



SAFETY DATA SHEET
For
VIVLODEX™ (meloxicam) Capsules (5 mg and 10 mg)

1. Identification

Product Name: VIVLODEX™ (meloxicam) capsules
Trade Name: VIVLODEX™
Synonyms: None
CAS Number: See Section 3 below.
Product Use: Used as a prescription-only human therapeutic.¹
Manufacturer/Supplier: Egalet US Inc.
Address: 600 Lee Road, Suite 100 Wayne, PA 19087
General Information: 610-833-4212
Emergency Contact Number: Call CHEMTREC Day or Night
Within USA and Canada: 1-800-424-9300 (CCN693919)
Outside USA and Canada: +1 703-527-3887 (collect calls accepted)

2. Hazards Identification

GHS Classification:

Health	Environmental	Physical
Acute Toxicity: Not classified Skin Corrosion: Not classified Eye Corrosion: Not classified Skin Sensitization: Not classified Carcinogenicity: Not classified Reproductive/Developmental: Not classified Target Organ Toxicity (Repeated): Not classified	Not classified	Not classified

GHS Label:

Symbols: None required	
Signal word: None required	
<u>Hazard Statements</u> None required - not classified according to	<u>Precautionary Statements</u> None required – not classified according to GHS criteria

¹Please refer to the package insert for specific therapeutic indications.

3. Composition / Information on Ingredients

Component	CAS Number	Concentration (%w/w)
Meloxicam	71125-38-7	4.0
Lactose Monohydrate	64044-51-5	16.54
Sodium Lauryl Sulfate	151-21-3	2.68
Microcrystalline cellulose	9004-34-6	69.78
Croscarmellose Sodium	74811-65-7	6.0
Sodium Stearyl Fumarate	4070-80-8	1.0

4. First Aid Measures

Eye:	In case of eye contact, flush with copious amounts of water for at least 15 minutes. Hold eyelids away from eyeball to ensure thorough rinsing. Seek medical attention immediately.
Skin:	If redness, dryness or other signs of irritation develop, wash the affected area with plenty of warm water and soap. If irritation persists, seek medical attention immediately.
Inhalation:	In the final form, not a likely route of exposure. However, in case of inhalation, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, administer oxygen. Seek medical attention immediately.
Ingestion:	In case of accidental ingestion, give the victim several glasses of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Do not force an unconscious or convulsing person to drink liquids or to vomit. Seek medical attention immediately.

5. Fire Fighting Measures

Suitable Extinguishing Media:	Use an appropriate media including water spray, dry powder, foam, carbon dioxide.
Firefighting Procedures:	Wear self-contained breathing apparatus and personal protective equipment to prevent contact with skin and eyes.
Unusual Fire and Explosion Hazards	Not applicable
Combustion Products	Product is non-flammable, but when heated to decomposition it may emit acrid smoke and irritating fumes.

6. Accidental Release Measures

Spill Response

Instructions:

The following spill response instructions only apply to bulk quantities of the material. Report emergency situations immediately. Non-essential personnel should be evacuated from the affected area. Spills should be cleaned up in a manner that minimizes exposure to personnel. Personnel involved in the clean-up of spills should wear the appropriate respiratory protection, gloves, eye protection, and protective coveralls. Remove all sources of heat and ignition. Cover spill with absorbent material and collect for disposal. Ventilate the area and clean spill area thoroughly with soap and water. Collect wash with absorbent material and transfer all waste to a labeled container for disposal. Observe all applicable regulations when disposing of this substance.

7. Handling and Storage

General Handling

In a manufacturing setting or other situation where exposure to aerosols may occur, appropriate personal protective equipment, including respiratory protection, must be worn. Use good personal hygiene – wash hands and exposed skin thoroughly with soap and water after use. Remove any contaminated clothing and clean before reuse. Destroy contaminated belts and shoes and other items that cannot be decontaminated.

Keep away from heat and flame. Keep operating temperatures below ignition temperatures at all times. Use non-sparking tools.

Storage

When not in use, store in a cool, dry, well-ventilated area, in tightly sealed containers that are labeled in accordance with OSHA's Hazard Communication Standard [29 CFR 1910.1200]. Keep away from ignition sources including electrostatic charge, heat, sparks, open flame, and strong oxidizers. In case of insufficient ventilation, wear suitable respiratory protection. Keep this product out of the reach of children. Protect from physical damage. Do not cut, grind, or weld on or near containers unless the proper precautions are taken.

8. Exposure Controls / Personal Protection

Exposure Limits

Component Name	OSHA PEL (TWA)	ACGIH TLV (TWA)	NIOSH REL
Meloxicam	N.E.	N.E.	N.E.
Lactose Monohydrate	15 mg/m ³ [5 mg/m ³]	N.E.	N.E.
Sodium Lauryl Sulfate	15 mg/m ³ [5 mg/m ³]	N.E.	N.E.
Microcrystalline cellulose	15 mg/m ³ [5 mg/m ³]	N.E.	N.E.
Croscarmellose Sodium	15 mg/m ³ [5 mg/m ³]	N.E.	N.E.
Sodium Stearyl Fumarate	15 mg/m ³ [5 mg/m ³]	N.E.	N.E.

