

1. IDENTIFICATION

Product Name	:	FAMOTIDINE
CAS Number	:	[76824-35-6]
Chemical Name (s)	:	N'-(aminosulfonyl)-3-[[[2-[diaminomethylene]amino]-4-thiazolylmethyl]thio] (or) [1-Amino-3-[[[2-[(diaminomethylene)amino]]-4-thiazolyl]-methyl]thio] propylidene]sulfamide (or) 3-[[2-(Diaminomethyleneamino)thiazol-4-yl]methylthio]-N'-sulfamoyl propanimidamide
Recommended use	:	For manufacturing, processing, or repacking.
Recommended restrictions	:	Not for use as a drug. Not for administration to humans or animals
Manufacturer information	:	SMS Pharmaceuticals Limited, Unit-VII Kandivalasa (Village) Poosapatirega (Mandal), Vizianagaram District – 535 204 Andhra Pradesh, INDIA
Telephone	:	Tele: +91-8922-258051, +91-8374532104, +91-8374532106, +91-7680924444 & +91-7680932222.
Website	:	www.smspharma.com

2. HAZARD IDENTIFICATION

Hazard description & Symbol	:	None
Risk phrases	:	None
Safety phrases	:	S22: Do not breathe dust. S24-25: Avoid any inhalation, contact with skin and eyes. Wear suitable protective clothing and gloves. S36/37: Wear suitable protective clothing and gloves.
Classification (REGULATION (EC) No 1272/2008:		
Acute toxicity, category 4	:	None
Eye irritation, category 2	:	None
Specific target organ toxicity	:	None
Skin irritation, category 2	:	None

Classification:

Adverse Effects: Damage to liver. Exposure may produce an allergic reaction. Psychiatric disorders. Gastrointestinal disorders. 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: 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 hyper sensitization.

Medical Conditions Aggravated by Exposure: Hypersensitive 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

Label elements

Hazard Pictogram : None

Single word : None

Hazard statement(s) : None

Precautionary statement(s) : None

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	Common name and synonyms	CAS number	Composition
N'-(aminosulfonyl)-3-[[[2-[diaminomythylene)amino]-4-thiazoylmethyl] thio]	Famotidine	[76824-35-6]	Pure material

4. FIRST AID MEASURE

General information : 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.

Inhalation : May cause Inhalation Remove to fresh air.

Skin contact : May cause irritation. Flush with copious quantities of water.

Eye contact : May cause irritation. Flush with copious quantities of water.

Ingestion : May cause irritation. Flush out mouth with water. This material is rapidly but incompletely absorbed from the gastrointestinal tract. Effects begin within 60 minutes and last between 12 and 24 hours.

5. FIRE FIGHTING MEASURES

Suitable Extinguishing Media : Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.

Unsuitable Extinguishing Media	:	Water with full jet.
Unusual fire and explosion hazards	:	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.
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.
6. ACCIDENT RELEASE MEASURES		
Personal Related Precautions	:	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.
Environmental Precaution	:	Prevent entry into waterways, sewers, surface drainage systems and poorly ventilated areas.
Methods and material For Containment and cleaning up	:	Wear approved respiratory protection, chemically compatible gloves, and protective clothing. Wipe up spillage or collect spillage using a high- efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labeled container for disposal. Wash spill site.
7. HANDLING AND STORAGE		
Precautions for safe handling	:	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.
Conditions for safe storage	:	Keep container tightly closed. Keep container in a cool, well-ventilated area.
Storage	:	Preserve in well closed containers, Protect from light. Store below 30°C.
8. EXPOSURE CONTROLS/ PERSONAL PROTECTION		
Information on the system design	:	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.
Exposure limits	:	Industry: 0.1 mg/m ³
Ventilation	:	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.
General protective and Hygienic measures	:	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.
Respirators	:	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 / *MSHA-Approved Respirator.
Eye protection	:	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.
Skin protection	:	Protective coveralls should be worn. The sleeves should either be taped or have gloves worn over them to prevent material from contacting the skin.
9. PHYSICAL AND CHEMICAL PROPERTIES		
Appearance	:	White or Yellowish white crystalline powder.
Odor	:	Odorless.

