MATERIAL SAFETY DATA SHEET

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

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

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

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Misoprostol Tablets

Trade Name:	CYTOTEC; MISODEX
Synonyms:	NAPRATEC (in combination with Naproxen Tablets)
Chemical Family:	Mixture
Intended Use:	Pharmaceutical product for the treatment of ulcers

2. HAZARDS IDENTIFICATION

Appearance: White to off-white tablet
Signal Word: WARNING

Statement of Hazard: May damage fertility or the unborn child.

Additional Hazard Information:
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.

EU Indication of danger: Toxic to reproduction: Category 1

EU Hazard Symbols:

EU Risk Phrases:
R60 - May impair fertility.
R61 - May cause harm to the unborn child.

Australian Hazard Classification (NOHSC): Hazardous Substance. Non-Dangerous Goods.

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	Classification	%
Misoprostol	59122-46-2	Not listed	T;R25 T;R60 T;R61	<1%
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Sodium starch glycolate	9063-38-1	Not listed	Not Listed	*
Hydrogenated castor oil	8001-78-3	232-292-2	Not Listed	*
Hypromellose	9004-65-3	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: 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 thorougly 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.

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.

Hazardous Combustion Products: Emits toxic fumes of carbon monoxide and oxides of nitrogen.

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. Avoid dust formation.

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 thoroughly after handling. Releases to the environment should be avoided.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Misoprostol

Pfizer OEL TWA-8 Hr:	0.7 µg/m^3

Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA)	= 10 mg/m^3 TWA
Australia TWA	= 10 mg/m^3 TWA
Belgium OEL - TWA	= 10 mg/m^3 TWA
Estonia OEL - TWA	= 10 mg/m^3 TWA
France OEL - TWA	= 10 mg/m^3 VME
Ireland OEL - TWAs	= 10 mg/m^3 TWA = 4 mg/m^3 TWA
Latvia OEL - TWA	= 2 mg/m^3 TWA
OSHA - Final PELS - TWAs:	= 15 mg/m^3 TWA total = 5 mg/m^3 TWA
Portugal OEL - TWA	= 10 mg/m^3 TWA
Romania OEL - TWA	= 10 mg/m^3 TWA
Spain OEL - TWA	= 10 mg/m^3 VLA-ED

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

Analytical Method: Analytical method available for Misoprostol. Contact Pfizer Inc for further information.

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:

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:

Physical State:	Tablet	**Color:**	White to off-white
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: Not determined
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.

Hazardous Decomposition Products: Hazardous combustion products may include oxides of carbon , nitrogen

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)

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

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

Hypromellose
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))

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.

Mobility, Persistence and Degradability: Half life = 78 Day(s) (Loam)

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

Misoprostol
Daphnia LC-50 48 Hours > 932.5 mg/L
Rainbow Trout LC-50 72 Hours > 26.4 mg/L
Skeletonema Algae EC-50 72 Hours > 104 mg/L
Skeletonema Algae 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.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered.

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Symbol: T
EU Indication of danger: Toxic to reproduction: Category 1

EU Risk Phrases:

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

EU Safety Phrases:

S22 - Do not breathe dust.
S36/37 - Wear suitable protective clothing and gloves.
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:
WARNING
May damage fertility or the unborn child.

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A

Misoprostol

California Proposition 65	developmental toxicity, initial date 4/1/90
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4

Microcrystalline cellulose

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

Sodium starch glycolate

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

Hydrogenated castor oil

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-292-2

Hypromellose

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R25 - Toxic if swallowed.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.

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

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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