



# MATERIAL SAFETY DATA SHEET

Revision date: 07-Nov-2008

Version: 1.6

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

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### Material Name: FELDENE® (Piroxicam) Gel

<b>Trade Name:</b>	Feldene®; Felden®; Dolonex®
<b>Chemical Family:</b>	Mixture
<b>Intended Use:</b>	Pharmaceutical product used as non-steroidal, anti-inflammatory drug (nsaid)

## 2. HAZARDS IDENTIFICATION

**Appearance:** Clear pale yellow gel  
**Signal Word:** WARNING

**Statement of Hazard:** May damage the unborn child.

### Additional Hazard Information:

**Short Term:** May cause eye irritation (based on components) . Active ingredient may be harmful if swallowed. May cause allergic reactions in susceptible individuals. Exposure to high concentrations may cause irritation, headache, drowsiness, and symptoms of alcohol intoxication.

**Long Term:** Chronic ingestion of ethanol has been associated with an increased incidence of cancer, liver cirrhosis, and congenital malformations.

**Known Clinical Effects:** Topical application of this material may cause effects similar to those seen in clinical use including mild or moderate local irritation, erythema, rash, pityroid desquamation, pruritus, and related local reactions at the application site. Common adverse effects associated with oral administration of piroxicam include serious gastrointestinal toxicity such as bleeding, ulceration, and perforation and kidney toxicity. Other piroxicam treatment-related effects include headache, dizziness, blurred vision, ringing in the ears, skin rashes and itching, swelling, and liver effects. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.

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

### EU Hazard Symbols:



### EU Risk Phrases:

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### 2. HAZARDS IDENTIFICATION

**Australian Hazard Classification (NOHSC):**

R61 - May cause harm to the unborn child.  
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 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	Classification	%
Piroxicam	36322-90-4	252-974-3	Repr.Cat.1;R61 Xn;R22 T;R48/25	0.5
Benzyl Alcohol	100-51-6	202-859-9	Xn;R20/22	*
Ethanol	64-17-5	200-578-6	F;R11	*
Hydroxyethyl cellulose	9004-62-0	Not listed	Not Listed	*
Propylene glycol	57-55-6	200-338-0	Not Listed	*
Diisopropanolamine	110-97-4	203-820-9	Xi;R36	*

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Carbomer	9003-01-4	Not listed	Not Listed	*
Purified water	7732-18-5	231-791-2	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:** 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

<b>Extinguishing Media:</b>	Use carbon dioxide, dry chemical, or water spray.
<b>Hazardous Combustion Products:</b>	Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.
<b>Fire Fighting Procedures:</b>	Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Evacuate area and fight fire from a safe distance.
<b>Fire / Explosion Hazards:</b>	Fine particles (such as dust and mists) may fuel fires/explosions.

### 6. ACCIDENTAL RELEASE MEASURES

<b>Health and Safety Precautions:</b>	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
<b>Measures for Cleaning / Collecting:</b>	Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.
<b>Measures for Environmental Protections:</b>	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
<b>Additional Consideration for Large Spills:</b>	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

<b>General Handling:</b>	Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.
<b>Storage Conditions:</b>	Store as directed by product packaging.

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### 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>

#### Carbomer

Austria OEL - MAKs Listed  
Finland OEL - TWA Listed  
Hungary OEL - TWA Listed  
Netherlands OEL - TWA Listed  
Slovenia OEL - TWA Listed

#### Benzyl Alcohol

Bulgaria OEL - TWA Listed  
Czech Republic OEL - TWA Listed  
Latvia OEL - TWA Listed  
Lithuania OEL - TWA Listed  
Poland OEL - TWA Listed

