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

Product Identifier

Material Name: Diclofenac and Misoprostol Tablets
Trade Name: ARTHROTEC; ARTHOTEC; MISOFENAC
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as non-steroidal, anti-inflammatory drug (nsaid)

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification
Acute Oral Toxicity: Category 4
Skin Corrosion/Irritation: Category 2
Serious Eye Damage/Eye Irritation: Category 2
Reproductive Toxicity: Category 1B

EU Classification:
EU Indication of danger: Harmful
Toxic to Reproduction: Category 2

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

Label Elements

Signal Word: Danger

Hazard Statements:
H315 - Causes skin irritation
H319 - Causes serious eye irritation
H302 - Harmful if swallowed
H360D - May damage the unborn child
Other Hazards
Australian Hazard Classification (NOHSC):

Note:
This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diclofenac Sodium</td>
<td>15307-79-6</td>
<td>239-346-4</td>
<td>T; R25; Xi,R36/38; Repr. Cat.2, R61; RS2/53</td>
<td>Skin Irrit 2 (H315) Acute Tox.3 (H301) Acute Tox. 3 (H301) Repr.1B (H360D) Aquatic Chronic 3 (H412)</td>
<td>8-15</td>
</tr>
<tr>
<td>Misoprostol</td>
<td>59122-46-2</td>
<td>Not Listed</td>
<td>T;R25 Repr.Cat.1;R60-61</td>
<td>Acute Tox. 3 (H301) Repr.1A (H360FD)</td>
<td>&lt;1.0</td>
</tr>
<tr>
<td>Silicon dioxide, colloidal NF</td>
<td>7631-86-9</td>
<td>231-545-4</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td></td>
</tr>
<tr>
<td>Talc (non-asbestiform)</td>
<td>14807-96-6</td>
<td>238-877-9</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td></td>
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<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td></td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td></td>
</tr>
<tr>
<td>Corn Starch</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td></td>
</tr>
<tr>
<td>Lactose Monohydrate</td>
<td>64044-51-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td></td>
</tr>
<tr>
<td>Povidone</td>
<td>9003-39-8</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td></td>
</tr>
<tr>
<td>Crospovidone</td>
<td>9003-39-8</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td></td>
</tr>
<tr>
<td>Hydrogenated castor oil</td>
<td>8001-78-3</td>
<td>232-292-2</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td></td>
</tr>
<tr>
<td>Hydroxypropyl methylcellulose</td>
<td>9004-65-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td></td>
</tr>
<tr>
<td>Methacrylic acid copolymer</td>
<td>25086-15-1</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td></td>
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<tr>
<td>Triethyl Citrate</td>
<td>77-93-0</td>
<td>201-070-7</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td></td>
</tr>
</tbody>
</table>

PZ00318
4. FIRST AID MEASURES

Description of 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.

Most Important Symptoms and Effects, Both Acute and Delayed

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.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Not applicable

Advice for Fire-Fighters

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

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

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

Environmental Precautions

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

Methods and Material for Containment and Cleaning Up

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.
7. HANDLING AND STORAGE

Precautions for Safe 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 thoroughly after handling. 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.

Conditions for Safe Storage, Including any Incompatibilities
Storage Conditions: Store as directed by product packaging.
Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Misoprostol
Pfizer OEL TWA-8 Hr: 0.7 µg/m³

Silicon dioxide, colloidal NF
Australia TWA 2 mg/m³
Austria OEL - MAKs 4 mg/m³
0.3 mg/m³
Czech Republic OEL - TWA 0.1 mg/m³
4.0 mg/m³
Estonia OEL - TWA 2 mg/m³
Finland OEL - TWA 5 mg/m³
Germany - TRGS 900 - TWAs 4 mg/m³
Germany (DFG) - MAK 4 mg/m³
Ireland OEL - TWAs 6 mg/m³
2.4 mg/m³
Latvia OEL - TWA 1 mg/m³
OSHA - Final PELs - Table Z-3 Mineral D: 20 mppcf
Listed
Slovakia OEL - TWA 4.0 mg/m³
Switzerland OEL -TWAs 4 mg/m³
0.3 mg/m³

