

SAFETY DATA SHEET

Section 1: Identification			
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Product	Diclofenac Sodium Delayed-Release Tablets, USP 75mg		
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	70512-784-60 (bottles of 60's)		
Section 2: Hazard(s) Identification			
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Toxic if swallowed. May be toxic if inhaled. Harmful :dander of serious damage to health by prolonged exposure if swallowed. Possible risk of harm to the unborn child. May cause gastro-intestinal disturbances, nausea, vomiting, diarrhea, abdominal cramps. Exposure may lead into bleeding, ulceration or perforation of the gastro-intestinal tract. May affect central nervous system including drowsiness and tiredness. May cause kidney deterioration. May cause allergic reactions. Blurred vision may occur, as liver function disorder, hypotension and respiratory depression.			
Section 3: Composition/Information on Ingredients			
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Diclofenac Sodium	CAS 15307-79-6	$C_{14}H_{10}Cl_2NaNO_2$	MW: 318.13
EC No:	239-346-4		
NB:	Non-steroidal anti-inflammatory		
Section 4: First-Aid Measures			
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Inhalation: Remove to fresh air. If breathing becomes difficult, call a physician. Skin contact: Flush with copious amounts of water and soap for at least 15 minutes. Remove contaminated clothing and shoes. Eye contact: Assure adequate flushing by separating the eyelids with fingers. Flush with copious amounts of water for at least 15 minutes. Ingestion: Wash out mouth with water and administer fresh water provided that the person is conscious. In case of reactions described in hazards identification or other severe, immediate or persisting symptoms, seek medical advice and call the nearest poison centre. Show the label and this safety data sheet.			

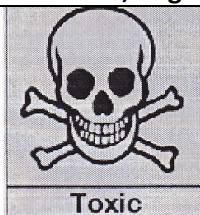
Section 5: Fire-Fighting Measures	
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<p>Extinguishing media: carbon dioxide, dry chemical powder or appropriate foam. Water spray.</p> <p>Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes. Emits toxic fumes under fire conditions. Avoid spills into drains, surface, ground water and soil.</p> <p>Dangerous combustion products: COx, NOx, HCl and other noxious gases or vapours in case of incomplete combustion.</p>	
Section 6: Accidental Release Measures	
Section 6, Accidental Release Measures	
<p>Switch off electrical equipment and any other sources of ignition. Evacuate area. Wear self-contained breathing apparatus, appropriate boots and heavy rubber gloves. Collect residues manually, by wiping with a small quantity of ethanol, place in a bag and hold for waste disposal. Avoid raising dust/mist. Ventilate area and wash spill site with water/detergent solution after material pick up is complete. Keep away from drains, surface- and groundwater and soil.</p>	
Section 7: Handling and Storage	
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<p>Ensure adequate ventilation.</p> <p>Handling: Avoid inhalation. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Recommended for quality reasons. Handle protected from humidity.</p> <p>Storage: Keep unopened in the original container, protected from light and humidity at about 2-8°C for quality reasons. Keep tightly closed. Protect from heat, sources of ignition and direct sunlight.</p>	
Section 8: Exposure Controls / Personal Protection	
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<p>OEL: 0.25 mg/m³</p> <p>Handling in fume hood is recommended. Mechanical exhaust, safety shower and eye bath required.</p> <p>Respiratory protection: Protecting mask (filter P3)</p> <p>Hand protection: compatible chemical-resistant gloves</p> <p>Eye protection: wear protective chemical safety goggles</p> <p>Skin protection: wear protective coat</p>	
Section 9: Physical and Chemical Properties	
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<p>Appearance: White or slightly yellowish, slightly hygroscopic, crystalline powder</p> <p>Solubility: Sparingly soluble in water, freely soluble in methanol, soluble in ethanol (96 per cent), slightly soluble in acetone.</p> <p>Melting point: about 280°C with decomposition</p> <p>pH: 6-8 (20g/l, 25°C)</p> <p>Log Pow: 1.56</p>	
Section 10: Stability and Reactivity	
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<p>Stability: Stable under recommended conditions of use</p> <p>Conditions to avoid: Humidity</p> <p>Materials to avoid: Strong oxidizing agents, acrolein, benzyl alcohol, nickel nitride</p>	

Dangerous decomposition products:		COx, NOx, HCl and other substances in case of incomplete decomposition. Hazardous polymerisation will not occur.
Section 11: Toxicological Information		
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RTECS No: AG6330000		
See actual entry in RTECS for complete information.		
LD50 (oral-rat):	53 mg/kg	
LC50 (inhalation-rat):	No data available	
LC50 (skin-rat):	No data available	
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Carcinogenicity. Mutagenicity. Reproductive toxicity and Sensitisation:		
Possible risk of harm to the unborn child. No sensitising, carcinogenic or mutagenic potential has been shown in animal experiments.		
CMR Classification:	Repr. Cat. 3 overexposure might include: headache; nausea.	
Section 12: Ecological Information		
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Ecotoxicity:	Harmful to aquatic organisms, may cause long-term adverse effects on the aquatic environment.	
LC50 (fish-96h):	214 mg/l	
EC50 (daphnies-48h):	about 70 mg/l	
EC50 (algae-96h):	72 mg/l	
Biodegradation:	Not readily biodegradable (55% in 28 days)	
Bioaccumulation and mobility		
Sparingly soluble in water.		
Log Pow:	1.56. Risk of redistribution into fats is low.	
BCF:	No data available	
Section 13: Disposal Considerations		
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Incinerate in an approved facility.		
Observe all federal, state and local environmental regulations.		
Section 14: Transport Information		
Section 14, Transport Information		
Transport regulation	UN Classification	
	UN number shipping name - Class (other risk) – PG	

IATA/ICAO (air)	UN 2811 - Class 6.1 Toxic solid, organic, n.o.s. (diclofenac sodium) - PGIII
ADR/RID (road/railway)	UN 2811 - Class 6.1 Toxic solid, organic, n.o.s. (diclofenac sodium) - PGIII
IMDG (sea)	UN 2811 - Class 6.1 Toxic solid, organic, n.o.s. (diclofenac sodium) - PGIII

Section 15: Regulatory Information

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R phrases:

R25	Toxic if swallowed.
R48/22	Harmful: danger of serious damage to health by prolonged exposure if swallowed.
R52/53	Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R63	Possible risk of harm to the unborn child.

S phrases:

S22	Do not breathe dust.
S36/37	Wear suitable protective clothing and gloves.
S61	Avoid release to the environment. Refer to special instructions/safety data sheet.

CMR Classification: Repr. Cat. 3

Section 16: Other Information

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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.