



MATERIAL SAFETY DATA SHEET

Revision date: 04-Jan-2007

Version: 1.1

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

Pfizer Inc
Pfizer Pharmaceuticals Group
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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

Material Name: Piroxicam IM Injectable Solution

Trade Name: FELDENE(R)
Chemical Family: Mixture
Intended Use: Pharmaceutical active used as non-steroidal, anti-inflammatory drug (nsaid)

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Piroxicam	36322-90-4	252-974-3	2.0
Ethanol	64-17-5	200-578-6	10
Benzyl Alcohol	100-51-6	202-859-9	<1.0
Sodium hydroxide	1310-73-2	215-185-5	**
Hydrogen chloride	7647-01-0	231-595-7	**

Ingredient	CAS Number	EU EINECS List	%
Propylene glycol	57-55-6	200-338-0	*
Niacinamide	98-92-0	202-713-4	*
Sodium dihydrogen phosphate dihydrate	13472-35-0	Not listed	*
Water for injection	7732-18-5	231-791-2	*

Additional Information: * Proprietary
** to adjust pH
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: Clear greenish/yellow solution
Signal Word: WARNING

Statement of Hazard: May be harmful if swallowed.
May damage the unborn child.
May cause allergic reaction in aspirin-sensitive individuals
Can cause gastrointestinal and kidney effects
May cause blood, liver, and central nervous system effects

Additional Hazard Information:

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Short Term: May cause eye and skin irritation (based on components) . Accidental ingestion may cause effects similar to those seen in clinical use. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions.

Known Clinical Effects: Ingestion of this material may cause effects similar to those seen in clinical use including serious gastrointestinal toxicity such as bleeding, ulceration, and perforation and kidney toxicity. Clinical use of this drug has caused headache, dizziness, blurred vision, ringing of the ears, skin rash, itching, swelling, liver effects.

EU Indication of danger: Toxic to reproduction: Category 1
Harmful

EU Hazard Symbols:



EU Risk Phrases:

R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.
R61 - May cause harm to the unborn child.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients 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: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Wash skin with soap and water. Remove contaminated clothing and shoes. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. 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: Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.

Fire Fighting Procedures: Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Evacuate area and fight fire from a safe distance.

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.

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Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. 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: Use appropriate ventilation. Avoid contact with eyes, skin and clothing.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Piroxicam
Pfizer OEL TWA-8 Hr: 0.1 mg/m³

Propylene glycol
Australia TWA = 10 mg/m³ TWA
= 150 ppm TWA
= 474 mg/m³ TWA

Ethanol
OSHA - Final PELS - TWAs: = 1000 ppm TWA
= 1900 mg/m³ TWA
ACGIH Threshold Limit Value (TWA) = 1000 ppm TWA
Australia TWA = 1000 ppm TWA
= 1880 mg/m³ TWA

Sodium hydroxide
OSHA - Final PELS - TWAs: 2 mg/m³
ACGIH Ceiling Threshold Limit: = 2 mg/m³ Ceiling
Australia PEAK = 2 mg/m³ Peak

Hydrogen chloride
ACGIH Ceiling Threshold Limit: = 2 ppm Ceiling
Australia PEAK = 5 ppm Peak
= 7.5 mg/m³ Peak

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

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

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Good general ventilation should be sufficient to control airborne levels. For laboratory use, handle in a lab fume hood.

Personal Protective Equipment:

Hands: Rubber gloves
Eyes: Safety glasses or goggles
Skin: Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
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.

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9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Solution	Color:	Clear greenish/yellow
Odor:	Slight Alcohol	Molecular Formula:	Mixture
Molecular Weight:	Mixture		
pH:	7.5-8.5		

10. STABILITY AND REACTIVITY

Stability:	Stable
Conditions to Avoid:	None known
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers.
Polymerization:	Will not occur

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)

Piroxicam

Mouse Oral LD50 360 mg/kg
Rat Oral LD50 270 mg/kg
Mouse IP LD50 360 mg/kg
Rat IP LD50 220 mg/kg
Dog Oral LD50 > 700 mg/kg

Propylene glycol

Mouse Oral LD50 22,000 mg/kg
Rat Oral LD50 20,000 mg/kg
Rabbit Dermal LD50 20,800 mg/kg

