

SAFETY DATA SHEETS

This SDS packet was issued with item:

078933791

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078934395

Safety Data Sheet

SECTION 1. IDENTIFICATION	
Common/Trade Name: Meloxicam Tablets USP	
Chemical Name: 4-hydroxy-2 methyl-N-(5-methyl-2-thiazolyl)-2H-1,2-benzothiazine-3-carboxamide-1,1-dioxide	
Synonyms: None	
Molecular Formula: C ₁₄ H ₁₃ N ₃ O ₄ S ₂	
Molecular Weight: 351.4	
CAS No: 71125-38-7	
Product Group: Non-steroidal anti-inflammatory drugs (NSAIDs).	
Manufacturer's Name	Unichem Laboratories Limited
Address	Unichem Laboratories Limited, Pilerne, Bardez, Goa, INDIA
Marketed by	Unichem Pharmaceuticals (USA), Inc. Hasbrouck Heights, NJ 07604
Phone Number	201-226-0240 (Fax : 201-368-0407)
Emergency Phone No.	1-866-562-4616
Recommended Use: Relief of pain from osteoarthritis & rheumatoid arthritis	
Restriction on Use: Prescription Only.	
SECTION 2. HAZARD(s) IDENTIFICATION	
Emergency Overview	Physical State: 7.5 mg: Light yellow, round, flat, uncoated tablets impressed with letter U and L on one side and tablet code 7.5 on the other side. 15 mg: Light yellow, oblong, biconvex, uncoated tablets impressed with letter U and L on one side and tablet code 15 on the other side. Odor: Odorless WARNING! May be harmful if swallowed. Accidental ingestion of large amounts may be harmful.
Primary Route(s) of Entry	Ingestion
Potential Health Effects:	Eyes Not expected to be a hazard to the eye in final pharmaceutical form. Skin Not expected to be a hazard to the skin. Can cause hypersensitive reactions resulting in rash, redness, itching and inflammation. Inhalation Not expected to be an inhalation hazard in final pharmaceutical form. Ingestion May be harmful if ingested. Ingestion may cause headache, gastrointestinal bleeding, ulceration and perforation of the stomach.
Toxicity Data:	See Section 11
Effects of Overexposure:	The potential for exposure is reduced in finished pharmaceutical form. Overexposure by ingestion may cause headache, gastrointestinal bleeding and rash. In rare cases, may cause liver disease.
Target Organs:	Gastrointestinal tract

SECTION 3. COMPOSITION / INFORMATION ON INGREDIENTS		
Composition	CAS #	Quantity
Meloxicam (active ingredient)	71125-38-7	7.5 mg and 15 mg.
REFER to PHYSICIAN'S DESK REFERENCE for common components		
SECTION 4. FIRST AID MEASURES		
Eye Contact	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 symptoms persist.	
Skin Exposure	Wash with soap and water. Get medical attention if symptoms occur.	
Ingestion	Call a physician or poison control center immediately.	
Inhalation	Should not pose a hazard in the final form. If breathing is difficult, move to fresh air. Get medical attention immediately.	
SECTION 5. FIRE-FIGHTING MEASURES		
Flammability	Lower: N/A	Upper: N/A
Flash Point	Not Applicable	
Extinguishing Media	Use water spray, dry chemical, carbon dioxide or material appropriate for fire in surrounding area	
Special Fire Fighting Procedures	Wear full protective clothing and self-contained breathing apparatus.	
Unusual Fire/Explosion Hazards	Not Applicable.	
Hazardous Combustion Products	Carbon dioxide, carbon monoxide, oxides of sulfur, oxides of nitrogen	
SECTION 6. ACCIDENTAL RELEASE MEASURES		
STEPS TO BE TAKEN IF SIGNIFICANT QUANTITIES ARE SPILLED: Use appropriate personal protective equipment (see Section 8). Sweep up and containerize spill material in a compatible container. Dispose according to applicable regulations. Incineration of the waste at an approved facility is recommended.		
SECTION 7. HANDLING AND STORAGE		
Precautions General Handling:	Observe good industrial hygiene practices.	
Storage	Store at 20° to 25°C (68° to 77°F) [See USP]. Keep container closed tightly. Protect from light and moisture. Store away from foodstuffs.	
SECTION 8. EXPOSURE CONTROLS / PERSONAL PROTECTION		
Exposure Limits	None	
Engineering Controls	Not required when handling tablets or containers. Ventilation should be matched to conditions.	
Respiratory Protection	Not required when handling tablets or containers. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary. Ventilation should be matched to conditions.	
Personal Protection	Not required when handling tablets. If containers are compromised or exposure is likely -- wear: Goggles, Lab Coat, Gloves	
Recommended Facilities	Eye wash, washing facilities	

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES					
Appearance	Round or Capsule shaped, flat or biconvex Uncoated tablets	Melting point	Not available	Solubility in water	Insoluble (active)
Odor	Odorless	Boiling point	Not available	Specific Gravity	Not available
Taste	Not available	Vapor Pressure	Not available	Flashpoint	Not available
pH	Not available	Density	Not available	Flammability Limits	Not available
SECTION 10. STABILITY AND REACTIVITY					
Stability		Stable			
Incompatibility		None known			
Hazardous Decomposition		Oxides of carbon, oxides of nitrogen, oxides of sulfur			
Conditions to Avoid		Excessive heat, light			
Hazardous Polymerization		Will not occur.			
SECTION 11. TOXICOLOGICAL INFORMATION					
Acute Toxicity:					
Active Ingredient:					
LD50 Oral (rat): 84 mg/kg					
LD50 Oral (mouse): 470 mg/kg					
Carcinogenicity: Not listed as a carcinogen or potential carcinogen by NTP, IARC Monographs or OSHA.					
SECTION 12. ECOLOGICAL INFORMATION					
No information is currently available on the environmental impact of this product.					
SECTION 13. DISPOSAL CONSIDERATIONS					
Waste Disposal Considerations: Dispose of material according to federal, state and local disposal regulations or company operating procedures. Disposal by incineration is recommended.					
At home: Discard away from children's reach.					
SECTION 14. TRANSPORT INFORMATION					
This product is not subject to the regulations for the safe transport of hazardous chemicals.					
DOT: Not regulated					
TDG: Not regulated					
IATA: Not regulated					
IMDG: Not regulated					
SECTION 15. REGULATORY INFORMATION					
DEA: Meloxicam is not a controlled substance					
FDA: Meloxicam is an approved prescription medication.					
SECTION 16. OTHER INFORMATION					
ABBREVIATIONS:					
N/A – not applicable					
Prepared by: Unichem Laboratories Limited					
References:					
1. PDR – Physicians Desk Reference					
2. Meloxicam Tablets USP, Package Insert, Unichem Laboratories Limited					
Date: October 21, 2016 - Version: 002					
Prepared by: Unichem Laboratories Limited					
SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION					

Notice to Reader: To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.