Talc (non-asbestiform)
ACGIH Threshold Limit Value (TWA) 2 mg/m³
Australia TWA 2.5 mg/m³
Austria OEL - MAKs 2 mg/m³
Belgium OEL - TWA 2 mg/m³
Bulgaria OEL - TWA 1.0 fiber/cm³
6.0 mg/m³
3.0 mg/m³
Czech Republic OEL - TWA 2.0 mg/m³
Denmark OEL - TWA 0.3 fiber/cm³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Material</th>
<th>Lithuania OEL - TWA</th>
<th>ACGIH Threshold Limit Value (TWA)</th>
<th>10 mg/m³</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium stearate</td>
<td>0.5 fiber/cm³</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hungary OEL - TWA</td>
<td>2 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ireland OEL - TWA</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.8 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>2 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Netherlands OEL - TWA</td>
<td>0.25 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OSHA - Final PELs - Table Z-3 Mineral D:</td>
<td>20 mppcf</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>4.0 mg/m³</td>
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</tr>
<tr>
<td></td>
<td>1.0 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>2 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>2 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>2 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>10 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Slovenia OEL - TWA</td>
<td>2 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>2 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sweden OEL - TWA</td>
<td>2 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Switzerland OEL -TWAs</td>
<td>2 mg/m³</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Microcrystalline cellulose

<table>
<thead>
<tr>
<th>Material</th>
<th>Lithuanian OEL - TWA</th>
<th>ACGIH Threshold Limit Value (TWA)</th>
<th>5 mg/m³</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>10 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>5 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>5 mg/m³</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Corn Starch

<table>
<thead>
<tr>
<th>Material</th>
<th>ACGIH Threshold Limit Value (TWA)</th>
<th>10 mg/m³</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Australia TWA</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Belgium OEL - TWA</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Bulgaria OEL - TWA</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Czech Republic OEL - TWA</td>
<td>4.0 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Greece OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
</tbody>
</table>
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Diclofenac Sodium
Pfizer Occupational Exposure Band (OEB):

**OEB2** (control exposure to the range of >100ug/m³ to < 1000ug/m³)

**Exposure Controls**

**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.

**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 the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Material Name: Diclofenac and Misoprostol Tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Physical State:</strong> Tablets</td>
</tr>
<tr>
<td><strong>Color:</strong> White</td>
</tr>
<tr>
<td><strong>Odor:</strong> No data available.</td>
</tr>
<tr>
<td><strong>Odor Threshold:</strong> No data available.</td>
</tr>
<tr>
<td><strong>Molecular Formula:</strong> Mixture</td>
</tr>
<tr>
<td><strong>Molecular Weight:</strong> Mixture</td>
</tr>
<tr>
<td><strong>Solvent Solubility:</strong> No data available.</td>
</tr>
<tr>
<td><strong>Water Solubility:</strong> No data available.</td>
</tr>
<tr>
<td><strong>pH:</strong> No data available.</td>
</tr>
<tr>
<td><strong>Melting/Freezing Point (°C):</strong> No data available.</td>
</tr>
<tr>
<td><strong>Boiling Point (°C):</strong> No data available.</td>
</tr>
<tr>
<td><strong>Partition Coefficient: (Method, pH, Endpoint, Value)</strong></td>
</tr>
<tr>
<td><strong>Povidone</strong> No data available</td>
</tr>
<tr>
<td><strong>Corn Starch</strong> No data available</td>
</tr>
<tr>
<td><strong>Crosopovidone</strong> No data available</td>
</tr>
<tr>
<td><strong>Talc (non-asbestiform)</strong> No data available</td>
</tr>
<tr>
<td><strong>Lactose Monohydrate</strong> No data available</td>
</tr>
<tr>
<td><strong>Silicon dioxide, colloidal NF</strong> No data available</td>
</tr>
<tr>
<td><strong>Magnesium stearate</strong> No data available</td>
</tr>
</tbody>
</table>
9. PHYSICAL AND CHEMICAL PROPERTIES

Hydrogenated castor oil
No data available
Microcrystalline cellulose
No data available
Hydroxypropyl methylcellulose
No data available
Triethyl Citrate
No data available
Methacrylic acid copolymer
No data available
Diclofenac Sodium
Predicted Log P  4.51
Misoprostol
No data available