Benzyl Alcohol

Rat Oral LD50 1.23 g/kg
Rat Intravenous LD50 53 mg/kg

Ethanol

Mouse Oral LD50 3,450 g/m³
Rat Oral LD50 7,060 mg/kg
Mouse Inhalation LC50 4h 39 g/m³
Rat Inhalation LC50 10h 20,000 ppm

Niacinamide

Rat Oral LD50 3500 mg/kg
Mouse Oral LD50 2500 mg/kg
Rat Subcutaneous LD50 1680 g/kg
Mouse IP LD50 2050 mg/kg
Rabbit Dermal LD 50 >2000 mg/kg

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Sodium hydroxide

Mouse IP LD50 40 mg/kg

Hydrogen chloride

Rat Inhalation LC50 1H 3,124 ppm

Mouse Inhalation LC50 1H 1,108 ppm

Mouse Oral LD50 900 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)

Piroxicam

Eye Irritation Rabbit Non-irritating

Skin Irritation Rabbit Non-irritating

Propylene glycol

Skin Irritation Rabbit Mild

Eye Irritation Rabbit Mild

Benzyl Alcohol

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Moderate

Skin Irritation Guinea Pig Moderate

Ethanol

Eye Irritation Rabbit Severe

Sodium hydroxide

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Severe

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

Piroxicam

3 Month(s) Rat Oral 5 mg/kg/day NOAEL Gastrointestinal System

3 Month(s) Monkey Oral 2.5 mg/kg/day Gastrointestinal system

18 Month(s) Rat Oral 1 mg/kg/day NOAEL Gastrointestinal system, Kidney

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

Piroxicam

Reproductive & Fertility Rat Oral 10 mg/kg/day NOAEL No effects at maximum dose

Peri-/Postnatal Development Rat Oral 2 mg/kg/day LOAEL Developmental toxicity

Fertility and Embryonic Development Rat Oral 10 mg/kg/day NOAEL No effects at maximum dose, Not Teratogenic

Fertility and Embryonic Development Rabbit Oral 10 mg/kg/day NOAEL No effects at maximum dose, Not Teratogenic

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

Piroxicam

In Vitro Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative

In Vitro Cytogenetics Human Lymphocytes Negative

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

Piroxicam

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2 Year(s) Rat Oral 1 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.

Hydrogen chloride
IARC: Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided.

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

Ethanol

Fingerling Trout	NPDES	LC50	24 Hours	11,200 mg/L
Rainbow Trout	NPDES	LC50	96 Hours	12,900 mg/L
Fathead minnow	NPDES	LC50	96 Hours	14,200 mg/L

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

EU Risk Phrases:
R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.
R61 - May cause harm to the unborn child.

EU Safety Phrases:
S22 - Do not breathe dust.
S36 - Wear suitable protective clothing.
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:

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WARNING

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Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A



Piroxicam

Australia (AICS): Standard for the Uniform Scheduling for Drugs and Poisons:	Present Schedule 4
EU EINECS List	252-974-3

Propylene glycol

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-338-0

Ethanol

California Proposition 65	developmental toxicity, initial date 10/1/87 (when in alcoholic beverages)
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-578-6

Niacinamide

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	202-713-4

Sodium dihydrogen phosphate dihydrate

Australia (AICS):	Present
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Benzyl Alcohol

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	202-859-9

Sodium hydroxide

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 1000 lb final RQ = 454 kg final RQ
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS List	215-185-5

Water for injection

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Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-791-2

Hydrogen chloride

CERCLA/SARA 313 Emission reporting	= 1.0 % de minimis concentration acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 2270 kg final RQ
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	= 5000 lb final RQ
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	= 500 lb TPQ gas only
Inventory - United States TSCA - Sect. 8(b)	= 5000 lb EPCRA RQ gas only
Australia (AICS):	T
Standard for the Uniform Scheduling for Drugs and Poisons:	Present
EU EINECS List	Schedule 5
	Schedule 6
	231-595-7

16. OTHER INFORMATION

Reasons for Revision: Updated Section 3 - Hazard Identification. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 15 - Regulatory Information.

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

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End of Safety Data Sheet