

MATERIAL SAFETY DATA SHEET

Boehringer Ingelheim Pharmaceuticals, Inc.

Mobic® Oral Suspension

900 Ridgebury Road
P.O. Box 368
Ridgefield, CT 06877

(203) 798-5521 9AM - 4PM EST

11/02/05

EMERGENCY TELEPHONE NUMBER
CHEMTREC - 24 hours
1-800-424-9300

1. SUBSTANCE IDENTIFICATION

CHEMICAL NAME: 4-hydroxy-2-methyl-N-(5-methyl-2-thiazolyl)-2H-1,2-benzothiazine-3-carboxamide-1,1-dioxide

GENERIC NAME: Meloxicam

MOLECULAR FORMULA: C₁₄H₁₃N₃O₄S₂

TRADEMARK: Mobic®

MOLECULAR WEIGHT: 351.4

CHEMICAL FAMILY: Enolic acid group of nonsteroidal anti-inflammatory drugs (NSAID)

CAS NUMBER: 71125-38-7

PRODUCT USE: For relief of signs and symptoms of osteoarthritis and rheumatoid arthritis in adults and of pauciarticular or polyarticular course Juvenile Rheumatoid Arthritis in patients 2 years of age and older.

SYNONYMS: Meloxicam, Mobic®

2. HAZARD IDENTIFICATION

EMERGENCY OVERVIEW

Physical State: 7.5mg/ 5mL, Yellow green tinged viscous suspension with a raspberry odor

WARNING!

May be harmful if swallowed.

Potential Health Effects – Product:

CONTRAINDICATIONS: Hypersensitivity to Mobic® or to any other component of the therapeutic system. Patients with aspirin-sensitive asthma have been associated with severe bronchospasm. Since cross reactivity has been reported between aspirin and other NSAIDs (Non-steroidal anti-inflammatory drugs), Mobic® should not be administered to patients with this form of aspirin sensitivity and should be used with caution in patients with pre-existing asthma. Mobic® should be used with caution in patients with a prior history of peptic ulcer disease and/or gastrointestinal bleeding. Mobic® is not recommended in patients with advanced renal disease.

Mobic® Oral Suspension

Mobic® Oral Suspension should be used with caution in patients with hypertension. ADVERSE REACTIONS TO PRODUCT: **Mobic® Oral Suspension** can cause serious gastrointestinal inflammation, bleeding, ulceration, perforation of the stomach, small or large intestine which can be fatal. The longer the duration of use increases the likelihood of developing a serious gastrointestinal event. Long term administration of NSAIDs has resulted in renal papillary necrosis and other renal injury effects. Skin reactions including erythema (reddening), pruritus (itching), and contact dermatitis (inflammation) may occur. Other side effects reported include fatigue, malaise, dizziness, dry mouth, arrhythmia, palpitations, tachycardia, increase in liver function tests, nervousness, somnolence, dyspnea, increase in blood pressure, low red blood cells, Stevens-Johnson syndrome, sweating and alterations in urinary system.

WARNING

Patients with liver dysfunction should be evaluated prior to initiating treatment with Mobic®. NSAIDs (Nonsteroidal anti-inflammatory drugs) can inhibit platelet aggregation and have shown to prolong bleeding time in some patients.

Emergency treatment should be received immediately if shortness of breath, trouble breathing, slurred speech, chest pain, weakness in one part or side of the body or swelling of the face or throat occurs.

Overdosage: Symptoms of overdosage include lethargy, drowsiness, nausea, vomiting and epigastric pain. Cholestyramine significantly increases the clearance of Meloxicam by 50%.

ROUTES OF ENTRY: Ingestion

ACUTE EXPOSURE:

INHALATION: Not expected to be an inhalation hazard.

EYE CONTACT: Not expected to be a hazard to the eye.

SKIN CONTACT: Can cause hypersensitive reactions. Exposure may cause redness, itching and inflammation.

INGESTION: May be harmful if ingested. Ingestion may cause gastrointestinal irritation, ulceration, bleeding and perforation. Ingestion may cause dizziness, headache and other systemic effects.

CHRONIC EXPOSURE: Possible hypersensitization (development of abnormal sensitivity).

TARGET ORGANS: Gastrointestinal system, hemotopoietic system, liver, kidneys

MEDICAL CONDITIONS POTENTIALLY AGGRAVATED BY EXPOSURE: Caution should be exercised in patients with a history of gastrointestinal disease or those receiving treatment with anticoagulants. See package insert for more information.

OSHA REGULATORY STATUS: OSHA Exempt for product. FDA Regulated.

CARCINOGENICITY: Not listed as a carcinogen or potential carcinogen by NTP, IARC Monographs or OSHA.

