



# MATERIAL SAFETY DATA SHEET

Revision date: 04-Jan-2007

Version: 1.1

Page 1 of 7

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

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**CHEMTREC (24 hours): 1-800-424-9300**

**Emergency telephone number:**  
**ChemSafe (24 hours): +44 (0)208 762 8322**

### 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

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Oxaprozin Potassium	174064-08-5	Not listed	600 mg ***
Microcrystalline cellulose	9004-34-6	232-674-9	*
Titanium dioxide	13463-67-7	236-675-5	*
Colloidal silicon dioxide	7631-86-9	231-545-4	*
Corn Starch	9005-25-8	232-679-6	*

Ingredient	CAS Number	EU EINECS List	%
Hypromellose	9004-65-3	Not listed	*
FD&C Blue no. 1 aluminum lake	68921-42-6	272-939-6	*
Polyethylene glycol	25322-68-3	Not listed	*
Stearic acid	57-11-4	200-313-4	*

**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.

# MATERIAL SAFETY DATA SHEET

Material Name: Oxaprozin Potassium Tablets  
Revision date: 04-Jan-2007

Page 2 of 7  
Version: 1.1

**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.

# MATERIAL SAFETY DATA SHEET

Material Name: Oxaprozin Potassium Tablets  
Revision date: 04-Jan-2007

Page 3 of 7  
Version: 1.1

**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/m<sup>3</sup> TWA total  
= 5 mg/m<sup>3</sup> TWA  
ACGIH Threshold Limit Value (TWA) = 10 mg/m<sup>3</sup> TWA  
Australia TWA = 10 mg/m<sup>3</sup> TWA

### Titanium dioxide

OSHA - Final PELs - TWAs: = 15 mg/m<sup>3</sup> TWA total  
ACGIH Threshold Limit Value (TWA) = 10 mg/m<sup>3</sup> TWA  
Australia TWA = 10 mg/m<sup>3</sup> TWA

### Colloidal silicon dioxide

OSHA - Final PELs - Table Z-3 Mineral D: (80)/(% SiO<sub>2</sub>) mg/m<sup>3</sup> TWA  
= 20 mppcf TWA  
Australia TWA = 2 mg/m<sup>3</sup> TWA

### Corn Starch

OSHA - Final PELs - TWAs: = 15 mg/m<sup>3</sup> TWA total  
= 5 mg/m<sup>3</sup> TWA  
ACGIH Threshold Limit Value (TWA) = 10 mg/m<sup>3</sup> TWA  
Australia TWA = 10 mg/m<sup>3</sup> 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/m<sup>3</sup> to < 1000ug/m<sup>3</sup>)

**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:**

## MATERIAL SAFETY DATA SHEET

Material Name: Oxaprozin Potassium Tablets  
Revision date: 04-Jan-2007

Page 4 of 7  
Version: 1.1

**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:

<b>Physical State:</b>	Tablets	<b>Color:</b>	Blue
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

### 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 LD 50 50 mg/kg

##### **Stearic acid**

Rat Oral LD50 > 4640 mg/kg  
Rabbit Dermal LD50 > 5000 mg/kg

##### **Oxaprozin**

Rat Oral LD 50 4470 mg/kg  
Rat Inhalation LC 50 >307 mg/m<sup>3</sup>

##### **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 SAFETY DATA SHEET

Material Name: Oxaprozin Potassium Tablets  
Revision date: 04-Jan-2007

Page 5 of 7  
Version: 1.1

### 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

### Microcrystalline cellulose

Skin Irritation Rabbit Non-irritating  
Eye Irritation Rabbit Non-irritating

### 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 LOEL Fetotoxicity  
Embryo / Fetal Development Rat Oral 500 mg/kg/day NOEL Not Teratogenic  
Embryo / Fetal Development Rabbit Oral 30 mg/kg/day LOEL 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

## 12. ECOLOGICAL INFORMATION

**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

## MATERIAL SAFETY DATA SHEET

Material Name: Oxaprozin Potassium Tablets  
Revision date: 04-Jan-2007

Page 6 of 7  
Version: 1.1

Hyallolela azteca OECD LC-50 96 Hours 137.2 mg/L  
Daphnia OECD NOEC 48 Hours 12 mg/L  
Daphnia OECD EC-50 48 Hours 19.2 mg/L  
Selenastrum capricornutum EC-50 48-72 Hours 8.8 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**

# MATERIAL SAFETY DATA SHEET

Material Name: Oxaprozin Potassium Tablets  
Revision date: 04-Jan-2007

Page 7 of 7  
Version: 1.1

<b>Inventory - United States TSCA - Sect. 8(b)</b>	XU
<b>Australia (AICS):</b>	Present
<b>Standard for the Uniform Scheduling for Drugs and Poisons:</b>	Schedule 4
<b>Titanium dioxide</b>	
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS List</b>	236-675-5
<b>FD&amp;C Blue no. 1 aluminum lake</b>	
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS List</b>	272-939-6
<b>Polyethylene glycol</b>	
<b>Inventory - United States TSCA - Sect. 8(b)</b>	XU
<b>Australia (AICS):</b>	Present
<b>Colloidal silicon dioxide</b>	
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS List</b>	231-545-4
<b>Corn Starch</b>	
<b>Inventory - United States TSCA - Sect. 8(b)</b>	XU
<b>Australia (AICS):</b>	Present
<b>EU EINECS List</b>	232-679-6
<b>Stearic acid</b>	
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS List</b>	200-313-4

## 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

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**End of Safety Data Sheet**