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

Product Identifier

Material Name: Oxaprozin Tablets
Trade Name: Daypro Tablets
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against
Intended Use: Pharmaceutical product used as non-steroidal, anti-inflammatory drug (nsaid)

Details of the Supplier of the Safety Data Sheet
Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

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
Contact E-Mail: pfizer-MSDS@pfizer.com

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture
GHS - Classification
Reproductive Toxicity: Category 2
Acute aquatic toxicity: Category 2
Chronic aquatic toxicity: Category 2

EU Classification:
EU Indication of danger: Dangerous for the Environment
Toxic to Reproduction: Category 3

EU Risk Phrases:
R51/53 - Toxic to aquatic organisms. May cause long-term adverse effects in the aquatic environment.
R63 - Possible risk of harm to the unborn child.

Label Elements
Signal Word: Warning
Hazard Statements:
H361d - Suspected of damaging the unborn child
H411 - Toxic to aquatic life with long lasting effects
Precautionary Statements:
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P273 - Avoid release to the environment
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P391 - Collect spillage
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards
Australian Hazard Classification (NOHSC):
Hazardous Substance. Dangerous Goods.

Note:
This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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

<table>
<thead>
<tr>
<th>Hazardous</th>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Oxaprozin</td>
<td>21256-18-8</td>
<td>244-296-1</td>
<td>Repr 3; R63;R51/53</td>
<td>Repr 2 (H361d)Chronic 2 (H411)</td>
<td>600 mg***</td>
</tr>
<tr>
<td></td>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td>Starch</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>236-675-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

|           | Hydroxypropyl methylcellulose  | 9004-65-3  | Not Listed            | Not Listed         | Not Listed                 | *    |
|           | Methylcellulose                | 9004-67-5  | Not Listed            | Not Listed         | Not Listed                 | *    |
|           | Polacrilin potassium           | None known | Not Listed            | Not Listed         | Not Listed                 | *    |
|           | Polyethylene glycol            | 25322-68-3 | Not Listed            | Not Listed         | Not Listed                 | *    |

Additional Information:
* Proprietary
*** per tablet/capsule/lozenge/suppository
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.
4. FIRST AID MEASURES

Description of 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 induces vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

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.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

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

Fire / Explosion Hazards: Not applicable

Advice for Fire-Fighters

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

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

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.

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

Precautions for Safe Handling
Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). 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.

Conditions for Safe Storage, Including any Incompatibilities
Storage Conditions: Store as directed by product packaging.
Specific end use(s): Pharmaceutical product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters
Refer to available public information for specific member state Occupational Exposure Limits.

Microcrystalline cellulose
ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Estonia OEL - TWA 10 mg/m³
France OEL - TWA 10 mg/m³
Ireland OEL - TWA 10 mg/m³
Ireland OEL - TWAs 4 mg/m³
Latvia OEL - TWA 2 mg/m³
OSHA - Final PELS - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³
Romania OEL - TWA 10 mg/m³
Russia OEL - TWA 6 mg/m³
Spain OEL - TWA 10 mg/m³
Switzerland OEL -TWAs 3 mg/m³
Vietnam OEL - TWAs 10 mg/m³
5 mg/m³

Polyethylene glycol
Austria OEL - MAKs 1000 mg/m³
Germany - TRGS 900 - TWAs 1000 mg/m³
Germany (DFG) - MAK 1000 mg/m³ average molecular weight 200-600
Slovakia OEL - TWA 1000 mg/m³
Slovenia OEL - TWA 1000 mg/m³
Switzerland OEL -TWAs 1000 ppm

Starch
ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Bulgaria OEL - TWA 10.0 mg/m³
Czech Republic OEL - TWA 4.0 mg/m³
Greece OEL - TWA 10 mg/m³
5 mg/m³
Ireland OEL - TWAs 10 mg/m³
4 mg/m³
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Material Name: Oxaprozin Tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>P.Z. 00174 Revision date: 05-Jan-2007</td>
</tr>
<tr>
<td>Version: 1.3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Exposure Controls</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>15 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>4 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Switzerland OEL - TWAs</td>
<td>3 mg/m³</td>
</tr>
</tbody>
</table>

