SAFETY DATA SHEETS

This SDS packet was issued with item:

078950200

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078950029

VKT Pharma Private Limited
Survey No. 21-27, Derasam (Village)
Ranasthalam (Mandalam), Srikakulam (District)
AP, India - 532 409

Material Safety Data Sheet
Famotidine Tablets, USP

Section 1: Identification

Product Name: Famotidine Tablets, USP 20mg and 40mg.
Category : Used in Gastrointestinal Disorders
Manufacturer: VKT Pharma Private Limited,
Survey No: 21-27, Derasam village,
Ranasthalam Mandal,
Srikakulam District,
Andhra Pradesh-532409
India.

Section 2: Composition/Information on Ingredients

Ingredient	CAS Number	%
Famotidine	76824-35-6	20mg/40mg***
Microcrystalline Cellulose	9004-34-6	#
Starch	9005-25-8	#
Sodium Starch Glycolate	9063-38-1	#
Hydroxy Propyl cellulose	9004-65-3	#
Magnesium Stearate	557-04-0	#
Hypermellose	9004-65-3	#
Titanium Dioxide	13463-67-7	#
Triacetin	104-76-1	#
Polyethylene Glycol	25322-68-3	#
Talc	14807-96-6	#

Additional Information: # Proprietary
***per tablet
Ingredients indicated as hazards have been assessed under standards for workplace safety.

Section 3: Hazards Identification

Fire and Explosion: Expected to be non-combustible.

Health Environment: Famotidine is contraindicated in patients:

- Breastfed Babies

No information is available about the potential of this product to produce adverse environmental effects

Section 4: Composition and Information on Ingredients

Ingredients	CAS	Strength
Famotidine	76824-35-6	20mg and 40mg.

Section 5: First - Aid Measures

Inhalation: Remove to fresh air and keep patient at rest, seek medical attention immediately

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes, seek medical attention immediately.

Skin Contact: Remove immediately contaminated clothes wash affected skin with plenty of water.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately

NOTES TO HEALTH PROFESSIONALS

Medical Treatment: Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center. Protect the patient's airway and support ventilation and perfusion. Meticulously monitor and maintain, within acceptable limits, the patient's vital signs, blood gases, serum electrolytes, etc.

Known Clinical Effects: Adverse effects most commonly reported in clinical use include headache, nausea and gastrointestinal disturbances, Occasional translent changes reported in liver function tests, but no liver damage seen, Individuals sensitive to these materials in its chemical class may develop allergic reactions,. Secreted in human breast milk.

Section 6: Fire - fighting measures

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Formation of toxic gases is possible during heating in fire

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self contained breathing apparatus.

Fire and Explosion Hazards: Not applicable

Section 7: Accidental Release Measures

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

Section 8: Handling and Storage

General Handling: If tablets or capsules are crushed and /or broken, avoid breathing dust and avoid contact with eyes, skin and clothing.

Storage Condition: Store as directed by product packaging.

Section 9: Exposure Controls/Personal Protection

Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling

Personal Protective Equipment:

Hands: Not required for the normal use of this product. Wear protective gloves when working with large quantities.

Eyes: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

Skin: Not required for the normal use of this product. Wear protective clothing when working with large quantities.

Respiratory protection: Not required for the normal use of this product. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

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Section 10: Physical and Chemical Properties

Physical Form: Famotidine tablets USP 20 mg and 40 mg as follows

NDC	Strength	Quantity	Description
67877-842-01	20 mg	100 tablets in 1 HDPE Container	round white to off-white film-coated tablets debossed with "V" on one side and "15" on the other side
67877-842-10		1000 tablets in 1 HDPE Container	round white to off-white film-coated tablets debossed with "V" on one side and "15" on the other side
67877-889-01	40 mg	100 tablets in 1 HDPE Container	round white to off-white film-coated tablets debossed with "V" on one side and "45" on the other side
67877-889-05		500 tablets in 1 HDPE Container	round white to off-white film-coated tablets debossed with "V" on one side and "45" on the other side

Section 10: Stability and Reactivity

Stable under recommended storage conditions.

Section 11: Toxicological Information

RTECS Number : UA2300000 ·
Information on toxicological effects
Acute toxicity: ·
LD/LC50 values that are relevant for classification:

Oral	TDLO	4 ml/kg/7D intermittent (man)
	LD50	4,686 mg/kg (mouse) 4,049 mg/kg (rat)
	Intraperitoneal LD50	778 mg/kg (mouse) 800 mg/kg (rat)
	Subcutaneous LD50	800 mg/kg (mouse) 800 mg/kg (rat)
	Intravenous LD50	254 mg/kg (mouse) 204 mg/kg (rat)

Primary irritant effect: · on the skin: Irritant to skin and mucous membranes.
on the eye: Irritating effect.
Sensitization: No sensitizing effects known.
Additional toxicological information:

Carcinogenic categories

ARC (International Agency for Research on Cancer) Substance is not listed.

NTP (National Toxicology Program) Substance is not listed.

OSHA-Ca (Occupational Safety & Health Administration) Substance is not listed.

Section 12: Ecological Information

No relevant studies identified.

Section 13: Disposal Considerations

Incinerate in an approved facility. Follow all federal state and local environmental regulations.

Section 14: Transport Information

IATA/ICAO - Not Regulated

IATA Proper shipping Name	:	N/A
IATA UN/ID No	:	N/A
IATA Hazard class	:	N/A
IATA Packaging Group	:	N/A
IATA Label	:	N/A

IMDG - Not Regulated

IMDG Proper shipping Name	:	N/A
IMDG UN/ID/No	:	N/A
IMDG Hazard class	:	N/A
IMDG Flash Point	:	N/A
IMDG Label	:	N/A

DOT - NOT Regulated

DOT Proper shipping Name	:	N/A
DOT UN/ID No	:	N/A
DOT Hazard Class	:	N/A
DOT Flash Point	:	N/A
DOT packing group	:	N/A
DOT Label	:	N/A

Section 15: Regulatory Information

This Section Contains Information relevant to compliance with other Federal and/or state laws.

Section 16: Other Information

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Prepared by: 09/11/2023

Verified by: VKT PHARMA PVT. LTD. DERASAM VILLAGE 09/11/2023