Decomposition Temperature (°C): No data available.
Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammability:
  Autoignition Temperature (Solid) (°C): No data available
  Flammability (Solids): No data available
  Flash Point (Liquid) (°C): No data available
  Upper Explosive Limits (Liquid) (% by Vol.): No data available
  Lower Explosive Limits (Liquid) (% by Vol.): No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable at normal conditions
Possibility of Hazardous Reactions
  Oxidizing Properties: No data available
  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
Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: The information included in this section describes the potential hazards of the individual ingredients.
Short Term: May cause eye irritation, May cause skin irritation. (based on components).
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on blood, spleen, reproductive system, gastrointestinal system. Animal studies indicate that this material may cause adverse effects on the developing fetus.
11. TOXICOLOGICAL INFORMATION

Known Clinical Effects: Clinical use has caused effects on the gastrointestinal system, including abdominal pain, nausea, vomiting, diarrhea, constipation, peptic ulcer, acid reflux, and gastrointestinal bleeding. Clinical use has resulted in liver effects. Symptoms may include jaundice, liver function test abnormalities, and hepatitis. Clinical use has caused effects on the nervous system, including drowsiness, anxiety, dizziness, visual disturbances. Serious allergic reactions, including anaphylaxis, have been reported. Clinical use of this drug has caused decreased red blood cell count (anemia), effects on blood forming organs. Drugs of this class may cause menstrual irregularities, cramps, pain, postmenopausal menstrual bleeding, miscarriage, uterine rupture, bleeding and death. Miscarriages have been seen in pregnant women taking this drug. Clinical use has caused effects on the cardiovascular system, including heart attack (myocardial infarction), stroke.

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

<table>
<thead>
<tr>
<th>Povidone</th>
<th>Rat</th>
<th>Oral</th>
<th>LD50</th>
<th>100 g/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Talc (non-asbestiform)</td>
<td>Rat</td>
<td>Oral</td>
<td>LD50</td>
<td>&gt; 1600 mg/kg</td>
</tr>
<tr>
<td>Lactose Monohydrate</td>
<td>Rat</td>
<td>Oral</td>
<td>LD 50</td>
<td>29700 mg/kg</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>Rat</td>
<td>Oral</td>
<td>LD50</td>
<td>&gt; 2000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>Inhalation</td>
<td>LC50</td>
<td>&gt; 2000 mg/m³</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>Rat</td>
<td>Oral</td>
<td>LD50</td>
<td>&gt; 5000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Rabbit</td>
<td>Dermal</td>
<td>LD50</td>
<td>&gt; 2000 mg/kg</td>
</tr>
<tr>
<td>Hydroxypropyl methylcellulose</td>
<td>Rat</td>
<td>Oral</td>
<td>LD50</td>
<td>&gt; 10,000 mg/kg</td>
</tr>
<tr>
<td>Diclofenac Sodium</td>
<td>Rat</td>
<td>Oral</td>
<td>LD 50</td>
<td>53-77 mg/kg</td>
</tr>
<tr>
<td>Misoprostol</td>
<td>Rat</td>
<td>Oral</td>
<td>LD 50</td>
<td>81 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>Inhalation</td>
<td>LC 50</td>
<td>&gt; 1.43mg/L</td>
</tr>
<tr>
<td></td>
<td>Mouse</td>
<td>Oral</td>
<td>LD 50</td>
<td>27mg/kg</td>
</tr>
</tbody>
</table>

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)

| Microcrystalline cellulose | Skin Irritation | Rabbit | Non-irritating |
|                           | Eye Irritation  | Rabbit | Non-irritating  |

| Diclofenac Sodium         | Skin Irritation | Positive |
|                         | Eye Irritation  | Positive |
## 11. TOXICOLOGICAL INFORMATION

