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

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

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

Material Name: Oxaprozin Potassium Tablets

Trade Name: Daypro Alta (TM)
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as non-steroidal, anti-inflammatory drug (nsaid)

2. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Hazardous Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxaprozin Potassium</td>
<td>174064-08-5</td>
<td>Not listed</td>
<td>600 mg ***</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>*</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>236-675-5</td>
<td>*</td>
</tr>
<tr>
<td>Colloidal silicon dioxide</td>
<td>7631-86-9</td>
<td>231-545-4</td>
<td>*</td>
</tr>
<tr>
<td>Corn Starch</td>
<td>9005-25-8</td>
<td>232-679-6</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>Hypermellose</td>
<td>9004-65-3</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>FD&amp;C Blue no. 1 aluminum lake</td>
<td>68921-42-6</td>
<td>272-939-6</td>
<td>*</td>
</tr>
<tr>
<td>Polyethylene glycol</td>
<td>25322-68-3</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Stearic acid</td>
<td>57-11-4</td>
<td>200-313-4</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 tablets
Signal Word: WARNING

Statement of Hazard: May cause damage to gastrointestinal system through prolonged or repeated exposure. Toxic to aquatic life with long lasting effects.

Additional Hazard Information:
Short Term: May cause mild eye irritation. May cause slight skin irritation. (based on components). Accidental ingestion may cause effects similar to those seen in clinical use.
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. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. Clinical use has resulted in liver effects. Symptoms may include jaundice, liver function test abnormalities, and hepatitis. Other nonsteroidal anti-inflammatory drugs (NSAIDs) are known to impact delivery, late fetal development, and lactation.

EU Indication of danger: Dangerous for the Environment

EU Hazard Symbols: 

EU Risk Phrases: R51/53 - Toxic to aquatic organisms. May cause long-term adverse effects in the aquatic environment.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates 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: Rinse thoroughly with plenty of water, also under the eyelids. If irritation occurs or persists, get medical attention.

Skin Contact: Wash exposed area with soap and water, remove contaminated clothing and obtain medical assistance if irritation occurs.

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.

5. FIRE FIGHTING MEASURES

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

Hazardous Combustion Products: Emits toxic fumes of carbon monoxide and oxides of nitrogen.

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

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 as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Microcrystalline cellulose

- 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

Titanium dioxide

- 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

Colloidal silicon dioxide

- OSHA - Final PELs - Table Z-3 Mineral D: (80)/(% SiO2) mg/m³ TWA
  - 20 mppcf TWA
- Australia TWA 2 mg/m³ TWA

Corn 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

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Oxaprozin Potassium

- Pfizer Occupational Exposure Band (OEB): OEB2 (control exposure to the range of >100ug/m³ to < 1000ug/m³)

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels within the OEB range.

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: None required under normal conditions of use. If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

9. PHYSICAL AND CHEMICAL PROPERTIES:

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Tablets</th>
<th>Color:</th>
<th>Blue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

10. STABILITY AND REACTIVITY

Stability: Stable at normal conditions
Conditions to Avoid: None known
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 various forms of the active ingredient. The remaining information describes the potential hazards of the individual ingredients.

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

**Hypromellose**
- Rat Oral LD50 > 10,000 mg/kg

**Titanium dioxide**
- Rat Oral LD50 > 7500 mg/kg
- Rat Subcutaneous LD50 50 mg/kg

**Stearic acid**
- Rat Oral LD50 > 4640 mg/kg
- Rabbit Dermal LD50 > 5000 mg/kg

**Oxaprozin**
- Rat Oral LD50 4470 mg/kg
- Rat Inhalation LC50 >307 mg/m³

**Microcrystalline cellulose**
- Rat Oral LD50 > 5000 mg/kg
- Rabbit Dermal LD50 > 2000 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)
Material Name: Oxaprozin Potassium Tablets
Revision date: 04-Jan-2007

Polyethylene glycol
Eye Irritation  Rabbit  Mild
Skin Irritation  Rabbit  Mild

Stearic acid
Skin Irritation  Rabbit  Mild

Oxaprozin
Eye Irritation  Rabbit  Mild
Skin Irritation  Rabbit  Mild
Skin Sensitization - LLNA  Guinea Pig  Negative

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

Oxaprozin
6 Month(s)  Rat  Oral  157 mg/kg/day  NOEL
1 Year(s)  Non-human Primate  Oral  54 mg/kg/day  NOEL

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

Oxaprozin
Reproductive & Fertility  Rat  Oral  400 mg/kg/day  LOAEL  Fetotoxicity
Embryo / Fetal Development  Rat  Oral  500 mg/kg/day  NOEL  Not Teratogenic
Embryo / Fetal Development  Rabbit  Oral  30 mg/kg/day  LOAEL  Teratogenic

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

Oxaprozin
Bacterial Mutagenicity (Ames)  Salmonella  Negative

Carcinogen Status:  See below

Titanium dioxide
IARC:  Group 2B
OSHA:  Present

Colloidal silicon dioxide
IARC:  Group 3

Environmental Overview:  Toxic to aquatic organisms. May cause long term adverse effects in the aquatic environment.

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Oxaprozin
Rainbow Trout  OECD  NOEC  96 Hours  31.3 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: N
EU Indication of danger: Dangerous for the Environment
EU Risk Phrases: R51/53 - Toxic to aquatic organisms. May cause long-term adverse effects in the aquatic environment.
EU Safety Phrases: S61 - Avoid release to the environment. Refer to special instructions/Safety data sheets.

OSHA Label:
WARNING
May cause damage to gastrointestinal system through prolonged or repeated exposure.
Toxic to aquatic life with long lasting effects.

Canada - WHMIS: Classifications

WHMIS hazard class: Class D, Division 2, Subdivision B

Microcrystalline cellulose
  Inventory - United States TSCA - Sect. 8(b) XU
  Australia (AICS): Present
  EU EINECS List 232-674-9

Hypromellose
16. OTHER INFORMATION

Reasons for Revision: Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 11 - Toxicology Information.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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.

End of Safety Data Sheet