



SAFETY DATA SHEET

NAME OF PRODUCT: DICLOFENAC MISOPROSTOL

SECTION 1: IDENTIFICATION

PRODUCT NAME: Diclofenac Misoprostol, 50/0.2 mg and 75/0.2 mg

MANUFACTURER: Eagle Pharmaceuticals, Inc.
ADDRESS: 50 Tice Boulevard,
Woodcliff Lake, NJ 07677

PHONE: (201) 326-5300

CHEMICAL FORMULA: $C_{14}H_{10}Cl_2NO_2Na$ and $C_{22}H_{38}O_5$

PRODUCT USE: Nonsteroidal anti-inflammatory drug (NSAID)

NOTE: This product is exempt from the OSHA Hazard Communication Standard, because it is a tablet in solid, final form for direct administration to the patient. This Safety Data Sheet is provided for informational purposes only.

SECTION 2: HAZARDS IDENTIFICATION

No signal words, hazard statements, pictograms, or precautionary statements required.

The active ingredients Diclofenac Sodium and Misoprostol are both considered to have potential for damaging fertility or the unborn child.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Diclofenac Sodium

CAS NO.	% WT
15307-79-6	~8% (50 mg tablet), ~11% (75 mg tablet)

Misoprostol

CAS NO.	% WT
59122-46-2	<0.1% in each formulation

NOTE: ~89-92% other nonhazardous ingredients

SECTION 4: FIRST AID MEASURES

EYES: If dust is created and gets in eyes, immediately flush eyes with large amounts of water for at least 15 minutes. Contact physician if irritation persists.

SKIN: If dust is created, remove any contaminated clothing and wash skin with soap and water.

INGESTION: Do not induce vomiting. Treat supportively for any symptoms. In case of acute overdosage, gastric lavage is recommended. Induced diuresis may be beneficial because diclofenac sodium and misoprostol metabolites are excreted in the urine .

INHALATION: If dust is created and inhaled, move to fresh air. Call a physician if symptoms develop or persist.



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SECTION 5: FIRE-FIGHTING MEASURES

EXTINGUISHING MEDIA: Any agent suitable for surrounding materials

SPECIAL FIRE FIGHTING PROCEDURES: None

UNUSUAL FIRE AND EXPLOSION HAZARDS: None

HAZARDOUS DECOMPOSITION PRODUCTS: None

SECTION 6: ACCIDENTAL RELEASE MEASURES

ACCIDENTAL RELEASE MEASURES: No special precautions are needed for spills of solid tablets.

If tablets are crushed and dust is created, wipe up using a method that minimizes the potential for inhalation, such as a damp cloth. Gloves may be also be appropriate to avoid skin irritation.

SECTION 7: HANDLING AND STORAGE

HANDLING AND STORAGE: Store at controlled room temperature.

OTHER PRECAUTIONS: Routine caution in handling potent drugs

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS: None needed under ordinary conditions of usage

VENTILATION: No special requirements

RESPIRATORY PROTECTION: None needed under ordinary conditions of usage.

EYE PROTECTION: None needed under ordinary conditions of usage.

SKIN PROTECTION: None needed under ordinary conditions of usage.

OTHER PROTECTIVE CLOTHING OR EQUIPMENT: N/A

EXPOSURE GUIDELINES: N/A



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SECTION 11: TOXICOLOGICAL INFORMATION

TOXICOLOGICAL INFORMATION:

No exposure via skin contact, eye contact, inhalation or ingestion is expected under normal conditions of use of this product.

Accidental or intentional unprescribed ingestion may cause gastrointestinal discomfort and (in rare cases) adverse events including bleeding, ulceration, and perforation of the stomach or intestines; may trigger anaphylactic-like reactions in people with pre-existing asthma; and may cause abortion (sometimes incomplete), premature labor, or birth defects in pregnant women.

SECTION 12: ECOLOGICAL INFORMATION

The environmental characteristics of the formulated product have not been fully investigated. The following aquatic toxicity information is available for Diclofenac Sodium:

Diclofenac Sodium

Oncorhynchus mykiss (Rainbow Trout)	EC-50	96 Hours, 130.6 mg/L
Daphnia magna (Water Flea)	EC50	48 Hours, 68 mg/L
Skeletonema costatum (Marine Diatom)	EC-50	48 Hours, 42 mg/L
Skeletonema costatum (Marine Diatom)	EC-50	72 Hours, 100 mg/L

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD: Waste material should be disposed of as appropriate for potent drugs

SECTION 14: TRANSPORT INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION: Not Regulated

IATA: Not Regulated



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SECTION 15: REGULATORY INFORMATION

U.S. FEDERAL REGULATIONS:

TSCA (TOXIC SUBSTANCE CONTROL ACT): Exempt

CERCLA (COMPREHENSIVE RESPONSE COMPENSATION, AND LIABILITY ACT): N/A

SARA TITLE III (SUPERFUND AMENDMENTS AND REAUTHORIZATION ACT):

311/312 HAZARD CATEGORIES: N/A

313 REPORTABLE INGREDIENTS: N/A

STATE REGULATIONS: N/A

SECTION 16: OTHER INFORMATION

OTHER INFORMATION:

SHEET DATE: November 5, 2014

CONTACT PERSON FOR ADDITIONAL INFORMATION: Michael Bella, Director-Supply Chain

DISCLAIMER: The information in this sheet is believed to be accurate and represents the best information currently available. However, we make no warranty express or implied, with respect to such information, and we assume no liability resulting from its use.