### Misoprostol

- Skin Irritation: Rabbit, Mild

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

<table>
<thead>
<tr>
<th>Study Duration</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Target Organ</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 Day(s)</td>
<td>Rat</td>
<td>Oral</td>
<td>14 mg/kg</td>
<td>LOAEL</td>
<td>None identified</td>
</tr>
<tr>
<td>5 Week(s)</td>
<td>Mouse</td>
<td>Oral</td>
<td>9 mg/kg</td>
<td>LOAEL</td>
<td>Lungs, Spleen</td>
</tr>
<tr>
<td>26 Week(s)</td>
<td>Rat</td>
<td>Oral</td>
<td>50 mg/kg</td>
<td>LOAEL</td>
<td>Blood, Gastrointestinal system</td>
</tr>
</tbody>
</table>

#### Misoprostol

<table>
<thead>
<tr>
<th>Study Duration</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Target Organ</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 Week(s)</td>
<td>Dog</td>
<td>Intravenous</td>
<td>10 µg/kg/day</td>
<td>LOEL</td>
<td>Liver, Blood</td>
</tr>
<tr>
<td>13 Week(s)</td>
<td>Rat</td>
<td>Oral</td>
<td>120 µg/kg/day</td>
<td>LOEL</td>
<td>Gastrointestinal system</td>
</tr>
<tr>
<td>13 Week(s)</td>
<td>Dog</td>
<td>Oral</td>
<td>30 µg/kg/day</td>
<td>LOEL</td>
<td>Gastrointestinal system</td>
</tr>
<tr>
<td>1 Year(s)</td>
<td>Rat</td>
<td>Oral</td>
<td>160 µg/kg/day</td>
<td>LOEL</td>
<td>Gastrointestinal system</td>
</tr>
<tr>
<td>1 Year(s)</td>
<td>Dog</td>
<td>Oral</td>
<td>30 µg/kg/day</td>
<td>LOEL</td>
<td>Gastrointestinal system</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Material</th>
<th>Study Type/Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point/Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diclofenac Sodium</td>
<td>Embryo / Fetal Development</td>
<td>Rat Oral</td>
<td>24 mg/kg</td>
<td>LOAEL Maternal toxicity, Fetotoxicity</td>
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</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Material</th>
<th>Study Type/Species</th>
<th>Cell Type/Organism</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lactose Monohydrate</td>
<td>In Vitro</td>
<td>Bacterial Mutagenicity (Ames)</td>
<td>Negative</td>
</tr>
<tr>
<td>Diclofenac Sodium</td>
<td>Bacterial Mutagenicity (Ames)</td>
<td>Salmonella</td>
<td>Negative</td>
</tr>
<tr>
<td>Misoprostol</td>
<td>Bacterial Mutagenicity (Ames)</td>
<td>Salmonella</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>In Vitro Mouse Lymphoma</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sister Chromatid Exchange</td>
<td>Negative</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Material</th>
<th>Study Duration</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diclofenac Sodium</td>
<td>4 Week(s)</td>
<td>Dog</td>
<td>Intravenous</td>
<td>10 µg/kg/day</td>
<td>LOEL</td>
<td>Fertility</td>
</tr>
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</tbody>
</table>

### Misoprostol

- Reproductive & Fertility: Rat Oral 10 mg/kg/day, LOEL Fertility
- Embryotoxicity:
- NOAEL Not Teratogenic
- Lungs, Spleen
- Blood, Gastrointestinal system
- Liver, Blood
- Gastrointestinal system
SAFETY DATA SHEET

Material Name: Diclofenac and Misoprostol Tablets
Revision date: 06-Mar-2015

11. TOXICOLOGICAL INFORMATION

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

Povidone
IARC: Group 3 (Not Classifiable)

Crospovidone
IARC: Group 3 (Not Classifiable)

Talc (non-asbestiform)
IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview:
May have harmful effects on the aquatic environment. Releases to the environment should be avoided. This formulation has not been tested as a whole, the following apply to component substance(s):

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Diclofenac Sodium
Onchorhynchus mykiss (Rainbow Trout) EC50 96 Hours 130.6 mg/L
Daphnia magna (Water Flea) EC50 48 Hours 68 mg/L
Skeletonema costatum (Marine Diatom) ErC50 48 Hours 42 mg/L
Skeletonema costatum (Marine Diatom) EC50 72 Hours 100 mg/L

Misoprostol
Daphnia LC-50 48 Hours > 932.5 mg/L
Onchorhynchus mykiss (Rainbow Trout) LC-50 72 Hours > 26.4 mg/L
Skeletonema costatum (Marine Diatom) ErC50 72 Hours > 104 mg/L
Skeletonema costatum (Marine Diatom) NOEC 26.5 mg/L