Odor threshold	:	Not available
pH Value	:	Not available
Melting point	:	163 - 164 °C
Freezing point	:	Not available
Initial boiling point	:	Not available
Flash Point	:	>93.3 °C (CC)
Evaporation rate	:	Not available
Flammability	:	Not available
Explosion limits	:	Industry: 0.1 mg/m ³
Vapour pressure	:	Not available
Relative density	:	Not available
Solubility	:	Very slightly soluble in water, freely soluble in glacial acetic acid, very slightly soluble in anhydrous ethanol, practically insoluble in ethyl acetate. It dissolves in dilute mineral acids (Freely soluble in 10% hydrochloric acid).
Partition coefficient	:	Not available
Auto- ignition temperature	:	Not available
Decomposition temperature	:	Not available
10. STABILITY AND REACTIVITY		
Chemical Stability:	:	This product is expected to be stable.
Possibility of hazardous reactions:	:	Avoid excessive heat. (Temperatures above 70°C may result in exothermic decomposition.)
Conditions to Avoid:	:	Avoid exposure to light.
Materials to avoid:	:	Strong oxidizing agents.
Hazardous decomposition products	:	When heated to decomposition, material emits toxic fumes of NO _x and SO _x . Emits toxic fumes under fire conditions.
11. TOXICOLOGICAL INFORMATION		
Acute Toxicity	:	Oral Toxicity: LD50 (oral-rat): > 4049 mg/kg.
Summary comments	:	Causes irritation and possible sensitization. Avoid contact. Flush with copious quantities of soap and water.
Chronic Effects on Humans	:	Not available.

Other Toxic Effects on Humans : Hazardous in case of skin contact (irritant), of ingestion, of inhalation.

Special Remarks on Toxicity to Animals: : Not available.

Special Remarks on Chronic Effects on Humans : May cause adverse reproductive effects (female fertility, Fototoxicity and birth defects based on animal studies. Famotidine appears in human milk.

Special Remarks on other Toxic Effects on Humans:
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 gastrointestinal tract irritation.
May affect behavior, brain, liver, and urinary system.
Cardiovascular system, respiration (dyspnea).

12. ECOLOGICAL INFORMATION

This material is not readily biodegradable. Daphnia magna EC50: 220 mg/liter/48 hrs.

Ecotoxicity: Not available.

BOD5 and COD: Not available.

Products of Biodegradation: Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the Products of Biodegradation: The product itself and its products of degradation are not toxic.

Special Remarks on the Products of Biodegradation: Not available.

13. DISPOSAL CONSIDERATIONS

Waste disposal : Dispose of waste in accordance with all applicable state and local laws.

Recommendation: : Disposal must be made according to official regulations.

14. TRANSPORT INFORMATION

UN Number : Not regulated.

UN proper shipping Name : Not regulated.

Transport hazard class : Not regulated.

Packing group : Not regulated.

Marine Pollutant : Not regulated.

Storage : Protected from Light.

15. REGULATORY INFORMATION

Hazard description & Symbol : None

Risk phrases : None

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Safety phrases	S22 : Do not breathe dust S24/25: Avoid any inhalation, contact with skin and eyes S36/37: Wear suitable protective clothing and gloves.
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Specific target organ toxicity	: None
Skin irritation, Category 2	: None

Label elements

Hazard Pictogram	: None
Single word	: None
Hazard statement(s)	: None
Precautionary statement(s)	: None

16. OTHER INFORMATION

The above information believed to be correct but does not support to be all inclusive and shall be used only as a guide. SMS Pharmaceuticals Limited shall not be held liable for any damages resulting from handling or from contact with above product.


 HOD/Designee Quality Assurance

