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

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Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300

Material Name: FELDENE® (Piroxicam) capsules

Trade Name: Feldene®
Chemical Family: Mixture
Intended Use: Pharmaceutical product 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>10 or 20 mg***</td>
</tr>
<tr>
<td>FD &amp; C Red No. 3 (E 127)</td>
<td>16423-68-0</td>
<td>240-474-8</td>
<td>*</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>*</td>
</tr>
<tr>
<td>Sodium lauryl sulfate</td>
<td>151-21-3</td>
<td>205-788-1</td>
<td>*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lactose NF, monohydrate</td>
<td>64044-51-5</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>FD &amp; C Blue No. 1</td>
<td>3844-45-9</td>
<td>223-339-8</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information:
* Proprietary
*** per tablet/capsule/lozenge/suppository
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: Blue capsules (10 mg) and maroon capsules (20 mg)
Signal Word: WARNING

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

Additional Hazard Information:
Short Term: Not an eye irritant Active ingredient is not a skin irritant (based on animal data) Can cause respiratory irritation 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. Other piroxicam treatment-related effects include headache, dizziness, blurred vision, ringing in the ears, skin rashes and itching, swelling, and liver effects.

EU Indication of danger: Toxic to reproduction: Category 1

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

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 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.
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: If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing.

Storage Conditions: Store in a cool, dry, well-ventilated area. Keep container tightly closed when not in use. Protect from light.

Storage Temperature: 15-30°C

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Starch
OSHA - Final PELS - TWAs: = 15 mg/m³ TWA total
= 5 mg/m³ TWA
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA

Magnesium stearate
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA except stearates of toxic metals
Australia TWA = 10 mg/m³ TWA

Sodium lauryl sulfate
Pfizer OEL TWA-8 Hr: 0.3 mg/m³
Pfizer STEL 0.75 mg/m³
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.

Personal Protective Equipment:

Hands: Not required for the normal use of this product. Wear protective gloves when working with large quantities.

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:
10. STABILITY AND REACTIVITY

Stability: Stable
Conditions to Avoid: None known
Incompatible Materials: 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)

Starch
Mouse IP LD50 6600 mg/kg

Magnesium stearate
Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m³

Sodium lauryl sulfate
Rat Oral LD50 1288 mg/kg

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

FD & C Red No. 3 (E 127)
Rat Oral LD50 1840 mg/kg
Mouse Oral LD50 1264 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.

Inhalation Acute Toxicity: No data available
Ingestion Acute Toxicity: See Acute toxicity table

Irritation / Sensitization: (Study Type, Species, Severity)

Sodium lauryl sulfate
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

Piroxicam
Eye Irritation / Sensitization
No eye irritation was seen upon repeated installation of a 10 mg/ml solution of piroxicam, 10 times per day for 7 days or installation of 0.5 ml of a 1% solution for 21 days.

Skin Irritation / Sensitization
No skin irritation was observed for piroxicam when 500 mg of a 10% ointment was applied once or up to 500 mg of a 1% ointment was applied twice a day for one month.

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

Subchronic Effects
Subchronic oral toxicity studies were conducted in rats at doses up to 25 mg/kg/day and monkeys at doses up to 10 mg/kg/day for 3 months. In rats, gastric ulcers were seen at 10 and 25 mg/kg/day in males and females (more severe and numerous). In monkeys, minimal gastrointestinal lesions were observed at 10 mg/kg/day.

Chronic Toxicity
Chronic toxicity of this material was evaluated for 18 months in mice at doses up to 8 mg/kg/day and rats at doses up to 3 mg/kg/day, and for 1 year in dogs at a dose of 1 mg/kg/day and monkeys at doses up to 10 mg/kg/day. Gastrointestinal lesions and kidney necrosis were observed in mice at 4 or 8 mg/kg/day and male and female rats at 3 mg/kg/day and one female at the low dose (0.3 mg/kg). In dogs, gastrointestinal and kidney toxicity was associated with treatment. In monkeys, kidney toxicity was seen in the high dose females; no evidence of GI toxicity was seen at the dosage levels tested.

Chronic Effects/Carcinogenicity
No evidence of carcinogenic potential was seen in rats at doses up to 1 mg/kg/day for 2 years.

Reproduction & Development Toxicity: (Duration, 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

Reproductive Effects
No effects on fertility or reproductive performance were observed in rats. However, a slight inhibition of postnatal body weight gain was seen in pups at doses up to 10 mg/kg/day in a perinatal and postnatal development study in rats. Other nonsteroidal anti-inflammatory drugs (NSAIDs) are known to impact delivery, late fetal development, and lactation. Therefore, it is recommended that exposure late in pregnancy be avoided.

Teratogenicity
No evidence of teratogenic activity. Kidneys Gastrointestinal tract Reproductive system

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

Piroxicam

In Vitro Bacterial Mutagenicity (Ames) Salmonella, E. coli Negative
In Vitro Cytogenetics Human Lymphocytes Negative

Mutagenicity
No evidence of mutagenicity was observed in the following assays: S. typhimurium and E. coli bacteria mitotic recombination assay in yeast in vitro chromosomal aberration in human lymphocytes

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
At increase risk from exposure: Individuals who have shown hypersensitivity to this material and individuals with heart conditions and impaired kidney and/or liver functions may be more susceptible to toxicity in cases of overexposure.

Additional Information: FDA PREGNANCY CATEGORY C.

12. ECOLOGICAL INFORMATION

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

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

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 cause allergic reaction in aspirin-sensitive individuals.
Can cause gastrointestinal and kidney effects.
May cause blood, liver, and central nervous system effects.
Possible risk of harm to the unborn child.

Canada - WHMIS: Classifications
16. OTHER INFORMATION

Reasons for Revision: Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures. Updated Section 6 - Accidental Release Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations. 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