N.E. = Not Established, brackets [] = respirable fraction

Engineering Controls: In a manufacturing setting, local exhaust ventilation may be necessary to control air contaminants to their exposure limits. The use of local ventilation is recommended to control emissions near the source. Provide mechanical ventilation for confined spaces. Use explosion-proof ventilation equipment.

Personal Protective Equipment (PPE)

In a manufacturing setting, the following personal protective equipment requirements apply:

Eye Protection: Wear chemical safety goggles, safety glasses or face shield. Have eyewash stations available where eye contact can occur.

Skin Protection: Avoid skin contact. Wear gloves impervious to conditions of use. Additional protection may be necessary to prevent skin contact including the use of an apron, face shield, boots, or full body protection. A safety shower should be located in the work area.

Respiratory Protection: If exposure limits are exceeded, approved respiratory protection should be worn. Seek professional assistance for proper selection of respiratory protection.

9. Physical and Chemical Properties

Flash Point: N/A

Autoignition Temperature: N/A

Boiling Point: N/A

Melting Point: N/A

Lower Flammability Limit: N/A

Upper Flammability Limit: N/A

Specific Gravity: N/A

% Volatile: N/A

Vapor Pressure: N/A
Vapor Density: N/A
% Solubility in Water: N/A
Pour Point: N/A
Molecular Formula: N/A
Odor/Appearance: N/A

Evaporation Rate (Water=1): N/A
Viscosity: N/A
Octanol/Water Partition Coefficient: N/A
pH: N/A
Molecular Weight: N/A

10. Stability and Reactivity

Stability/Incompatibility: The mixture is stable under normal conditions of use.

11. Toxicology Information

Signs and Symptoms of Overexposure: In its final form, overexposure is unlikely. May cause slight irritation.

Eye Contact: May cause slight irritation.

Skin Contact: May cause slight irritation or rash.

Inhalation: In the final form, not a likely route of exposure. However, if the dry powder from broken capsules is inhaled may cause asthma, headache, nausea, stuffy nose, and dryness of throat.

Ingestion: If accidentally swallowed, may cause gastrointestinal effects including bleeding, ulceration, and perforation of the stomach or intestines.

Target Organ Effects: Gastrointestinal system, liver

Chronic Effects: No chronic effects have been determined for this mixture.

Acute Toxicity Values:

LD₅₀ (rat, oral) = 83.5 mg/kg (for Meloxicam)
LD₅₀ (rat, oral) > 10,000 mg/kg (for Lactose Monohydrate)
LD₅₀ (rat, oral) = 1,290 mg/kg (for Sodium Lauryl Sulfate)
LD₅₀ (rat, oral) > 5000 mg/kg (for Microcrystalline Cellulose)
LD₅₀ (rat, oral) > 2,000 mg/kg (for Croscarmellose Sodium)
LD₅₀ (rat, oral) > 10,000 mg/kg (for Sodium Stearyl Fumarate)

12. Ecological Information

Ecological impact data has not been determined for this mixture.

13. Disposal Considerations

Disposal Procedure: Must dispose of in accordance with all local, state, and federal regulations.

14. Transportation Information

In the current form, this material is not classified as a hazardous material or dangerous good under the USDOT, IATA, or IMO.

15. Regulatory Information

U. S. Federal Regulations

Not regulated.

Toxic Substance Control Act (TSCA): No ingredients are included on the TSCA inventory.

Clean Water Act (CWA): There are no ingredients in this mixture listed in the Clean Water Act.

Clean Air Act (CAA): There are no ingredients in this mixture listed under the Clean Air Act.

Superfund Amendments and Reauthorization Act (SARA) Title III Information: No ingredients are listed under SARA.

State Regulations

California: This product does not contain chemical(s) known to the State of California to cause cancer, birth defects or reproductive harm.

Canadian Environmental Protection Act: None of the compounds in this mixture are listed on the Canadian Domestic Substances list (DSL).

Canadian Workplace Hazardous Materials Information System (WHMIS):

This product is not controlled by the WHMIS.

European Inventory of Existing Chemicals (EINECS): There are three chemicals contained in this product that are included on the European Inventory of Existing Commercial Chemical Substances (Sodium Lauryl Sulfate, Microcrystalline Cellulose, and Sodium Stearyl Fumarate).

EU Classification: Not regulated.

EU Risk (R) and Safety (S) Phrases:

(S2): Keep out of the reach of children

16. Other Information

National Fire Protection Association (NFPA) Warnings

Health: 1 Flammability: 0 Reactivity: 0 Other: 0

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Disclaimer: Egalet US Inc. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, express or implied.

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