SAFETY DATA SHEET

Section 1: Identification	
Section 1, Identification	
Product	**Oxaprozin Capsules 300mg**
Distributor	SOLA Pharmaceuticals 655 Highlandia Drive Baton Rouge, LA. 70810 Tel: 866.747.7365 Fax: 800.754.9550 www.solameds.us info@solameds.us
NDC Number	70512-787-60 (bottle of 60's)

Section 2: Hazard(s) Identification

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Appearance:
White capsule
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.

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.

Section 3: Composition/Information on Ingredients

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Ingredient	CAS Number	%
Oxaprozin	21256-18-8	300mg**
Microcrystalline cellulose	9004-34-6	*
Hypromellose 2910	9004-65-3	*
Starch, Corn	9005-25-8	*
Sodium Starch Glycolate Type A	9063-38-1	*
Stearic Acid	57-11-4	*
Silicon Dioxide	7631-86-9	*

* Proprietary
** Per capsule

Section 4: First-Aid Measures

Section 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.

Section 5: Fire-Fighting Measures

Section 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 selfcontained breathing apparatus.
Fire / Explosion Hazards:
Not applicable

Section 6: Accidental Release Measures

Section 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.

Section 7: Handling and Storage

Section 7, Handling and Storage

General Handling:
If 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.

Section 8: Exposure Controls / Personal Protection

Section 8, Exposure Controls / Personal Protection

Microcrystalline cellulose

OSHA – Final PELS – TWAs	= 15mg/m^3 TWA total
	= 5mg/m^3 TWA
ACGIH Threshold Limit Value (TWA)	= 10mg/m^3 TWA
Australia TWA	= 10mg/ m^3 TWA

Magnesium stearate

ACGIH Threshold Limit Value (TWA)	= 10mg/ m^3 TWA except stearates of toxic metals
Australia TWA	= 10mg/ m^3 TWA

Starch

OSHA – Final PELS – TWAs	= 15mg/ m^3 TWA total
	= 5mg/ m^3 TWA
ACGIH Threshold Limit Value (TWA)	= 10mg/ m^3 TWA
Australia TWA	= 10mg/ m^3 TWA

Titanium dioxide

OSHA – Final PELS – TWAs	= 15mg/ m^3 TWA total
ACGIH Threshold Limit Value (TWA)	= 10mg/ m^3 TWA
Australia TWA	= 10mg/ m^3 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.

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:
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.

Section 9: Physical and Chemical Properties

Section 9, Physical and Chemical Properties

Physical State	Capsules	**Color**	White
Molecular Formula	Mixture	**Molecular Weight**	Mixture

Section 10: Stability and Reactivity

Section 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.

Section 11: Toxicological Information

Section 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	LD50	4470 mg/kg
Rat	Inhalation	LC50	>307mg/mg^3

Microcrystalline cellulose

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

Hypromellose

Rat	Oral	LD50	>10,000mg/kg

Magnesium stearate

Rat	Oral	LD50	>2000mg/kg
Rat	Inhalation	LC50	>2000 mg/mg^3

Starch

Mouse	IP	LD50	6600mg/kg

Titanium dioxide

Rat	Oral	LD50	>7500mg/kg
Rat	Subcutaneous	LD50	

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)

Oxaprozin

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

Microcrystalline cellulose

Eye Irritation	Rabbit	Non-irritating
Skin 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	54mg/kg/day	NOEL

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

Oxaprozin

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

Section 12: Ecological Information

Section 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.mg/L
Hyallela Azteca	OECD	LC-50	96 hours	137.2mg/L
Daphnia	OECD	NOEC	48 hours	12mg/L
Daphnia	OECD	EC-50	48 hours	19.2mg/L
Selenastrum capricomutum		EC-50	48 – 72 hours	8.8mg/L

Section 13: Disposal Considerations

Section 13, Disposal Considerations

Disposal Procedures:
Dispose of waste in accordance with all applicable laws and regulations.

Section 14: Transport Information

Section 14, Transport Information

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

Section 15: Regulatory Information

Section 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
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

Section 16: Other Information

Section 16, Other Information

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

SOLA shall not be held liable for any damage resulting from handling or from contact with the above product. SOLA reserves the right to revise this Safety Data Sheet.