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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Reproductive Toxicity: Category 1A

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
SAFETY DATA SHEET

Material Name: Misoprostol Tablets
Revision date: 01-Oct-2018

Other Hazards
An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

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</th>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Misoprostol</td>
<td>59122-46-2</td>
<td>Not Listed</td>
<td>Acute Tox. 3 (H301) Repr.1A (H360FD)</td>
<td>&lt;1%</td>
<td></td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>Not Listed</td>
<td>*</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hazardous</th>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrogenated castor oil</td>
<td>8001-78-3</td>
<td>232-292-2</td>
<td>Not Listed</td>
<td>*</td>
<td></td>
</tr>
<tr>
<td>Hydroxypropyl methylcellulose</td>
<td>9004-65-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
<td></td>
</tr>
<tr>
<td>Sodium starch glycolate</td>
<td>9063-38-1</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</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 CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

<table>
<thead>
<tr>
<th>Description of First Aid Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye Contact:</td>
</tr>
<tr>
<td>Skin Contact:</td>
</tr>
<tr>
<td>Ingestion:</td>
</tr>
<tr>
<td>Inhalation:</td>
</tr>
</tbody>
</table>

Most Important Symptoms and Effects, Both Acute and Delayed

PZ00195
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.

Fire / Explosion Hazards: Not applicable

Advice for Fire-Fighters
During all firefighting 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. Cleanup 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
Refer to available public information for specific member state Occupational Exposure Limits.
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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 10 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). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands: Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes: Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin: Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection: Under normal conditions of use, 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 (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Tablet
Odor: No data available.
Molecular Formula: Mixture
Solvent Solubility: No data available
Water Solubility: No data available
pH: No data available.

Color: White to off-white
Odor Threshold: No data available.
Molecular Weight: Mixture
9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Melting/Freezing Point (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling Point (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition Coefficient: (Method, pH, Endpoint, Value)</td>
<td>No data available</td>
</tr>
<tr>
<td>Misoprostol</td>
<td>No data available</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>No data available</td>
</tr>
<tr>
<td>Sodium starch glycolate</td>
<td>No data available</td>
</tr>
<tr>
<td>Hydrogenated castor oil</td>
<td>No data available</td>
</tr>
<tr>
<td>Hydroxypropyl methylcellulose</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition Temperature (°C):</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation Rate (Gram/s):</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Pressure (kPa):</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Density (g/ml):</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative Density:</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity:</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability:</td>
<td>No data available</td>
</tr>
<tr>
<td>Autoignition Temperature (Solid) (°C):</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (Solids):</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash Point (Liquid) (°C):</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper Explosive Limits (Liquid) (% by Vol.):</td>
<td>No data available</td>
</tr>
<tr>
<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>No data available</td>
</tr>
<tr>
<td>Oxidizing Properties:</td>
<td>Fine particles (such as dust and mists) may fuel fires/explosions.</td>
</tr>
<tr>
<td>Conditions to Avoid:</td>
<td>As a precautionary measure, keep away from strong oxidizers</td>
</tr>
<tr>
<td>Incompatible Materials:</td>
<td>No data available</td>
</tr>
<tr>
<td>Hazardous Decomposition Products:</td>
<td>No data available</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.
11. TOXICOLOGICAL INFORMATION

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

Misoprostol
- Rat  Oral  LD 50  81 mg/kg
- Rat  Inhalation  LC 50  > 1.43mg/L
- Mouse  Oral  LD 50  27mg/kg

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

Hydroxypropyl methylcellulose
- Rat  Oral  LD50  > 10,000 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)

Misoprostol
- Skin Irritation  Rabbit  Mild

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

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

Misoprostol
- 4 Week(s)  Dog  Intravenous  10 µg/kg/day  LOEL  Liver, Blood
- 13 Week(s)  Rat  Oral  120 µg/kg/day  LOEL  Gastrointestinal system
- 13 Week(s)  Dog  Oral  30 µg/kg/day  LOEL  Gastrointestinal system
- 1 Year(s)  Rat  Oral  160 µg/kg/day  LOEL  Gastrointestinal system
- 1 Year(s)  Dog  Oral  30 ug/kg/day  LOEL  Gastrointestinal system

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

Misoprostol
- Reproductive & Fertility  Rat  Oral  10 mg/kg/day  LOAEL  Fertility
- Embryo / Fetal Development  Rabbit  Oral  1 mg/kg/day  LOAEL  Embryotoxicity
- Embryo / Fetal Development  Mouse  Oral  30 mg/kg  LOAEL  Embryotoxicity
- Embryo / Fetal Development  Rabbit  Oral  1 mg/kg/day  NOAEL  Not Teratogenic
- Embryo / Fetal Development  Rat  Oral  10 mg/kg/day  NOAEL  Not Teratogenic

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

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

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

PZ00195
11. TOXICOLOGICAL INFORMATION

Misoprostol
21 Month(s) Mouse Oral 16 mg/kg/day NOAEL Not carcinogenic
24 Month(s) Rat Oral 2.4 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.

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
Oncorhynchus 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

**Misoprostol**
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: development toxicity 4/1/1990
- Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4
- 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
- EU EINECS/ELINCS List: 232-674-9

**Hydrogenated castor oil**
- 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: 232-292-2

**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

**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 CLP/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.
SAFETY DATA SHEET

Material Name: Misoprostol Tablets
Revision date: 01-Oct-2018

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 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity.

Revision date: 01-Oct-2018
Prepared by: Product Stewardship Hazard Communication

Pfizer 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, 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