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

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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Piroxicam</td>
<td>36322-90-4</td>
<td>252-974-3</td>
<td>2.0</td>
</tr>
<tr>
<td>Ethanol</td>
<td>64-17-5</td>
<td>200-578-6</td>
<td>10</td>
</tr>
<tr>
<td>Benzyl Alcohol</td>
<td>100-51-6</td>
<td>202-859-9</td>
<td>&lt;1.0</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>215-185-5</td>
<td>**</td>
</tr>
<tr>
<td>Hydrogen chloride</td>
<td>7647-01-0</td>
<td>231-595-7</td>
<td>**</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>200-338-0</td>
<td>*</td>
</tr>
<tr>
<td>Niacinamide</td>
<td>98-92-0</td>
<td>202-713-4</td>
<td>*</td>
</tr>
<tr>
<td>Sodium dihydrogen phosphate dihydrate</td>
<td>13472-35-0</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Water for injection</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>*</td>
</tr>
</tbody>
</table>

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:
Material Name: Piroxicam IM Injectable Solution
Revision date: 04-Jan-2007

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 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.
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)

Australia TWA:

= 1000 ppm TWA
= 1880 mg/m³ TWA

Sodium hydroxide

OSHA - Final PELS - TWAs:

= 2 mg/m³

ACGIH Ceiling Threshold Limit:

Australia PEAK

= 2 mg/m³ Ceiling
= 2 mg/m³ Peak

Hydrogen chloride

ACGIH Ceiling Threshold Limit:

Australia PEAK

= 2 ppm Ceiling
= 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.


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.
9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State: Solution
Odor: Slight Alcohol
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
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
\textit{In Vitro} Bacterial Mutagenicity (Ames)  \textit{Salmonella} , \textit{E. coli}  Negative
\textit{In Vitro} Cytogenetics  Human Lymphocytes  Negative

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

Piroxicam
Material Name: Piroxicam IM Injectable Solution
Revision date: 04-Jan-2007

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.
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
- **Australia (AICS):** Present
- **Standard for the Uniform Scheduling for Drugs and Poisons:** 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

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
- **EU EINECS List:** 215-185-5

Water for injection
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