

MATERIAL SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE AND THE COMPANY

Material	Meloxicam Tablets 7.5 mg or 15 mg
Manufacturer	Lupin Limited Mumbai 400 098 INDIA
Distributor	Lupin Pharmaceuticals, Inc. Harborplace Tower, 21 st 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
Meloxicam	71125-38-7	7.5 mg /Tablet or 15 mg/ Tablet
Non-hazardous ingredients	-----	q.s.

3. HAZARDOUS IDENTIFICATION

Statement of Hazard/Risk Phrase	May cause skin, eye, or respiratory tract irritation.
Precautionary Measures	Do not get in eyes, on skin, on clothing. Avoid breathing dust, vapor, mist or gas. Use with adequate ventilation. Wash thoroughly after handling.
Primary route(s) of Exposure	Inhalation, ingestion and eye or skin contact.
Effects of Overexposure	Acute: Gastrointestinal irritation, ulceration or bleeding. Headache. Dizziness. See Package Insert for additional information on overdose. Chronic: Liver effects such as jaundice, hepatitis and hepatic failure have occurred with NSAIDs. Long term administration of NSAIDs has caused renal papillary necrosis and other renal changes.

Medical Conditions Aggravated by Exposure

Meloxicam Tablets are contraindicated for individuals with known hypersensitivity to Meloxicam or those who have experienced asthma, urticaria or allergic type reactions to NSAIDs, including aspirin. Caution should be exercised for patients with a history of gastrointestinal disease or those receiving treatment with anticoagulants. See the package insert for more information.

4. FIRST AID MEASURES

Ingestion

Get medical attention to determine whether vomiting or evacuation of stomach is necessary. Do not give anything by mouth to an unconscious or convulsing person.

Inhalation

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

Skin Contact

Remove contaminated clothing. Wash affected areas with plenty of water and soap if available, for several minutes. Seek medical attention if irritation or rash develops and persists.

Eye Contact

Flush eyes with large amounts of running water for 15 minutes. Hold eyelids open. Get immediate medical attention

Antidotes

No specific antidote exists.

5. FIRE-FIGHTING MEASURES

Fire and Explosion Hazards

Not expected for the product, although the packaging is combustible

Extinguishing Media

Water, carbon dioxide, or dry chemical.

Special Firefighting Procedures

Although material will not ignite, if heated strongly in a fire situation product may decompose forming carbon dioxide, carbon monoxide, oxides of nitrogen and sulfur. NIOSH approved SCBA and full protective gear for firefighters is recommended if product is involved in a major fire. If possible, contain and collect firefighting water for later disposal.

Hazardous Combustion Products

Carbon monoxide. Carbon dioxide. Nitrogen oxides. Sulfur oxides.

Unusual Fire and Explosion Hazards

As with all finely divided organic powders, it is advisable to eliminate explosion hazards by methods such as grounding mechanical equipment in contact with the material to prevent the buildup of static electricity, inerting the atmosphere or controlling dust levels.

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.
Decontamination Procedure	No specific decontamination or detoxification procedures have been identified for this product. Water can be used for clean-up and decontamination operations.

7. HANDLING AND STORAGE

Precautions for Safe Handling and Use	Avoid generating dust or mist and contact with skin, eyes and clothing. Use with adequate ventilation. Wash thoroughly after handling. Launder contaminated clothing before reuse. Do not get in eyes, on skin or clothing. Avoid breathing dust or mist. Use adequate dust/vapor control
Storage	Store at 20°-25°C (68°-77°F) [See USP Controlled Room Temperature]. Keep in a dry place.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

PERSONAL PROTECTIVE EQUIPMENT

Eye Protection	Safety glasses with side shields.
Respirators	In operations where mists or aerosols are generated, wear a NIOSH approved respirator that has been selected by a technically qualified person for the specific conditions.
Other Equipment or Procedures	Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.
Work/Hygienic Practices	Do not permit eating, drinking or smoking near this material.

9. PHYSICAL & CHEMICAL PROPERTIES

Physical Form	Tablet.
Appearance	7.5 mg Tablets: Light yellow, round, biconvex tablets. 15 mg Tablets: Light yellow, oval, biconvex tablets.

10. STABILITY AND REACTIVITY

Stable under recommended storage conditions.

11. TOXICOLOGICAL INFORMATION

Oral Toxicity (RAT)	In an oral toxicity study, the LD 50 was 84mg/kg. Main signs of toxicity included reduced motor activity, anemia and cyanosis. (Rabbit): LD 50 320 mg/kg (Mouse): LD 50 470 mg/kg
Genotoxicity	Meloxicam showed no mutagenic or clastogenic activity in the Ames, the host mediated, the micronucleus, the HGPRT and the chromosomal aberration tests in cultured Chinese hamster ovary cells.
Carcinogenicity	IARC, NTP or OSHA does not list Ingredient(s) as carcinogenic. Studies showed no tumorigenic or carcinogenic potential up to a dose of 0.8mg/kg in rats and 8mg/kg in mice.
Repeated dose studies	Repeated dose studies showed characteristic changes reported with other NSAIDs (gastrointestinal ulceration and erosion). Long term studies showed renal papillary necrosis.
Teratogenicity	Doses up to 4mg/kg in rats and 80mg/kg in rabbits showed no signs of teratogenicity. Doses of 0.125 mg/kg in rats caused elevations still births. 20mg/kg and higher in rabbits was embryotoxic.

12. ECOLOGICAL INFORMATION

No information available.

13. DISPOSAL CONSIDERATION

Waste Disposal Method

Dispose of by incineration in accordance with applicable international, national, state, and/or local waste disposal regulations.

14. TRANSPORT INFORMATION

Not regulated for transportation by the United States Department of Transportation (DOT), International Maritime Organization (IMO), or International Air Transport Association (IATA). May be subject to state and/or local transportation requirements.

15. REGULATORY INFORMATION

No information available.

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.