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

Product Identifier

Material Name: Misoprostol Tablets

Trade Name: CYTOTEC; MISODEX

Chemical Family: Mixture

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

Intended Use: Pharmaceutical product for the treatment of ulcers

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

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number: CHEMTREC (24 hours): 1-800-424-9300

Contact E-Mail: pfizer-MSDS@pfizer.com This e-mail address should not be used to report suspected adverse events.

Emergency telephone number: International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Reproductive Toxicity: Category 1A

EU Classification:

EU Indication of danger: Toxic to reproduction: Category 1

EU Risk Phrases:

R60 - May impair fertility.
R61 - May cause harm to the unborn child.

Label Elements

Signal Word: Danger

Hazard Statements: H360FD - May damage fertility. May damage the unborn child.

Precautionary Statements:

P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations
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>Hazardous 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>Misoprostol</td>
<td>59122-46-2</td>
<td>Not Listed</td>
<td>T;R25</td>
<td>Acute Tox. 3 (H301) Repr.1A (H360FD)</td>
<td>&lt;1%</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>
</tbody>
</table>

<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>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>Sodium starch glycolate</td>
<td>9063-38-1</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures
Eye Contact: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Remove contaminated clothing and shoes and thoroughly wash skin with soap or mild detergent and water. If irritation occurs or persists, get 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: Emits toxic fumes of carbon monoxide and oxides of nitrogen.
Products:
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. Avoid dust formation.

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.

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
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
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Misoprostol

Pfizer OEL TWA-8 Hr: 0.7 µg/m³

Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA): 10 mg/m³
Australia TWA: 10 mg/m³
Belgium OEL - TWA: 10 mg/m³
Estonia OEL - TWA: 10 mg/m³
France OEL - TWA: 10 mg/m³
Ireland OEL - TWAs: 4 mg/m³
Latvia OEL - TWA: 2 mg/m³
OSHA - Final PELS - TWAs: 15 mg/m³
Portugal OEL - TWA: 10 mg/m³
Romania OEL - TWA: 10 mg/m³
Russia OEL - TWA: 6 mg/m³
Spain OEL - TWA: 10 mg/m³
Switzerland OEL -TWAs: 3 mg/m³
Vietnam OEL - TWAs: 10 mg/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>Physical State:</th>
<th>Tablet</th>
<th>Color:</th>
<th>White to off-white</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor:</td>
<td>No data available.</td>
<td>Odor Threshold:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility:</td>
<td>No data available</td>
<td>Water Solubility:</td>
<td>No data available</td>
</tr>
<tr>
<td>pH:</td>
<td>No data available</td>
<td>Melting/Freezing Point (°C):</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling Point (°C):</td>
<td>No data available</td>
<td>Partition Coefficient: (Method, pH, Endpoint, Value)</td>
<td></td>
</tr>
<tr>
<td>Misoprostol</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Substance</th>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microcrystalline cellulose</td>
<td>Decomposition Temperature (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Sodium starch glycolate</td>
<td>Evaporation Rate (Gram/s)</td>
<td>No data available</td>
</tr>
<tr>
<td>Hydrogenated castor oil</td>
<td>Vapor Pressure (kPa)</td>
<td>No data available</td>
</tr>
<tr>
<td>Hydroxypropyl methylcellulose</td>
<td>Vapor Density (g/ml)</td>
<td>No data available</td>
</tr>
<tr>
<td></td>
<td>Relative Density</td>
<td>No data available</td>
</tr>
<tr>
<td></td>
<td>Viscosity</td>
<td>No data available</td>
</tr>
<tr>
<td></td>
<td>Flammability</td>
<td>No data available</td>
</tr>
<tr>
<td></td>
<td>Autoignition Temperature (Solid) (°C):</td>
<td>No data available</td>
</tr>
<tr>
<td></td>
<td>Flammability (Solids):</td>
<td>No data available</td>
</tr>
<tr>
<td></td>
<td>Flash Point (Liquid) (°C):</td>
<td>No data available</td>
</tr>
<tr>
<td></td>
<td>Upper Explosive Limits (Liquid) (% by Vol.):</td>
<td>No data available</td>
</tr>
<tr>
<td></td>
<td>Lower Explosive Limits (Liquid) (% by Vol.):</td>
<td>No data available</td>
</tr>
</tbody>
</table>

