

MATERIAL SAFETY DATA SHEET

**Boehringer Ingelheim
Pharmaceuticals, Inc.**

Product name
Mobic Tablets

DATE ISSUED: 7/00

EMERGENCY TELEPHONE NUMBER CHEMTREC - 24 hours 1-800-424-9300 (203) 798- 4081

1. SUBSTANCE IDENTIFICATION

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

GENERIC NAME: Meloxicam

MOLECULAR FORMULA: C₁₄ H₁₃ N₃ O₄ S₂
TRADEMARK: Mobic

MOLECULAR WEIGHT: 351.4

CHEMICAL FAMILY: enolic acid group of non-steroidal anti-inflammatory drugs (NSAID)

CAS NUMBER:

PRODUCT USE: Treatment of rheumatoid arthritis, osteoarthritis and ankylosing spondylitis

SYNONYMS: Meloxicam, Mobic

2. COMPONENTS PER UNIT DOSE

MATERIAL	WEIGHT	EXPOSURE LIMITS	
Active Ingredient: Meloxicam	7.5 mg	TWA: N/E	
Inert Ingredients	Exposure Limits	Inert Ingredient	Exposure Limits
Sodium Citrate	N/E	Lactose	N/E
Microcrystalline cellulose	10 mg/m ³	Polyvidone	N/E
Anhydrous colloidal silica	10 mg/m ³	crospolyvidone	N/E
Magnesium Stearate	N/E		

3. HAZARD IDENTIFICATION

EMERGENCY OVERVIEW
Meloxicam is a yellow solid, practically insoluble in water
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:

Mobic is 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. EMERGENCY FIRST AID PROCEDURES

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

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.

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.

INJECTION: In case of accidental injection, wash and thoroughly disinfect, get medical attention.

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

5. FIRE AND EXPLOSION HAZARD DATA

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

FIRE EXTINGUISHING MEDIA: Water, carbon dioxide, or dry chemical.

SPECIAL FIRE FIGHTING 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.

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.

HAZARDOUS COMBUSTION PRODUCTS: Carbon monoxide. Carbon dioxide. Nitrogen oxides. Sulfur oxides.

6. SPILL AND ACCIDENTAL RELEASE MEASURES

STEPS TO BE TAKEN IN THE EVENT OF A SPILL: Remove ignition sources; control the generation of dust/vapors; provide ventilation and respiratory, skin and eye protection to prevent overexposure. Keep out of drains; prevent entry to surface water, groundwater and soil.

7. 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.

8. CONTROL MEASURES

RESPIRATORY PROTECTION: 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.

VENTILATION: Use local exhaust at point of manufacture or use to prevent exposure to dust.

PERSONAL PROTECTIVE EQUIPMENT

Eye Protection: Safety glasses with side shields or goggles Other: Eye wash

Protective Clothing: for exposed areas of skin Protective gloves: Rubber gloves

WORK/HYGIENIC PRACTICES: Do not permit eating, drinking or smoking near this material.

9. PHYSICAL/CHEMICAL CHARACTERISTICS

APPEARANCE AND ODOR OF ACTIVE INGREDIENT: Odorless, yellow solid. Mobic tablets are yellow, round, biconvex, and uncoated.

Boiling Point: NA

Vapor Pressure (mm Hg): Not known

Vapor Density: Not known

Water Solubility: Highly insoluble

Specific Gravity: NA

Melting Point: Not known

Mol Wgt: 351.4

10. REACTIVITY DATA

PHYSICAL CONDITIONS TO AVOID: Not established

INCOMPATIBILITY WITH OTHER MATERIALS: Not established

HAZARDOUS DECOMPOSITION PRODUCTS: Carbon monoxide. Carbon dioxide. Nitrogen oxides. Sulfur oxides.

HAZARDOUS POLYMERIZATION: Does not occur.

STABILITY: Stable.

11. TOXICOLOGICAL INFORMATION

ACUTE STUDIES for ACTIVE INGREDIENT:

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

REPEATED DOSE STUDIES

Repeated dose studies showed characteristic changes reported with other NSAIDs (gastrointestinal ulceration and erosion). Long term studies showed renal papillary necrosis.

OTHER STUDIES:

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.

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.

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.

12. ECOLOGICAL INFORMATION

No information available

13. DISPOSAL CONSIDERATIONS

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

ABBREVIATIONS:

BIPI - Boehringer Ingelheim Pharmaceuticals, Inc.

N/A - Not applicable

N/D - Not determined

N/E - Not Established

PREPARATION INFORMATION

Prepared by: Environmental Affairs & Safety

Date: 7/00

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