MATERIAL SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE AND THE COMPANY

Material **Famotidine for Oral Suspension USP**
40 mg/5 mL

Manufacturer
Lupin Limited
Goa 403 722
INDIA

Distributor
Lupin Pharmaceuticals, Inc.
Harborplace Tower, 21st Floor
111, South Calvert Street
Baltimore, MD 21202
United States
Tel. 001-410-576-2000
Fax 001-410-576-2221

2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS	Quantity
FAMOTIDINE	76824-35-6	40 mg/5 mL
Non-hazardous ingredients	----------	q.s.

3. HAZARDOUS IDENTIFICATION

Fire and Explosion Assume that this product is capable of sustaining combustion.

Health Hypersensitivity to any component of these products. Cross sensitivity in this class of compounds has been observed. Therefore, famotidine should not be administered to patients with a history of hypersensitivity to other H_2-receptor antagonists.

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

4. FIRST AID MEASURES

Ingestion — If conscious, give water to drink and induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. Obtain medical attention.

Inhalation — Move individual to fresh air. Obtain medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance.

Skin Contact — Remove contaminated clothing and flush exposed area with large amounts of water. Wash all exposed areas of skin with plenty of soap and water. Obtain medical attention if skin reaction occurs.

Eye Contact — Flush eyes with plenty of water. Get medical attention.

NOTES TO HEALTH PROFESSIONALS

Treat according to locally accepted protocols.

In the event of overdosage, treatment should be symptomatic and supportive. Unabsorbed material should be removed from the gastrointestinal tract, the patient should be monitored, and supportive therapy should be employed.

5. FIRE-FIGHTING MEASURES

Fire and Explosion Hazards — Assume that this product is capable of sustaining combustion.

Extinguishing Media — Water spray, carbon dioxide, dry chemical powder or appropriate foam.

Special Firefighting Procedures — For single units (packages): No special requirements needed.

Hazardous Combustion Products — Hazardous combustion or decomposition products are expected when the product is exposed to fire.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions — Wear protective clothing and equipment consistent with the degree of hazard.

Environmental Precautions — For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.

Clean-up Methods Collect and place it in a suitable, properly labeled container for recovery or disposal.

7. HANDLING AND STORAGE

Handling No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.

Storage Preserve in well-closed, light-resistant containers. Store at controlled room temperature.

Store Famotidine for Oral Suspension dry powder and suspension at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Suspension: Protect from freezing. Discard unused suspension after 30 days

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

9. PHYSICAL & CHEMICAL PROPERTIES

Physical Form Famotidine for Oral Suspension is a white to off-white granular powder forming an off-white suspension with characteristic odor on constitution, containing 40 mg of famotidine per 5 mL.

The suspension is a cherry-banana-mint flavored.

50 mL NDC # 68180-150-01
Bottle containing 400 mg famotidine.

10. STABILITY AND REACTIVITY

Stable under recommended storage conditions.

11. TOXICOLOGICAL INFORMATION

Carcinogenesis, Mutagenesis, Impairment of Fertility:

In a 106 week study in rats and a 92-week study in mice given oral doses of up to 2000 mg/kg/day (approximately 2500 times the recommended human dose for active duodenal ulcer), there was no evidence of carcinogenic potential for famotidine.

Famotidine was negative in the microbial mutagen test (Ames test) using *Salmonella typhimurium* and *Escherichia coli* with or without rat liver enzyme activation at concentrations up to 10,000 mcg/plate. In *in vivo* studies in mice, with a micronucleus test and a chromosomal aberration test, no evidence of a mutagenic effect was observed.

In studies with rats given oral doses of up to 2000 mg/kg/day or intravenous doses of up to 200 mg/kg/day, fertility and reproductive performance were not affected

12. ECOLOGICAL INFORMATION

No relevant studies identified.

13. DISPOSAL CONSIDERATION

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

14. TRANSPORT INFORMATION

The Material Safety Data Sheet (MSDS) should accompany all shipments for reference in the event of spillage or accidental release. Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labeling for air, maritime, or ground transport purposes.

15. REGULATORY INFORMATION

No information found.

16. OTHER INFORMATION

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Lupin shall not be held liable for any damage resulting from handling or from contact with the above product. Lupin reserves the right to revise this MSDS.