



MATERIAL SAFETY DATA SHEET

Revision date: 18-Jul-2007

Version: 1.4

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

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

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

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

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.
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

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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 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.

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

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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/m³

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:	

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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

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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 µg/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)	<i>Salmonella</i>	Negative
<i>In Vitro</i> 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

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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

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**California Proposition 65
Standard for the Uniform Scheduling
for Drugs and Poisons:**

developmental toxicity, initial date 4/1/90
Schedule 4

Microcrystalline cellulose

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

XU
Present
232-674-9

Sodium starch glycolate

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

XU
Present

Hydrogenated castor oil

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

Present
Present
232-292-2

Hypromellose

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

XU
Present
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