



MATERIAL SAFETY DATA SHEET

Revision date: 05-Jan-2007

Version: 1.2

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

Pfizer Inc
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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 Tablets

Trade Name: Daypro Tablets
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	21256-18-8	244-296-1	600 mg***
Microcrystalline cellulose	9004-34-6	232-674-9	*
Magnesium stearate	557-04-0	209-150-3	*
Starch	9005-25-8	232-679-6	*
Titanium dioxide	13463-67-7	236-675-5	*

Ingredient	CAS Number	EU EINECS List	%
Hypromellose	9004-65-3	Not listed	*
Methylcellulose	9004-67-5	Not listed	*
Polacrillin potassium	None known	Not listed	*
Polyethylene glycol	25322-68-3	Not listed	*

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: White tablets
Signal Word: WARNING

Statement of Hazard: May cause gastrointestinal system 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.

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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.

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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

Magnesium stearate

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

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

Titanium dioxide

OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total
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

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.

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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: 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:

Physical State:	Tablets	Color:	White
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Stability: Stable at normal conditions

Conditions to Avoid: Not determined

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 the individual ingredients.

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

Oxaprozin

Rat Oral LD 50 4470 mg/kg
Rat Inhalation LC 50 >307 mg/m³

Microcrystalline cellulose

Rat Oral LD50 > 5000 mg/kg
Rabbit Dermal LD50 > 2000 mg/kg

Hypromellose

Rat Oral LD50 > 10,000 mg/kg

Magnesium stearate

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

Starch

Mouse IP LD50 6600 mg/kg

Titanium dioxide

Rat Oral LD50 > 7500 mg/kg
Rat Subcutaneous LD 50 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)

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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)

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

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
Hyallela 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

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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 gastrointestinal system effects

Canada - WHMIS: Classifications

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



Oxaprozin
Standard for the Uniform Scheduling
for Drugs and Poisons: Schedule 4
EU EINECS List 244-296-1

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

Hypromellose
Inventory - United States TSCA - Sect. 8(b) XU
Australia (AICS): Present

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Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
Methylcellulose	
Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
Magnesium stearate	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	209-150-3
Starch	
Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-679-6
Titanium dioxide	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	236-675-5
Polyethylene glycol	
Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present

16. OTHER INFORMATION

Reasons for Revision: Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures.
Updated Section 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information.
Updated Section 13 - Disposal Considerations.

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

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End of Safety Data Sheet