Aquatic Toxicity Comments: A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

Persistence and Degradability:
Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)

Diclofenac Sodium
Ready 55% After 28 Day(s) Not Ready

Bio-accumulative Potential:
Partition Coefficient: (Method, pH, Endpoint, Value)

Diclofenac Sodium
Predicted Log P 4.51
Mobility in Soil: No data available

### 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

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

**Canada - WHMIS: Classifications**

**WHMIS hazard class:**
- Class D, Division 1, Subdivision B
- Class D, Division 2, Subdivision A

**Diclofenac Sodium**

- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Australia (AICS): Present
- EU EINECS/ELINCS List: 239-346-4

**Misoprostol**

- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Developmental toxicity initial date 4/1/90
- Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4
### 15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Material Name</th>
<th>CERCLA/SARA 313 Emission reporting</th>
<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS):</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lactose Monohydrate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Povidone</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Crospovidone</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>Not Listed</td>
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<tr>
<td>Silicon dioxide, colloidal NF</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>231-545-4</td>
</tr>
<tr>
<td>Hydrogenated castor oil</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>232-292-2</td>
</tr>
<tr>
<td>Talc (non-asbestiform)</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>238-877-9</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>209-150-3</td>
</tr>
</tbody>
</table>
## 15. REGULATORY INFORMATION

### Microcrystalline cellulose
- **CERCLA/SARA 313 Emission reporting**: Not Listed
- **California Proposition 65**: Not Listed
- **Inventory - United States TSCA - Sect. 8(b)**: Present
- **Australia (AICS)**: Present
- **REACH - Annex XVII - Restrictions on Certain Dangerous Substances**: Use restricted. See item 9[f]. powder
- **EU EINECS/ELINCS List**: 232-674-9

### Hydroxypropyl methylcellulose
- **CERCLA/SARA 313 Emission reporting**: Not Listed
- **California Proposition 65**: Not Listed
- **Inventory - United States TSCA - Sect. 8(b)**: Present
- **Australia (AICS)**: Present
- **Standard for the Uniform Scheduling for Drugs and Poisons**: Schedule 4
- **EU EINECS/ELINCS List**: Not Listed

### Methacrylic acid copolymer
- **CERCLA/SARA 313 Emission reporting**: Not Listed
- **California Proposition 65**: Not Listed
- **Inventory - United States TSCA - Sect. 8(b)**: Present
- **Australia (AICS)**: Present
- **EU EINECS/ELINCS List**: Not Listed

### Triethyl Citrate
- **CERCLA/SARA 313 Emission reporting**: Not Listed
- **California Proposition 65**: Not Listed
- **Inventory - United States TSCA - Sect. 8(b)**: Present
- **Australia (AICS)**: Present
- **EU EINECS/ELINCS List**: 201-070-7

### Corn Starch
- **CERCLA/SARA 313 Emission reporting**: Not Listed
- **California Proposition 65**: Not Listed
- **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**: 232-679-6

## 16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3
SAFETY DATA SHEET

Material Name: Diclofenac and Misoprostol Tablets
Revision date: 06-Mar-2015
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Version: 3.0

Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed
Skin corrosion/irritation-Cat.2; H315 - Causes skin irritation
Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation
Reproductive toxicity-Cat.1B; H360D - May damage the unborn child
Hazardous to the aquatic environment, acute toxicity-Cat.3; H402 - Harmful to aquatic life
Hazardous to the aquatic environment, chronic toxicity-Cat.3; H412 - Harmful to aquatic life with long lasting effects
Reproductive toxicity-Cat.1A; H360FD - May damage fertility. May damage the unborn child.

T - Toxic
Xi - Irritant
Toxic to Reproduction: Category 2
Toxic to reproduction: Category 1

R25 - Toxic if swallowed.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.
R36/38 - Irritating to eyes and skin.
R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Data Sources: Pfizer proprietary drug development information.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 15 - Regulatory Information. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 16 - Other Information.

Revision date: 06-Mar-2015
Prepared by: Product Stewardship Hazard Communication

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