#### Ethanol

ACGIH Threshold Limit Value (TWA) = 1000 ppm TWA  
Australia TWA = 1000 ppm TWA  
= 1880 mg/m<sup>3</sup> TWA  
Austria OEL - MAKs Listed  
Belgium OEL - TWA Listed  
Bulgaria OEL - TWA Listed  
Czech Republic OEL - TWA Listed  
Denmark OEL - TWA Listed  
Estonia OEL - TWA Listed  
Finland OEL - TWA Listed  
France OEL - TWA Listed  
Germany - TRGS 900 - TWAs = 500 ppm TWA  
= 960 mg/m<sup>3</sup> TWA  
Germany (DFG) - MAK = 500 ppm MAK  
= 960 mg/m<sup>3</sup> MAK  
Greece OEL - TWA Listed  
Hungary OEL - TWA Listed  
Ireland OEL - TWAs = 1000 ppm TWA  
= 1900 mg/m<sup>3</sup> TWA  
Latvia OEL - TWA Listed  
Lithuania OEL - TWA Listed  
Netherlands OEL - TWA Listed  
OSHA - Final PELs - TWAs: = 1000 ppm TWA  
= 1900 mg/m<sup>3</sup> TWA  
Poland OEL - TWA Listed  
Portugal OEL - TWA Listed  
Romania OEL - TWA Listed  
Slovenia OEL - TWA Listed  
Spain OEL - TWA Listed  
Sweden OEL - TWAs = 1000 mg/m<sup>3</sup> LLV  
= 500 ppm LLV

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Propylene glycol

Australia TWA	= 10 mg/m <sup>3</sup> TWA = 150 ppm TWA = 474 mg/m <sup>3</sup> TWA
Ireland OEL - TWAs	= 10 mg/m <sup>3</sup> TWA = 150 ppm TWA = 470 mg/m <sup>3</sup> TWA
Latvia OEL - TWA	Listed
Lithuania OEL - TWA	Listed

#### 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. 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.

#### Environmental Exposure Controls:

Refer to specific Member State legislation for requirements under Community environmental legislation.

#### Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

#### 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:	Gel	Color:	Pale yellow
Odor:	Ethanollic odor	Molecular Formula:	Mixture
Molecular Weight:	Mixture		

pH: 7.2 - 8.2

Polymerization: Will not occur

### 10. STABILITY AND REACTIVITY

#### 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

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### 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)

##### **Benzyl Alcohol**

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

##### **Propylene glycol**

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

##### **Piroxicam**

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

##### **Ethanol**

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

**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)

##### **Benzyl Alcohol**

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Moderate  
Skin Irritation Guinea Pig Moderate

##### **Propylene glycol**

Skin Irritation Rabbit Mild  
Eye Irritation Rabbit Mild

##### **Piroxicam**

Eye Irritation Rabbit Non-irritating  
Skin Irritation Rabbit Non-irritating

##### **Ethanol**

Eye 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

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### 11. TOXICOLOGICAL INFORMATION

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

#### **Carcinogen Status:**

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.  
See below

##### **Carbomer**

IARC:

Group 3 (Not Classifiable)

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### 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. 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

Aqueous products containing alcohol at 24 percent or less are not subject to the requirements of the EU ADR, IATA, or IMDG. They are similarly exempt from US DOT requirements provided that they contain no less than 50 percent water.

### 15. REGULATORY INFORMATION

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

**EU Risk Phrases:**  
R61 - May cause harm to the unborn child.

**EU Safety Phrases:**  
S53 - Avoid exposure - obtain special instructions before use.

**OSHA Label:**  
WARNING  
May damage the unborn child.

#### **Canada - WHMIS: Classifications**

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



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## 15. REGULATORY INFORMATION



**Piroxicam**

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

**Carbomer**

CERCLA/SARA 313 Emission reporting	= 1.0 % de minimis concentration does not include copper phthalocyanine compounds substituted only with hydrogen and/or bromine and/or chlorine, Chemical Category N100
Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS): Standard for the Uniform Scheduling for Drugs and Poisons:	Present Schedule 4 Schedule 5 Schedule 6

**Benzyl Alcohol**

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

**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/ELINCS List	200-578-6

**Purified water**

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

**Hydroxyethyl cellulose**

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

**Propylene glycol**

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

**Diisopropanolamine**

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	203-820-9

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### 15. REGULATORY INFORMATION

### 16. OTHER INFORMATION

#### Text of R phrases mentioned in Section 3

R11 - Highly flammable.

R22 - Harmful if swallowed.

R36 - Irritating to eyes.

R61 - May cause harm to the unborn child.

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. Publicly available toxicity information. Safety data sheets for individual ingredients.

#### **Reasons for Revision:**

Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

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**