



MATERIAL SAFETY DATA SHEET

Revision date: 06-Feb-2012

Version: 2.0

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1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

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Material Name: Meloxicam Tablets

Trade Name:	Not established
Chemical Family:	Mixture
Intended Use:	Pharmaceutical product used as non-steroidal, anti-inflammatory drug (nsaid)

2. HAZARDS IDENTIFICATION

Appearance: Tablets
Signal Word: DANGER

Statement of Hazard: Harmful if swallowed.
May damage the unborn child.

Additional Hazard Information:

Short Term: Accidental ingestion may cause effects similar to those seen in clinical use.
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on heart and gastrointestinal system.

Known Clinical Effects: Ingestion of this material may cause effects similar to those seen in clinical use including serious gastrointestinal toxicity such as bleeding, ulceration, and perforation and kidney toxicity. Occasional, transient changes reported in liver function tests, but no liver damage seen. Other nonsteroidal anti-inflammatory drugs (NSAIDs) are known to impact delivery, late fetal development, and lactation. Hypersensitivity reactions may also occur in susceptible individuals.

EU Classification
EU Indication of danger: Harmful
Toxic to reproduction: Category 1

EU Hazard Symbols:



EU Risk Phrases:

EU Risk Phrases:

R22 - Harmful if swallowed.
R61 - May cause harm to the unborn child.
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

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2. HAZARDS IDENTIFICATION

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Meloxicam	71125-38-7	Not Listed	T;R25 Repr.Cat.1;R61	7.5 or 15 mg***
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*
Silica colloidal, Ph. Eur.	112945-52-5	Not Listed	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Lactose NF, anhydrous	63-42-3	200-559-2	Not Listed	*
Sodium citrate	68-04-2	200-675-3	Not Listed	*
Crospovidone	9003-39-8	Not Listed	Not Listed	*
Povidone	9003-39-8	Not Listed	Not Listed	*
Lactose NF, monohydrate	64044-51-5	Not Listed	Not Listed	*

Additional Information: * Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

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Hazardous Combustion Products: Carbon monoxide, carbon dioxide, oxides of nitrogen, oxides of sulfur, hydrochloride, and other chlorine-containing compounds

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Not applicable

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

General Handling: Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Australia TWA	10 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Estonia OEL - TWA	10 mg/m ³
France OEL - TWA	10 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
	4 mg/m ³
Latvia OEL - TWA	2 mg/m ³
OSHA - Final PELS - TWAs:	15 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Romania OEL - TWA	10 mg/m ³
Spain OEL - TWA	10 mg/m ³

Silica colloidal, Ph. Eur.

Austria OEL - MAKs	4 mg/m ³
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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Magnesium stearate

ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Lithuania OEL - TWA	5 mg/m ³
Sweden OEL - TWAs	5 mg/m ³

Meloxicam

Pfizer Occupational Exposure Band (OEB): OEB 4 (control exposure to the range of >1ug/m³ to <10ug/m³)

Engineering Controls:

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Environmental Exposure Controls:

Refer to specific Member State legislation for requirements under Community environmental legislation.

Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands:

Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes:

Wear safety glasses or goggles if eye contact is possible.

Skin:

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection:

If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Tablets	Color:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Chemical Stability:

Stable under normal conditions of use.

Conditions to Avoid:

Fine particles (such as dust and mists) may fuel fires/explosions.

Incompatible Materials:

As a precautionary measure, keep away from strong oxidizers

11. TOXICOLOGICAL INFORMATION

General Information:

The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Povidone

Rat Oral LD50 100 g/kg

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11. TOXICOLOGICAL INFORMATION

Meloxicam

Rat Oral LD50 83.5 mg/kg
Mouse Oral LD50 470 mg/kg
Rabbit Oral LD50 320 mg/kg

Magnesium stearate

Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m³

Microcrystalline cellulose

Rat Oral LD50 > 5000 mg/kg
Rabbit Dermal LD50 > 2000 mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Meloxicam

Skin Sensitization - M & K Guinea Pig Negative

Microcrystalline cellulose

Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Non-irritating

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Meloxicam

52 Week(s) Rat Oral 0.2 mg/kg b.w. NOEL Kidney, Gastrointestinal System
4 Week(s) Dog Oral 0.4 mg/kg b.w. NOEL Gastrointestinal system, Kidney

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Meloxicam

Embryo / Fetal Development Rat Oral 1 mg/kg/day LOAEL Not teratogenic, Embryotoxicity, Maternal toxicity
Fertility and Embryonic Development Rat Oral 0.125 mg/kg/day LOAEL Neonatal mortality, Neonatal toxicity
Embryo / Fetal Development Rabbit Oral 1 mg/kg/day LOAEL Embryotoxicity, Not Teratogenic

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Meloxicam

Bacterial Mutagenicity (Ames) *Salmonella* Negative
In Vivo Micronucleus Mouse Bone Marrow Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Meloxicam

104 Week(s) Rat Oral 0.8 mg/kg/day NOEL Not carcinogenic
2 Year(s) Mouse Oral 8 mg/kg/day NOAEL Not carcinogenic

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Crospovidone

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11. TOXICOLOGICAL INFORMATION

IARC: Group 3 (Not Classifiable)

Povidone

IARC: Group 3 (Not Classifiable)

Silica colloidal, Ph. Eur.

IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Indication of danger: Harmful
Toxic to reproduction: Category 1

EU Risk Phrases: **EU Risk Phrases:**
R22 - Harmful if swallowed.
R61 - May cause harm to the unborn child.

EU Safety Phrases:
S22 - Do not breathe dust.
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:
DANGER

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15. REGULATORY INFORMATION

Harmful if swallowed.
May damage the unborn child.

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision B

Class D, Division 1, Subdivision B



Meloxicam

Standard for the Uniform Scheduling
for Drugs and Poisons: Schedule 4

Lactose NF, anhydrous

Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
REACH - Annex IV - Exemptions from the
obligations of Register: Present
EU EINECS/ELINCS List 200-559-2

Microcrystalline cellulose

Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 232-674-9

Sodium citrate

Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 200-675-3

Crospovidone

Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present

Povidone

Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present

Silica colloidal, Ph. Eur.

Australia (AICS): Present

Lactose NF, monohydrate

Australia (AICS): Present

Magnesium stearate

Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 209-150-3

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15. REGULATORY INFORMATION

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R25 - Toxic if swallowed.

R61 - May cause harm to the unborn child.

Data Sources: Publicly available toxicity information. Safety data sheets for individual ingredients.

Reasons for Revision: Updated Section 8 - Exposure Controls / Personal Protection.

Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet