



MATERIAL SAFETY DATA SHEET

Revision date: 15-Dec-2006

Version: 1.1

Page 1 of 9

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

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

Material Name: Phenazopyridine Hydrochloride Tablets

Trade Name: Pyridium
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as analgesic, antispasmodic

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Phenazopyridine hydrochloride	136-40-3	205-243-8	35-40
Starch	9005-25-8	232-679-6	*
Calcium carbonate	471-34-1	207-439-9	*
Kaolin	1332-58-7	Not listed	*
Talc (non-asbestiform)	14807-96-6	238-877-9	*
Titanium dioxide	13463-67-7	236-675-5	*

Ingredient	CAS Number	EU EINECS List	%
Lactose hydrous	64044-51-5	Not listed	*
Methylcellulose	9004-67-5	Not listed	*
Gelatin	9000-70-8	232-554-6	*
Stearic acid	57-11-4	200-313-4	*
Carboxymethyl Starch	9057-06-1	Not listed	*
Sugar	57-50-1	200-334-9	*
Gelatin	9000-70-8	232-554-6	*
Carnauba wax	8015-86-9	232-399-4	*
FD&C Yellow No. 6; (Sunset yellow)	2783-94-0	220-491-7	*
FD&C Blue No. 2	860-22-0	212-728-8	*
White wax	8006-40-4	Not listed	*
Acacia	9000-01-5	232-519-5	*
Confectioner's sugar	MIXTURE	Not listed	*
Tragacanth	9000-65-1	232-552-5	*
D&C Red #7 Calcium Lake	52821-04-9	Not listed	*

Additional Information:

* Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

MATERIAL SAFETY DATA SHEET

Material Name: Phenazopyridine Hydrochloride Tablets
Revision date: 15-Dec-2006

Page 2 of 9
Version: 1.1

Appearance: Reddish-violet tablet
Signal Word: WARNING

Statement of Hazard: Harmful if swallowed.
May cause damage to: liver, kidneys, blood and blood forming organs through prolonged or repeated exposure.
Suspected of causing cancer.

Additional Hazard Information:
Short Term: Overexposure may affect the ability of the blood to carry oxygen (methemoglobinemia) with symptoms of headache, dizziness and a blue color to the skin and lips. May be absorbed through the skin and cause systemic effects. May cause allergic reactions in susceptible individuals.

Known Clinical Effects: Adverse effects most commonly reported in clinical use include headache, dizziness, skin rash, gastrointestinal disturbances red discoloration of urine. Clinical use has resulted in liver effects. Symptoms may include jaundice, liver function test abnormalities, and hepatitis. Kidney dysfunction has been seen during clinical use. Effects on blood and blood-forming organs have also occurred.

EU Indication of danger: Harmful
Carcinogenic: Category 3

EU Hazard Symbols:



EU Risk Phrases:
R22 - Harmful if swallowed.
R40 - Limited evidence of a carcinogenic effect

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.

4. FIRST AID MEASURES

Eye Contact: Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.

Skin Contact: If irritation occurs or persists, get medical attention.

Ingestion: Get medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation: Remove to fresh air. If not breathing, give artificial respiration. Get medical attention immediately.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride, and other chlorine-containing compounds.

MATERIAL SAFETY DATA SHEET

Material Name: Phenazopyridine Hydrochloride Tablets
Revision date: 15-Dec-2006

Page 3 of 9
Version: 1.1

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.

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: If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Phenazopyridine hydrochloride Pfizer OEL TWA-8 Hr:	0.3 mg/m ³ , Skin
Starch	
OSHA - Final PELs - TWAs:	= 15 mg/m ³ TWA total = 5 mg/m ³ TWA
ACGIH Threshold Limit Value (TWA)	= 10 mg/m ³ TWA
Australia TWA	= 10 mg/m ³ TWA
Sugar	
OSHA - Final PELs - TWAs:	= 15 mg/m ³ TWA total = 5 mg/m ³ TWA
ACGIH Threshold Limit Value (TWA)	= 10 mg/m ³ TWA
Australia TWA	= 10 mg/m ³ TWA
Calcium carbonate	
OSHA - Final PELs - TWAs:	= 15 mg/m ³ TWA total = 5 mg/m ³ TWA
ACGIH Threshold Limit Value (TWA)	= 10 mg/m ³ TWA particulate matter containing no asbestos and <1% crystalline silica
ACGIH OELs - Notice of Intended Changes	Listed
Australia TWA	= 10 mg/m ³ TWA
Kaolin	
OSHA - Final PELs - TWAs:	= 15 mg/m ³ TWA total = 5 mg/m ³ TWA
ACGIH Threshold Limit Value (TWA)	= 2 mg/m ³ TWA
Australia TWA	= 10 mg/m ³ TWA

MATERIAL SAFETY DATA SHEET

Material Name: Phenazopyridine Hydrochloride Tablets
Revision date: 15-Dec-2006

Page 4 of 9
Version: 1.1

Talc (non-asbestiform)

OSHA - Final PELs - Table Z-3 Mineral D: = 20 mppcf TWA
ACGIH Threshold Limit Value (TWA) = 2 mg/m³ TWA
Australia TWA = 2.5 mg/m³ TWA containing no asbestos fibers

Titanium dioxide

OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA

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

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

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Personal Protective Equipment:

Hands: Not required for the normal use of this product. Wear protective gloves when working with large quantities.
Eyes: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.
Skin: Not required for the normal use of this product. Wear protective clothing when working with large quantities.
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:	Reddish-violet
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: None known
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.

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)

Starch

Mouse IP LD50 6600 mg/kg

Stearic acid

Rat Oral LD50 > 4640 mg/kg

Rabbit Dermal LD50 > 5000 mg/kg

MATERIAL SAFETY DATA SHEET

Material Name: Phenazopyridine Hydrochloride Tablets
Revision date: 15-Dec-2006

Page 5 of 9
Version: 1.1

Sugar

Rat Oral LD 50 29700 mg/kg
Mouse Oral LD 50 14000 mg/kg

Calcium carbonate

Rat Oral LD50 6450 mg/kg

Talc (non-asbestiform)

Rat Oral LD50 > 1600 mg/kg

Titanium dioxide

Rat Oral LD50 > 7500 mg/kg
Rat Subcutaneous LD 50 50 mg/kg

FD&C Blue No. 2

Rat Oral LD50 2 g/kg
Mouse Oral LD50 2500 mg/kg

FD&C Yellow No. 6; (Sunset yellow)

Rat Oral LD50 > 10,000 mg/kg
Mouse Oral LD50 > 6,000 mg/kg

Phenazopyridine hydrochloride

Rat Oral LD50 472 mg/kg
Mouse Intravenous LD 50 180 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)

Stearic acid

Skin Irritation Rabbit Mild

Acacia

Eye Irritation Rabbit Severe

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

Phenazopyridine hydrochloride

Embryo / Fetal Development Rat Oral 50 mg/kg/day NOEL Not teratogenic

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

FD&C Blue No. 2

Bacterial Mutagenicity (Ames) *Salmonella* Negative

Phenazopyridine hydrochloride

Bacterial Mutagenicity (Ames) *Salmonella* Positive
Mammalian Cell Mutagenicity Mouse Lymphoma Positive
Sister Chromatid Exchange Chinese Hamster Ovary (CHO) cells Positive
Chromosome Aberration Chinese Hamster Ovary (CHO) cells Positive
In Vivo Drosophila Equivocal

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

Phenazopyridine hydrochloride

MATERIAL SAFETY DATA SHEET

Material Name: Phenazopyridine Hydrochloride Tablets
Revision date: 15-Dec-2006

Page 6 of 9
Version: 1.1

78 Week(s) Rat Oral, in feed 3700 ppm LOEL Tumors, Gastrointestinal system
80 Week(s) Female Mouse Oral, in feed 600 ppm LOEL Tumors, Liver
80 Week(s) Male Mouse Oral, in feed 1200 ppm NOEL Not carcinogenic

Carcinogen Status: See below

Talc (non-asbestiform)

IARC: Group 3

Titanium dioxide

IARC: Group 2B

OSHA: Present

FD&C Yellow No. 6; (Sunset yellow)

IARC: Group 3

Phenazopyridine hydrochloride

IARC: Group 2B

NTP: Reasonably Anticipated To Be A Carcinogen

OSHA: Present

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Symbol: Xn
EU Indication of danger: Harmful
Carcinogenic: Category 3

EU Risk Phrases:
R22 - Harmful if swallowed.
R40 - Limited evidence of a carcinogenic effect

EU Safety Phrases:

MATERIAL SAFETY DATA SHEET

Material Name: Phenazopyridine Hydrochloride Tablets
Revision date: 15-Dec-2006

Page 7 of 9
Version: 1.1

S22 - Do not breathe dust.
S36/37 - Wear suitable protective clothing and gloves.

OSHA Label:

WARNING

Harmful if swallowed.

May cause damage to: liver, kidneys, blood and blood forming organs through prolonged or repeated exposure.

Suspected of causing cancer.

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A



Phenazopyridine hydrochloride

California Proposition 65

carcinogen, initial date 1/1/88

Australia (AICS):

Present

EU EINECS List

205-243-8

Starch

Inventory - United States TSCA - Sect. 8(b)

XU

Australia (AICS):

Present

EU EINECS List

232-679-6

Lactose hydrous

Australia (AICS):

Present

Methylcellulose

Inventory - United States TSCA - Sect. 8(b)

XU

Australia (AICS):

Present

Gelatin

Inventory - United States TSCA - Sect. 8(b)

XU

Australia (AICS):

Present

EU EINECS List

232-554-6

Stearic acid

Inventory - United States TSCA - Sect. 8(b)

Present

Australia (AICS):

Present

EU EINECS List

200-313-4

Carboxymethyl Starch

Inventory - United States TSCA - Sect. 8(b)

XU

Australia (AICS):

Present

Sugar

Inventory - United States TSCA - Sect. 8(b)

Present

Australia (AICS):

Present

EU EINECS List

200-334-9

MATERIAL SAFETY DATA SHEET

Material Name: Phenazopyridine Hydrochloride Tablets
Revision date: 15-Dec-2006

Page 8 of 9
Version: 1.1

Gelatin

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-554-6

Calcium carbonate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	207-439-9

Kaolin

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

Talc (non-asbestiform)

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	238-877-9

Carnauba wax

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	232-399-4

FD&C Yellow No. 6; (Sunset yellow)

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	220-491-7

FD&C Blue No. 2

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	212-728-8

Titanium dioxide

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	236-675-5

Acacia

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	232-519-5

Tragacanth

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-552-5

16. OTHER INFORMATION

Reasons for Revision:

Updated Section 3 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 13 - Disposal Considerations.

MATERIAL SAFETY DATA SHEET

Material Name: Phenazopyridine Hydrochloride Tablets
Revision date: 15-Dec-2006

Page 9 of 9
Version: 1.1

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 a warranty of any kind, expressed or implied.

End of Safety Data Sheet