3. COMPONENTS PER UNIT DOSE

MATERIAL	WT	EXPOSURE LIMITS
Active Ingredient: Meloxicam	7.5 mg /mL	150 ug/m ³ BIEL*
Excipients:		
Hydroxyethylcellulose		No TLV established
Sorbitol		No TLV established
Colloidal Silicon Dioxide		ACGIH 8-hr TLV-TWA 10 mg/m ³ (Generic group name: Precipitated silica and silica gel : Irritation) OSHA Z-3 8-hr TLV-TWA 20 mppcf (million particles/cubic foot)
Glycerol		ACGIH 8-hr TLV-TWA 10 mg/m ³ (Glycerin mist: Irritation) OSHA Z-1 PEL 5 mg/m ³ (Glycerin mist, respirable fraction) OSHA Z-1 PEL 15 mg/m ³ (Glycerin mist, total dust)
Xylitol		No TLV established
Monobasic Sodium Phosphate Dihydrate		No TLV established
Saccharin Sodium		No TLV established
Sodium Benzoate		No TLV established
Citric Acid Monohydrate		No TLV established
Raspberry Flavor		No TLV established

*BIEL is the BI Exposure Control Level. Where lower governmentally imposed occupational exposure limits exist, such limits should take precedence.

4. EMERGENCY FIRST AID PROCEDURES

Persons developing anaphylactic (life-threatening) reactions, such as difficulty in breathing or unconsciousness, must receive immediate medical attention.

Product:

INHALATION: Should not pose a hazard in final form. Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention immediately.

EYE CONTACT: Should not pose a hazard in final form. Any material that contacts the eye should be washed out immediately with water. If easy to do, remove contact lenses if worn. Get medical attention if irritation persists.

SKIN CONTACT: Should not pose a hazard in final form. Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention.

INGESTION: Call a physician or poison control center immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN: Mobic® overdose usually responds to symptomatic treatment and supportive treatment. Gastric lavage is recommended. Oral doses of cholestyramine given three times a day may be useful in accelerated removal of Meloxicam from the body following an overdose. Due to high protein binding, forced diuresis, alkalinization of the urine, hemodialysis or hemoperfusion may not be helpful.

5. FIRE AND EXPLOSION HAZARD DATA

Flash Point	Flammable Limits	
	Upper	Lower
N/A	N/A	N/A

FIRE EXTINGUISHING MEDIA: Water spray, dry chemical, carbon dioxide or material appropriate for surrounding fire.

SPECIAL FIRE FIGHTING PROCEDURES: Wear self-contained breathing apparatus and protective clothing. Cool fire exposed containers with water.

UNUSUAL FIRE AND EXPLOSION HAZARDS: None

HAZARDOUS COMBUSTION PRODUCTS: Carbon dioxide, carbon monoxide, nitrogen oxides, and sulfur oxides

6. SPILL AND ACCIDENTAL RELEASE MEASURES

STEPS TO BE TAKEN IF SIGNIFICANT QUANTITIES OF LIQUID IS SPILLED: Wear an approved respirator, eye protection, personal protective coverings and gloves. Use HEPA filtered vacuum or wet sweeping to clean up spillage. Place spillage in appropriate container for waste disposal. Wash contaminated clothing before use.

7. PRECAUTIONS FOR SAFE HANDLING AND USE

HANDLING AND STORAGE PRECAUTIONS: Store in tight container. Store at 25°C (77°F). Excursions permitted to 15°C - 30°C (59°F -86°F). Keep from freezing. Keep in a dry place. Store away from foodstuffs.

HANDLING SIGNIFICANT QUANTITIES OF LIQUID: Avoid contact with eyes, skin and clothing. Absorb spilled liquid and collect for disposal. Wash thoroughly after handling.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering Controls: Not generally required when handling containers or liquid. (See Section 3 for exposure limits). Good ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions.

Respiratory Protection: Not generally required when handling containers or liquid. The need for respiratory protection should be determined by an industrial hygiene survey. (See Section 3 for exposure limits). NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary.

PERSONAL PROTECTIVE EQUIPMENT: Not generally required when handling containers. If containers are compromised or exposure to the active ingredient or mixture is likely wear:

Eye Protection: Safety goggles w/side shields (or goggles)	Hand Protection: Neoprene or nitrile gloves
Protective Clothing: Laboratory coats	Other: Eye wash

WORK/HYGIENIC PRACTICES: Keep away from foodstuffs, beverages and feed. Immediately remove all soiled and contaminated clothing. Wash hands before breaks and at the end of work.