Titanium dioxide

<table>
<thead>
<tr>
<th>Exposure Controls</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>ACGIH OELs - Notice of Intended Changes</td>
<td>Listed</td>
</tr>
<tr>
<td>Australia TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>10.0 mg/m³</td>
</tr>
<tr>
<td>Denmark OEL - TWA</td>
<td>6 mg/m³</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>France OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>15 mg/m³</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>10.0 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Russia OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Switzerland OEL - TWAs</td>
<td>3 mg/m³</td>
</tr>
<tr>
<td>Vietnam OEL - TWAs</td>
<td>6 mg/m³</td>
</tr>
</tbody>
</table>

Magnesium Stearate

<table>
<thead>
<tr>
<th>Exposure Controls</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>5 mg/m³</td>
</tr>
</tbody>
</table>

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**

**Pfizer Occupational Exposure Band (OEB):** OEB 2 (control exposure to the range of 100µg/m³ to < 1000µg/m³)

**Exposure Controls**

**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. 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.
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Hands: Not required for the normal use of this product. Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

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. Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: Not required for the normal use of this product. 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>White</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor:</td>
<td>No data available.</td>
<td>Odor Threshold:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

Solvent Solubility: No data available
Water Solubility: No data available
pH: No data available
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available
Partition Coefficient: (Method, pH, Endpoint, Value)
Oxaprozin
No data available
Microcrystalline cellulose
No data available
Hydroxypropyl methylcellulose
No data available
Methylcellulose
No data available
Magnesium stearate
No data available
Polacrilin potassium
No data available
Starch
No data available
Polyethylene glycol
No data available
Titanium dioxide
No data available
Decomposition Temperature (°C): No data available.
Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammability:
Autoignition Temperature (Solid) (°C): No data available
Flammability (Solids): No data available
SAFETY DATA SHEET

Material Name: Oxaprozin Tablets
Revision date: 05-Jan-2007

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable at normal conditions
Possibility of Hazardous Reactions
- Oxidizing Properties: No data available
- Conditions to Avoid: Not determined
- Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
- Hazardous Decomposition: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: The information included in this section describes the potential hazards of the individual ingredients.
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.
Long Term: Animal studies have shown a potential to cause adverse effects on the fetus.
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.

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

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

Hydroxypropyl methylcellulose
- Rat Oral LD50 > 10,000 mg/kg

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

Titanium dioxide
- Rat Oral LD50 > 7500 mg/kg
- Rat Subcutaneous LD50 50 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)
11. TOXICOLOGICAL INFORMATION

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

**Microcrystalline cellulose**
Skin Irritation Rabbit Non-irritating  
Eye Irritation Rabbit Non-irritating  

**Polyethylene glycol**
Eye Irritation Rabbit Mild  
Skin Irritation Rabbit Mild  

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

<table>
<thead>
<tr>
<th>Substance</th>
<th>Duration</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxaprozin</td>
<td>6 Month(s)</td>
<td>Rat</td>
<td>Oral</td>
<td>157 mg/kg/day</td>
<td>NOEL</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1 Year(s)</td>
<td>Non-human Primate</td>
<td>Oral</td>
<td>54 mg/kg/day</td>
<td>NOEL</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Substance</th>
<th>Study Type</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxaprozin</td>
<td>Reproductive &amp; Fertility</td>
<td>Rat</td>
<td>Oral</td>
<td>400 mg/kg/day</td>
<td>LOAEL</td>
<td>Fetotoxicity</td>
</tr>
<tr>
<td></td>
<td>Embryo / Fetal Development</td>
<td>Rat</td>
<td>Oral</td>
<td>500 mg/kg/day</td>
<td>NOEL</td>
<td>Not Teratogenic</td>
</tr>
<tr>
<td></td>
<td>Embryo / Fetal Development</td>
<td>Rabbit</td>
<td>Oral</td>
<td>30 mg/kg/day</td>
<td>LOAEL</td>
<td>Teratogenic</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Substance</th>
<th>Study Type</th>
<th>Cell Type/Organism</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxaprozin</td>
<td>Bacterial Mutagenicity (Ames)</td>
<td>Salmonella</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>Micronucleus Mouse Bone Marrow</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Chromosome Aberration Human Lymphocytes</td>
<td>Negative</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Substance</th>
<th>Duration</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxaprozin</td>
<td>2 Year(s)</td>
<td>Rat</td>
<td>Oral</td>
<td>NOAEL</td>
<td>Not carcinogenic</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2 Year(s)</td>
<td>Female Mouse</td>
<td>Oral</td>
<td>NOAEL</td>
<td>Not carcinogenic</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2 Year(s)</td>
<td>Male Mouse</td>
<td>Oral</td>
<td>Liver, neoplasms</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Carcinogen Status:
See below

