formation, considered to be secondary to compensatory hypergastrinemia produced by extremely high doses of ranitidine. Ranitidine showed no evidence of carcinogenicity in life-span studies in mice and rats at doses up to 2000 mg/kg/day. Summary comments: Acute Potential Health Effects: Skin: May cause skin irritation. Eyes: Dust may cause eye irritation. Inhalation: Dust may cause respiratory tract irritation. Ingestion: May cause digestive tract irritation. May affect behavior, blood, cardiovascular system, urinary system, liver.
<b>Acute Toxicity - Inhalation</b>	No data available
<b>Acute Toxicity - Dermal</b>	No data available
<b>Acute Toxicity - Eye</b>	No data available
<b>Skin Corrosion/Irritation</b>	No data available
<b>Serious Eye Damage/Irritation</b>	No data available
<b>Respiratory or Skin Sensitization</b>	Causes irritation and possible sensitization. Avoid contact. Flush with copious quantities of soap and water.
<b>Germ Cell Mutagenicity</b>	No data available
<b>Carcinogenicity IARC</b>	No data available
<b>Carcinogenicity ACGIH</b>	No data available
<b>Carcinogenicity NTP</b>	No data available
<b>Carcinogenicity OSHA</b>	No data available
<b>Reproductive Toxicity</b>	No data available
<b>Specific Target Organ Toxicity - Single Exposure</b>	No data available
<b>Specific Target Organ Toxicity - Repeated Exposure</b>	No data available
<b>Aspiration Hazard</b>	No data available

## Section 12: Ecological Information

<b>Toxicity</b>	This material contains an active pharmaceutical ingredient that is not toxic to (Activated sludge microorganisms, Algae, Fish). The product itself and its products of degradation.
<b>Persistence and Degradability</b>	Hydrolysis: This material contains an active pharmaceutical ingredient that has been shown to be chemically stable in water. Hydrolysis is unlikely to be a significant depletion mechanism. Photolysis: This material contains an active pharmaceutical ingredient that has been shown to be chemically unstable in water when exposed to light. Aqueous photolysis may be a significant depletion mechanism. Biodegradation: This material contains an active pharmaceutical ingredient that is not readily biodegradable but is inherently biodegradable and is not expected to persist in the environment.
<b>Bio-accumulative Potential</b>	This material contains an active pharmaceutical ingredient that will not have a tendency to bioaccumulate in the food chain. Bioconcentration Factor: 1
<b>Mobility in Soil</b>	Solubility: This material contains an active pharmaceutical ingredient that for environmental fate predictions has solubility in water. Volatility: This material contains an active pharmaceutical ingredient that will not readily enter into the air from hard surfaces or from a container of the pure substance. Adsorption: This material contains an active pharmaceutical ingredient that is likely to adsorb to soil or sediment. It may persist in soil or sediment if released directly to the environment. Partitioning: This material contains an active pharmaceutical ingredient with octanol/water partition coefficient data that suggests that for environmental fate predictions the active pharmaceutical ingredient will not have the tendency to distribute into fats.
<b>Other Adverse Effects</b>	No data available

## Section 13: Disposal Considerations

<b>Waste Treatment Methods Product</b>	Dispose of waste in accordance with all applicable state and local laws.
<b>Waste Treatment Methods Packaging</b>	Disposal must be made according to official regulations.
<b>Special Precautions Landfill or Incinerations</b>	No data available
<b>Other Information</b>	No data available

## Section 14: Transport Information

<b>UN Number</b>	Not dangerous goods.
<b>UN Proper Shipping Name</b>	N/A
<b>Transport Hazard Class(es)</b>	N/A
<b>Packaging Group</b>	N/A
<b>Environmental Hazards</b>	No data available

## Section 15: Regulatory Information

Risk phrases : R36/37/38 : Irritating to eyes, respiratory system and skin. R42/43 : May cause sensitization by inhalation and skin contact. Hazard description & Symbol : Harmful; Irritant Xn Risk phrases R36/37/38 : Irritating to eyes, respiratory system and skin. R42/43 : May cause sensitization by inhalation and skin contact. Safety phrases S22 : Do not breathe dust. S36/37/39 : Wear suitable protective clothing, gloves and eye/face protection. S45 : In case of accident or if you feel unwell, seek medical advice immediately (show the label when possible). Classification (REGULATION (EC) No 1272/2008 Acute toxicity, category 4 H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled. Eye irritation, category 2 H319: Causes serious eye irritation. Specific target organ toxicity - single H335: May cause respiratory irritation. Skin irritation, Category 2 H315: Causes skin irritation, H317: May cause an allergic skin reaction. Label elements Hazard Pictogram : Single word Warning Hazard statement(s) H315: Causes skin irritation H317: May cause an allergic skin reaction. H319: Causes serious eye irritation. H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled. H335: May cause respiratory irritation. Precautionary statement(s) P280: Wear protective gloves/protective clothing/eye protection/face protection. P285: In case of inadequate ventilation wear respiratory protection. P302+P352: IF ON SKIN: Wash with plenty of soap and water. P304+P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P312: Call a POISON CENTER or doctor/physician if you feel unwell. DSCL (EEC): R36/38- Irritating to eyes and skin. S2- Keep out of the reach of children. S46- If swallowed, seek medical advice immediately and show this container or label. \*HMIS (U.S.A.): Health 2, Fire 1, Reactivity 0, Personal Protection E National Fire Protection Association (U.S.A.): Health : 2 Flammability : 1 Reactivity : 0

## Section 16: Other Information

<b>Additional Information</b>	Abbreviations: * CAS No.: Chemical abstracts service registration number. * EINECS No: European inventory of existing chemical substances number. * STEL: Short term exposure limit. * NIOSH: National institute for occupational safety and health. * MSHA: Mine safety and health administration. * HMIS: Hazardous material identification system. * DSCL(EEC): Dangerous substances classification and labeling (European Economic Community)
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<b>Revision Date</b>	01/08/2019 13:59

### Disclaimer

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