9. PHYSICAL/CHEMICAL CHARACTERISTICS

For Product:

APPEARANCE AND ODOR: 7.5 mg/mL, Yellow green tinged viscous suspension with a raspberry odor

Boiling Point: N/E

Vapor Pressure (mmHg): N/E

Vapor Density: N/E

Water Solubility: Dispersion

Freezing Point: N/E

Flammable Limits: N/A

Flashpoint: N/A

Specific Gravity: N/E

Melting Point: N/A

Evaporation Rate: N/E

Autoignition Temperature: N/A

Decomposition Temperature: N/A

Partition Coefficient (n-Octanol/water): N/A

Volatiles, %: N/A

10. REACTIVITY DATA

STABILITY: Stable

CONDITIONS TO AVOID: None known

INCOMPATIBLE MATERIALS: None known

HAZARDOUS DECOMPOSITION OR BY-PRODUCTS: Carbon monoxide, carbon dioxide, nitrogen oxides, and sulfur oxides

HAZARDOUS POLYMERIZATION: Will not occur.

11. TOXICOLOGICAL INFORMATION

ACUTE TOXICITY

Active Ingredient:

LD₅₀ Oral (mouse) - 470 mg/kg

LD₅₀ Oral (rabbit) - 320 mg/kg

LD₅₀ Oral (rat) - 84 mg/kg

Main signs of toxicity in the rat included reduced motor activity, anemia and cyanosis.

EYE IRRITATION: No data available.

SKIN IRRITATION: No data available.

REPEATED DOSE STUDIES:

Repeated dose studies showed characteristic changes reported with other NSAIDs (nonsteroidal anti-inflammatory drugs) such as gastrointestinal ulceration and erosion.

OTHER STUDIES:

GENOTOXICITY:

Mobic® Oral Suspension

Meloxicam showed no mutagenic or clastogenic activity in the Ames test, the host mediated the micronucleus, the HGPRT and the chromosomal aberration tests in cultured Chinese hamster ovary cells.

TERATOGENICITY:

Doses up to 4 mg/kg in rats and 80 mg/kg in rabbits showed no signs of teratogenicity. Doses of 0.125 mg/kg in rats caused elevations in still births. In rabbits, embryo toxicity was present in the 20 mg/kg and higher doses.

CARCINOGENICITY:

Not listed as a carcinogen or potential carcinogen by NTP, IARC Monographs or OSHA.

12. ECOLOGICAL INFORMATION

No information is available.

13. DISPOSAL CONSIDERATIONS

WASTE DISPOSAL CONSIDERATIONS: Dispose of in accordance with local, state and federal regulations. This product falls under hazardous chemical / pharmaceutical waste based on toxicity data. Recommended method is incineration.

For Product: (At Home):

Discard away from children's reach.

14. TRANSPORT INFORMATION

Product:

This product is not subject to the regulations for the safe transport of hazardous materials.

DOT: Not regulated	TDG: Not regulated
IATA: Not regulated	IMDG: Not regulated

15. REGULATORY INFORMATION

CANADIAN CONTROLLED PRODUCTS REGULATIONS: This product has been classified in according to the hazard criteria of the Canadian Controlled Products Regulations, Section 33, and the MSDS contains all required information.

WHMIS CLASSIFICATION FOR ACTIVE INGREDIENT: Controlled. D1B, D2A

WHMIS CLASSIFICATION FOR PRODUCT: Noncontrolled.

INVENTORY STATUS:

This material is **not** listed on the US TSCA Inventory. Therefore, it can only be used for TSCA exempt purposes such as R&D or drug use.

This material is **not** listed on the DSL Inventory.

16. OTHER INFORMATION

ABBREVIATIONS:

BIPI - Boehringer Ingelheim Pharmaceuticals, Inc.

N/A - Not applicable.

N/E - Not established.

PREPARATION INFORMATION

Prepared by: BIPI Environmental Affairs & Safety.

Date: 11/05

**SEE CURRENT PACKAGE INSERT FOR
FURTHER INFORMATION**

REFERENCES

1. American Hospital Formulary Service, 2003.
2. Ariel Research ChemExpert: Registry of Toxic Effects of Chemical Substances.
3. Ariel Research, ChemExpert: Reprotox
4. Ariel Research, Global Regulatory Database.
5. BIPI Mobic Package Insert
6. BIPI MSDS, July 2000.
7. Boehringer Ingelheim Medication Guide for Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)
8. Boehringer Ingelheim Package Insert for Mobic®, August 2005
9. Physician's Desk Reference, 2003.
10. U.S. FDA: Center for Drug Evaluation and Research, Drug Information.
11. U.S./FDA: Consumer Information Sheet
12. U.S. FDA: Meloxicam Oral Suspension: BPCA Summary, August 2005

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