10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>No data available</td>
</tr>
<tr>
<td>Chemical Stability</td>
<td>Stable under normal conditions of use.</td>
</tr>
<tr>
<td>Possibility of Hazardous Reactions</td>
<td></td>
</tr>
<tr>
<td>Oxidizing Properties</td>
<td>No data available</td>
</tr>
<tr>
<td>Conditions to Avoid</td>
<td>Not determined</td>
</tr>
<tr>
<td>Incompatible Materials</td>
<td>As a precautionary measure, keep away from strong oxidizers</td>
</tr>
<tr>
<td>Hazardous Decomposition Products</td>
<td>Hazardous combustion products may include oxides of carbon, nitrogen</td>
</tr>
</tbody>
</table>

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 be harmful if swallowed. May cause mild skin irritation (based on animal data). May cause stomach irritation, diarrhea, nausea, or vomiting.

Long Term: Animal studies indicate that this material may cause adverse effects on the liver and gastrointestinal system.

Known Clinical Effects: Ingestion of this material may cause effects similar to those seen in clinical use including effects on gastrointestinal disturbances and abdominal pain. 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. May cause adverse effects on the developing fetus.

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

Misoprostol

Rat Oral LD 50 81 mg/kg
11. TOXICOLOGICAL INFORMATION

**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:**

**Microcrystalline cellulose**
- Rat Oral LD50 > 5000 mg/kg
- Rabbit Dermal LD50 > 2000 mg/kg

**Hydroxypropyl methylcellulose**
- Rat Oral LD50 > 10,000 mg/kg

**Reproduction & Developmental Toxicity**

<table>
<thead>
<tr>
<th>Study Type, Species, Route, Dose, End Point, Effect(s)</th>
<th>Misoprostol Tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reproductive &amp; Fertility Rat Oral 10 mg/kg/day LOEL Fertility</td>
<td></td>
</tr>
<tr>
<td>Embryo / Fetal Development Rabbit Oral 1 mg/kg/day LOAEI Embryotoxicity</td>
<td></td>
</tr>
<tr>
<td>Embryo / Fetal Development Mouse Oral 30 mg/kg LOAEI Embryotoxicity</td>
<td></td>
</tr>
<tr>
<td>Embryo / Fetal Development Rabbit Oral 1 mg/kg/day NOAEI Not Teratogenic</td>
<td></td>
</tr>
<tr>
<td>Embryo / Fetal Development Rat Oral 10 mg/kg/day NOAEI Not Teratogenic</td>
<td></td>
</tr>
</tbody>
</table>

**Genetic Toxicity:**

- **Bacterial Mutagenicity (Ames):** *Salmonella* Negative
- **In Vitro Mouse Lymphoma:** Negative
- **Sister Chromatid Exchange:** Negative

**Carcinogenicity**

<table>
<thead>
<tr>
<th>Study Type, Species, Route, Dose, End Point, Effect(s)</th>
<th>Misoprostol Tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>21 Month(s) Mouse Oral 16 mg/kg/day NOAEI Not carcinogenic</td>
<td></td>
</tr>
<tr>
<td>24 Month(s) Rat Oral 2.4 mg/kg/day NOAEI Not carcinogenic</td>
<td></td>
</tr>
</tbody>
</table>

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

12. ECOLOGICAL INFORMATION

Environmental Overview: No harmful effects to aquatic organisms are expected.

Toxicity:

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

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: No data available

Bio-accumulative Potential: No data available

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
15. REGULATORY INFORMATION

Canada - WHMIS: Classifications
WHMIS hazard class:
Class D, Division 2, Subdivision A

Misoprostol
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 developmental toxicity initial date 4/1/90
Standard for the Uniform Scheduling Schedule 4
for Drugs and Poisons:
EU EINECS/ELINCS List Not Listed

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 Use restricted. See item 9(f). powder
Dangerous Substances:
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 Schedule 4
for Drugs and Poisons:
EU EINECS/ELINCS List Not Listed

Sodium starch glycolate
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

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3
Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed
Reproductive toxicity-Cat.1A; H360FD - May damage fertility. May damage the unborn child.
Toxic to reproduction: Category 1
T - Toxic
R25 - Toxic if swallowed.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.

Data Sources: Publicly available toxicity information. Safety data sheets for individual ingredients. Pfizer proprietary drug development information.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. 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 12 - Ecological Information.

Revision date: 27-Oct-2014
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