

Zydus Pharmaceuticals USA Inc

Material Safety Data Sheet

Product: Famotidine Powder for Oral Suspension USP, 40 mg per 5 mL

MSDS Date: 11-30-09

Product Name: Famotidine Powder for Oral Suspension USP, 40 mg/5 mL

Manufactured For: Zydus Pharmaceuticals USA Inc.

I. Product and Company Description

Navinta LLC
1499 Lower Ferry Road
Ewing, NJ 08618
USA

Product Information/Emergency:

609-883-1135

Chemical Name:

N/A

Synonym:

N/A

Molecular Formula:

N/A

Molecular Weight:

ND

II. Chemical Composition

Component	CAS#
Famotidine	76824-35-6
Xanthan Gum	11138-66-2
Microcrystalline cellulose	9004-34-6
Purified water	7732-18-5
Sucrose	57-50-1
Propyl Paraben Sodium	35285-69-9
Methyl Paraben Sodium	5026-62-0
Citric acid anhydrous	77-92-9
Sodium benzoate	532-32-1

III. Hazards Identification

A. Emergency Overview:

Physical Appearance and Odor:

White to off-white powder with no odor [cherry-mint flavor]

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B. Potential Health Effects:

Acute Eye:

May cause irritation.

Acute Skin:

May cause irritation.

Acute Inhalation:

May irritate the mucous membranes and upper respiratory tract. May cause allergic reactions.

Acute ingestion:

None expected under anticipated use conditions.

Chronic effects:

None

IV. First Aid Measures

First Aid Measures for Accidental Exposure:

Eye Exposure:

Immediately flush eyes with plenty of water for at least 15 minutes, lifting lower and upper eyelids occasionally, Get medical attention immediately.

Skin Exposure:

Immediately flush skin with plenty of soap and water for at least 15 minutes. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

Inhalation:

Remove to fresh air. Seek medical attention if respiratory irritation develops or if breathing becomes difficult,

Ingestion:

Rinse mouth well with water. Never give anything by mouth to an unconscious person. Get medical attention immediately.

V. Fire Fighting Measures

Fire Hazard Data:

Flash Point: NA

Method Used: NA

Ignition Temperature: NA

Flammability Limits (vol/vol%): Lower NA Upper: NA

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Extinguishing Media:

Water spray, dry chemical, or carbon dioxide as-appropriate for surrounding fire.

Special Fire Fighting Procedures:

In the event of a fire, wear full protective clothing and NIOSH-approved self-contained breathing apparatus with full! Face piece operated in the pressure demand or other positive pressure mode.

Unusual Fire and Explosion Hazards:

Fire or excessive heat may produce hazardous decomposition products. This material in sufficient quantity and reduced particle size is capable of creating a dust explosion.

Hazardous Decomposition Materials (Under Fire Conditions):

Oxides of carbon, nitrogen and sulfuric oxides

VI. Accidental Release Measures

Cleanup and Disposal of Spill:

Wear appropriate personal protective equipment as specified in Section 8, Avoid creating dusts and contain powder using standard lab procedures. Collect in an appropriate chemical waste container.

Dispose of materials according to the applicable Federal, State, or local regulations.

VII. Handling and Storage

Handling:

Use with adequate ventilation. Avoid contact with eyes or skin. Avoid creating dusts as they may cause an explosive potential. Use spark proof tools and grounding equipment.

Storage:

Keep in a tightly closed container. Store in a cool dry, ventilated area away from heat and flames.

VIII. Exposure Controls / Personal Protection

Exposure Guidelines:

Component	Exposure limits		
	ACGIH	NIOSH	OSHA-PELs
Famotidine	ND	ND	ND
Microcrystalline cellulose	ND	ND	ND
Purified water	NA	NA	NA
Sucrose	1Qmg/m ³ (TWA),	ND	Respirable: 5 mg/m ³ Total dust: 15 mg/m ³

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Engineering Controls:

Ventilation must be adequate to maintain the ambient workplace atmosphere below the exposure limit(s) outlined in the MSDS.

Respiratory Protection:

If the exposure limit is exceeded and engineering controls are not feasible follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Always use a NIOSH or EN approved respirator when necessary.

Eye/Face Protection:

Use chemical safety goggles and/or safety glasses where contact is possible. Maintain eye wash fountain and quick-drench facilities in work area.

Skin Protection:

Wear impervious protective clothing, including gloves, apron or coveralls, as appropriate, to prevent skin contact,

IX. Physical and Chemical Properties

Physical Appearance: White to off-white powder

Odor: None [cherry-mint flavor]

pH: ND

Specific Gravity: NO

Water Solubility: ND

Melting Point Range: ND

Boiling Point Range: ND

Freezing Point: ND

Vapor Pressure: Negligible

Vapor Density: ND

X. Stability and Reactivity

Chemical Stability:

Stable under standard use and storage conditions.

Conditions to Avoid:

Avoid excessive heat. Avoid creating dusts due to potential explosive hazards.

Materials / Chemicals to be Avoided:

None

Hazardous Decomposition Products:

Oxides of carbon, nitrogen and sulfuric oxides

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Hazardous Polymerization:

Should not occur

XI. Toxicological Information

Acute Oral Toxicity:

ND

Acute Dermal Toxicity:

ND

Acute Inhalation Toxicity:

ND

Chronic Toxicity:

Not identified to be a carcinogen by OSHA, NTP or IARC.

XII. Ecological Information

Ecotoxicological Information:

Degradation:	Not Determined
Accumulation:	Not Determined
Fish-Toxicity:	Not Determined

Chemical Fate Information:

Not Determined

XIII. Disposal Considerations

Waste Disposal Method:

Whatever cannot be saved for recovery or recycling should be managed in an appropriate and approved waste disposal facility. Processing, use or contamination of this product may change the waste management options. State and local disposal regulations may differ from federal disposal regulations.

Container Handling and Disposal:

Dispose of container and unused contents in accordance with federal, state, and local regulations.

XIV. Transportation Information

US Department of Transportation Shipping Name:

US Department of Transportation	Proper Shipping Name	Not Regulated
	Hazard Class	Not Regulated
	ID Number	Not Regulated
	Packaging Group	Not Regulated

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XV. Regulatory Information

Federal Regulations:

SARA Title III Hazard Classes:

Fire Hazard:	NO
Reactive Hazard:	NO
Release of Pressure:	NO
Acute Health Hazard:	NO
Chronic Health Hazard:	NO

SARA Section References:

Section 302 (RQ)
None of the chemicals in this material have an RQ,

Section 302 (TPQ)
None of the chemicals in this product have a TPQ.

Section 313
None

Toxic Substances Control Act (TSCA): All components are included in the inventory or are not required to be listed.

Other Regulations:

State:

None

California Prop. 65: None of the chemicals in this product are listed.

XVI. Other Information

National Fire Protection Association Hazard Ratings - NFPA(R):

Health Hazard:	1
Flammability:	0
Reactivity:	0

Key Legend Information:

N/A-Not Applicable

ND - Not Determined

ACGIH - American Conference of
Governmental Industrial Hygienists

OSHA - Occupational Safety and Health
Administration

TLV - Threshold Limit Value

PEL - Permissible Exposure Limit

TWA - Time Weighted Average

STEL - Short Term Exposure Limit

NTP - National Toxicology Program

IARC - International Agency for Research
on
Cancer

The information contained herein is based on the data available to us and is believed to be correct. However, Zydus Pharmaceuticals USA Inc makes no warranty, expressed or Implied regarding the accuracy of these data or the results to be obtained from the use thereof.