



# MATERIAL SAFETY DATA SHEET

Revision date: 14-Jan-2011

Version: 2.0

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

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Pfizer Pharmaceuticals Group  
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### Material Name: Piroxicam IM Injectable Solution

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

## 2. HAZARDS IDENTIFICATION

Appearance: Clear greenish/yellow solution  
Signal Word: WARNING

Statement of Hazard: May damage the unborn child.  
Can cause gastrointestinal and kidney effects May cause damage to gastrointestinal system through prolonged or repeated exposure.

Additional Hazard Information:  
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.  
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

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## 2. HAZARDS IDENTIFICATION

**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.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Piroxicam	36322-90-4	252-974-3	Repr.Cat.1;R61 Xn;R22 T;R48/25	2.0
Ethanol	64-17-5	200-578-6	F;R11	10
Benzyl Alcohol	100-51-6	202-859-9	Xn;R20/22	<1.0
Sodium hydroxide	1310-73-2	215-185-5	C;R35	**
Hydrogen chloride	7647-01-0	231-595-7	C;R35 T;R23	**

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

**Additional Information:** \* Proprietary  
\*\* to adjust pH  
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:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek 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.

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### 5. FIRE FIGHTING MEASURES

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

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

**Fire Fighting Procedures:** During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

**Fire / Explosion Hazards:** Flammable liquid and vapor

### 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 the spill or leak. Absorb spills with non-combustible absorbent material and transfer into a labeled container for disposal. Clean spill area thoroughly. Prevent discharge to

**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

Refer to available public information for specific member state Occupational Exposure Limits.

#### Piroxicam

Pfizer OEL TWA-8 Hr: 100µg/m<sup>3</sup>

#### Propylene glycol

Australia TWA 10 mg/m<sup>3</sup>  
150 ppm  
474 mg/m<sup>3</sup>

Ireland OEL - TWAs Listed  
Latvia OEL - TWA Listed  
Lithuania OEL - TWA Listed

#### Ethanol

ACGIH Threshold Limit Value (TWA) 1000 ppm TWA  
ACGIH OELs - Notice of Intended Changes Listed  
Australia TWA 1000 ppm  
1880 mg/m<sup>3</sup>

Austria OEL - MAKs Listed  
Belgium OEL - TWA Listed  
Bulgaria OEL - TWA Listed  
Czech Republic OEL - TWA Listed

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Denmark OEL - TWA	Listed
Estonia OEL - TWA	Listed
Finland OEL - TWA	Listed
France OEL - TWA	Listed
Germany - TRGS 900 - TWAs	500 ppm 960 mg/m <sup>3</sup>
Germany (DFG) - MAK	500 ppm MAK 960 mg/m <sup>3</sup> MAK
Greece OEL - TWA	Listed
Hungary OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Latvia OEL - TWA	Listed
Lithuania OEL - TWA	Listed
OSHA - Final PELs - TWAs:	1000 ppm 1900 mg/m <sup>3</sup>
Poland OEL - TWA	Listed
Portugal OEL - TWA	Listed
Romania OEL - TWA	Listed
Slovenia OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed
<b>Benzyl Alcohol</b>	
Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Latvia OEL - TWA	Listed
Lithuania OEL - TWA	Listed
Poland OEL - TWA	Listed
<b>Sodium hydroxide</b>	
ACGIH Ceiling Threshold Limit:	2 mg/m <sup>3</sup>
Australia PEAK	2 mg/m <sup>3</sup>
Austria OEL - MAKs	Listed
Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Estonia OEL - TWA	Listed
France OEL - TWA	Listed
Greece OEL - TWA	Listed
Hungary OEL - TWA	Listed
Japan - OELs - Ceilings	2 mg/m <sup>3</sup>
Latvia OEL - TWA	Listed
OSHA - Final PELs - TWAs:	2 mg/m <sup>3</sup>
Poland OEL - TWA	Listed
Slovenia OEL - TWA	Listed
Sweden OEL - TWAs	Listed
<b>Niacinamide</b>	
Latvia OEL - TWA	Listed
Lithuania OEL - TWA	Listed
<b>Hydrogen chloride</b>	
ACGIH Ceiling Threshold Limit:	2 ppm

