



# 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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New York, New York 10017  
1-212-573-2222

**Pfizer Ltd**  
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Sandwich, Kent  
CT13 9NJ  
United Kingdom  
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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 Suppositories

**Trade Name:** FELDENE(R)  
**Chemical Family:** Mixture  
**Intended Use:** Pharmaceutical product 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	1.05
Propyl gallate	121-79-9	204-498-2	*

Ingredient	CAS Number	EU EINECS List	%
Microcrystalline wax	63231-60-7	264-038-1	*
Hard fat	Not assigned	Not listed	*

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

## 3. HAZARDS IDENTIFICATION

**Appearance:** Off-white Suppository  
**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:**  
**Short Term:** Not an eye irritant Not a skin irritant (based on animal data) 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.

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

**Fire / Explosion Hazards:** Not determined

## 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.

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**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/m<sup>3</sup>

The exposure limit(s) listed for solid components are only relevant if dust 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:** 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:** Not required for the normal use of this product. 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>	Suppository	<b>Color:</b>	Off-white
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

### 10. STABILITY AND REACTIVITY

**Stability:** Stable  
**Conditions to Avoid:** Not determined  
**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 active ingredient

**Acute Toxicity: (Species, Route, End Point, Dose)**

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### 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

#### 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

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

### Piroxicam

3 Month(s) Rat Oral 5 mg/kg/day NOEL Gastrointestinal System  
3 Month(s) Monkey Oral 2.5 mg/kg/day Gastrointestinal system  
18 Month(s) Rat Oral 1 mg/kg/day NOEL Gastrointestinal system, Kidney

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

### Piroxicam

Reproductive & Fertility Rat Oral 10 mg/kg/day NOEL 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 NOEL No effects at maximum dose, Not Teratogenic  
Fertility and Embryonic Development Rabbit Oral 10 mg/kg/day NOEL 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 NOEL 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:

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

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## 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:**  
WARNING  
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

### Canada - WHMIS: Classifications

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



### Piroxicam

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

### Propyl gallate

<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present

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EU EINECS List	204-498-2
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Microcrystalline wax	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	264-038-1

### 16. OTHER INFORMATION

**Reasons for Revision:** Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures.  
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**