Titanium dioxide
IARC:
Group 2B (Possibly Carcinogenic to Humans)

12. ECOLOGICAL INFORMATION

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

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

Oxaprozin

Oncorhynchus mykiss (Rainbow Trout)  OECD  NOEC  96 Hours  31.3 mg/L
Hyallela azteca (Freshwater Amphipod)  OECD  LC-50  96 Hours  137.2 mg/L
Daphnia Magna (Water Flea)  OECD  NOEC  48 Hours  12 mg/L
Daphnia magna (Water Flea)  OECD  EC-50  48 Hours  19.2 mg/L
Selenastrum capricornutum (Green Alga)  ErC50  48-72 Hours  8.8 mg/L

Persistence and Degradability:  No data available
Bio-accumulative Potential:  No data available
Mobility in Soil:  No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods:  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

The following refers to all modes of transportation unless specified below.

This material is regulated for transportation as a hazardous material/dangerous good.

UN number:  UN 3077
UN proper shipping name:  Environmentally Hazardous Substance, Solid, n.o.s
Technical Shipping Name:  oxaprozin
Transport hazard class(es):  9
Packing group:  III
Environmental Hazard(s):  Marine Pollutant

5 kg/5L Exception:
Effective January 1, 2015, UN3082 and UN3077 materials contained in good quality packaging in the quantities listed below are not regulated as dangerous goods for transport by any mode:

* Single packagings containing a net quantity of 5 liters or less for liquids or a net mass of 5 kg or less for solids.
* Combination packagings containing a net quantity per inner packaging of 5 liters or less for liquids or a net mass of 5 kg or less for solids.
15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications
WHMIS hazard class:
Class D, Division 2, Subdivision A

Oxaprozin
  CERCLA/SARA 313 Emission reporting: Not Listed
  California Proposition 65: Not Listed
  Standard for the Uniform Scheduling for Drugs and Poisons:
    Schedule 4
  EU EINECS/ELINCS List: 244-296-1

Microcrystalline cellulose
  CERCLA/SARA 313 Emission reporting: Not Listed
  California Proposition 65: Not Listed
  Inventory - United States TSCA - Sect. 8(b): Present
  Australia (AICS):
    Use restricted. See item 9[f]. powder
  REACH - Annex XVII - Restrictions on Certain Dangerous Substances:
    EU EINECS/ELINCS List: 232-674-9

Hydroxypropyl methylcellulose
  CERCLA/SARA 313 Emission reporting: Not Listed
  California Proposition 65: Not Listed
  Inventory - United States TSCA - Sect. 8(b): Present
  Australia (AICS):
    Use restricted. See item 9[f]. powder
  Standard for the Uniform Scheduling for Drugs and Poisons:
    Schedule 4
  EU EINECS/ELINCS List: Not Listed

Methylcellulose
  CERCLA/SARA 313 Emission reporting: Not Listed
  California Proposition 65: Not Listed
  Inventory - United States TSCA - Sect. 8(b): Present
  Australia (AICS):
    Use restricted. See item 9[f]. powder
  EU EINECS/ELINCS List: Not Listed

Polacrilin potassium
  CERCLA/SARA 313 Emission reporting: Not Listed
  California Proposition 65: Not Listed
  EU EINECS/ELINCS List: Not Listed

Polyethylene glycol
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Material</th>
<th>CERCLA/SARA 313 Emission reporting</th>
<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS)</th>
<th>REACH - Annex IV - Exemptions from the obligations of Register</th>
<th>EU EINECS/ELINCS List</th>
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<td>Magnesium stearate</td>
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16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child
Hazardous to the aquatic environment, chronic toxicity-Cat.2; H411 - Toxic to aquatic life with long lasting effects

N - Dangerous for the environment
Toxic to Reproduction: Category 3
R63 - Possible risk of harm to the unborn child.
R51/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 15 - Regulatory Information.

Revision date: 05-Jan-2007
SAFETY DATA SHEET

Material Name: Oxaprozin Tablets
Revision date: 05-Jan-2007

Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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End of Safety Data Sheet