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Australia PEAK	5 ppm 7.5 mg/m <sup>3</sup>
Austria OEL - MAKs	Listed
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Cyprus OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Estonia OEL - TWA	Listed
Germany - TRGS 900 - TWAs	2 ppm 3 mg/m <sup>3</sup>
Germany (DFG) - MAK	2 ppm MAK 3.0 mg/m <sup>3</sup> MAK
Greece OEL - TWA	Listed
Hungary OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Italy OEL - TWA	Listed
Japan - OELs - Ceilings	5 ppm 7.5 mg/m <sup>3</sup>
Latvia OEL - TWA	Listed
Lithuania OEL - TWA	Listed
Luxembourg OEL - TWA	Listed
Malta OEL - TWA	Listed
Netherlands OEL - TWA	Listed
Poland OEL - TWA	Listed
Romania OEL - TWA	Listed
Slovenia OEL - TWA	Listed
Spain OEL - TWA	Listed

<b>Analytical Method:</b>	Analytical method available for Piroxicam. Contact Pfizer Inc for further information.
<b>Engineering Controls:</b>	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.
<b>Environmental Exposure Controls:</b>	Refer to specific Member State legislation for requirements under Community environmental legislation.
<b>Personal Protective Equipment:</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
<b>Hands:</b>	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Eyes:</b>	Wear safety glasses or goggles if eye contact is possible.
<b>Skin:</b>	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Respiratory protection:</b>	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

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

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

Polymerization: Will not occur

### 10. STABILITY AND REACTIVITY

**Chemical Stability:** Stable under normal conditions of use.  
**Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.  
**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)

##### **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 1230 mg/kg  
Rat Para-periosteal LD50 53 mg/kg  
Rat Inhalation LC50 46 mg/m<sup>3</sup>

##### **Ethanol**

Mouse Oral LD50 3,450 g/m<sup>3</sup>  
Rat Oral LD50 7,060 mg/kg  
Mouse Inhalation LC50 4h 39 g/m<sup>3</sup>  
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

##### **Sodium hydroxide**

Mouse IP LD50 40 mg/kg

##### **Hydrogen chloride**

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### 11. TOXICOLOGICAL INFORMATION

Rat Sub-tenon injection (eye) 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**

2 Year(s) Rat Oral 1 mg/kg/day NOAEL Not carcinogenic

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## 11. TOXICOLOGICAL INFORMATION

**Carcinogen Status:** None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

### Ethanol

IARC: Group 1  
NTP: Listed  
OSHA: Present

### 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
<i>Oncorhynchus mykiss</i> (Rainbow Trout)	NPDES	LC50	96 Hours	12,900 mg/L
<i>Pimephales promelas</i> (Fathead Minnow)	NPDES	LC50	96 Hours	14,200 mg/L

## 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

**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:**



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## 15. REGULATORY INFORMATION

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

### OSHA Label:

WARNING

May damage the unborn child.

Can cause gastrointestinal and kidney effects May cause damage to gastrointestinal system through prolonged or repeated exposure.

### Canada - WHMIS: Classifications

#### WHMIS hazard class:

Class D, Division 2, Subdivision A



### Piroxicam

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

### Propylene glycol

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

### Ethanol

California Proposition 65	carcinogen, initial date 7/1/88 (when associated with alcohol abuse) developmental toxicity, initial date 10/1/87 (when in alcoholic beverages)
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	200-578-6

### Sodium dihydrogen phosphate dihydrate

Australia (AICS):	Listed
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### Benzyl Alcohol

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

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## 15. REGULATORY INFORMATION

Australia (AICS):	Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5
EU EINECS/ELINCS List	Schedule 6
	215-185-5

### Water for injection

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

### Niacinamide

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

### 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
Australia (AICS):	Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Listed
EU EINECS/ELINCS List	Schedule 5
	Schedule 6
	231-595-7

## 16. OTHER INFORMATION

### Text of R phrases mentioned in Section 3

R61 - May cause harm to the unborn child.  
R22 - Harmful if swallowed.  
R11 - Highly flammable.  
R20/22 - Harmful by inhalation and if swallowed.  
R48/25 - Toxic: danger of serious damage to health by prolonged exposure if swallowed.

**Data Sources:** Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

**Reasons for Revision:** Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 15 - Regulatory Information. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 5 - Fire Fighting Measures. Updated Section 7 - Handling and Storage. Updated Section 10 - Stability and Reactivity. Updated Section 14 - Transport Information.

**Prepared by:** Product Stewardship Hazard Communications  
Pfizer Global Environment, Health, and Safety Operations

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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**