

Safety data Sheet		
Company Name:	Strides Shasun Ltd	SDS Number: SDS/D1-003-00
Section 1: Identification		
Product Identifier		
Product name:	Piroxicam capsules USP [10mg /20mg] [Hard gelatin]	
Trade name:	Not applicable	
Product Code No.:	2004100/2004101	
Relevant identified use of the substance or mixture and use advised against		
Recommended Use:	Pharmaceutical product used as non-steroidal, anti-inflammatory drug (NSAID)	
Restrictions on Use:	Not applicable	
Details of the supplier of the safety data sheet:		
Manufacturer name:	Strides Shasun Limited	
Address:	Strides Shasun Limited No 36/7, Suragajakkanahalli, Indlavadi Cross, Anekal Taluk, Bengaluru, Karnataka, India. 562106	
Telephone Number-General:	91 8067 840307/309	
Emergency Telephone Number:	91 8067 840307/309	
<i>Note: This safety data sheet is written to provide safety, health and environmental information for people handling the formulated product in the work place. It is not intended to provide information relevant to consumer use of the product (PIL will be applicable for consumer).</i>		
Section 2: Hazard Identification:		
Hazard Classification of chemical mixture	Not applicable	
Signal word	Warning	
Hazard Statement	May be harmful if swallowed. May cause allergic reaction in aspirin-sensitive individuals. Can cause gastrointestinal and kidney effects. May cause blood, liver, and central nervous system effects. Possible risk of harm to the unborn child.	
Additional Hazard Information		
Short Term:	Not an eye irritant Active ingredient is not a skin irritant (based on animal data) Can cause respiratory irritation Accidental ingestion may cause effects similar to those seen in clinical use. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions.	
Label elements		
Precautionary statements	Not applicable	
Storage/Disposal	Not applicable	
EU classification	Not applicable	
US GHS classification	Not applicable	

Section 3: Composition/Information on Ingredients			
Mixtures: Material does not meet the criteria of a substance according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS) and EU EINECS.			
Composition			
Components (Chemical Name)	Identifiers (CAS No.)	% Composition	Classification according to regulations (US GHS/EU EINECS)
Piroxicam	36322-90-4	*	252-974-3
Lactose monohydrate	64044-51-5	*	Not listed
FD & C Red No. 3 (E 127)	16423-68-0	*	240-474-8
FD & C Blue No. 1	3844-45-9	*	223-339-8
Starch	9005-25-8	*	232-679-6
Magnesium stearate	557-04-0	*	209-150-3
Sodium lauryl sulfate	151-21-3	*	205-788-1
*Percentage composition is not captured due to trade secret.			
Section 4: First aid measures			
General advice:	Not applicable		
Inhalation:	Remove to fresh air. If not breathing, give artificial respiration. Get medical attention immediately.		
Skin contact:	Wash skin with soap and water. Remove contaminated clothing and shoes. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention.		
Eye contact:	Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.		
Ingestion:	Get medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.		
Most important symptoms and effects both acute and delayed:			
Symptoms:	Not applicable		
Other hazards	Not applicable		
Indication of immediate medical attention and special treatment needed			
Notes for the doctor	Not applicable		
Special treatment	Not applicable		
Other information	Not applicable		
Section 5: Fire Fighting Measures			
Extinguishing media			
Suitable Extinguishing Media	Use carbon dioxide, dry chemical, or water spray.		
Unsuitable Extinguishing Media	Not applicable		

Firefighting Procedures	Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Evacuate area and fight fire from a safe distance.		
Unusual Fire and Explosion Hazards	Not Applicable		
Hazardous combustion products:	Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.		
Additional Information	Not applicable		
Section 6: Accidental Release Measures			
Personal precautions, protective equipment and emergency procedures			
Personal Precautions:	Not applicable		
Emergency Procedure	Not applicable		
Methods and material for containment and cleaning up			
Containment/Cleanup measures	Not applicable		
Prohibited materials	Not applicable		
Section 7: Handling and Storage			
Precautions for safe handling			
Patients/Consumers:			
Safe handling:	If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing.		
Fire Prevention	Not applicable		
Dust generation Preventions	Not applicable		
Environmental precautions	Not applicable		
Conditions for safe storage, including any incompatibilities			
Technical measures and Storage Conditions:	Store in a cool, dry, well-ventilated area. Keep container tightly closed when not in use. Protect from light. Storage Temperature: Store at room temperature 20°C to 25°C		
Special Packaging Materials	Not applicable		
Section 8: Exposure Controls and personal protection			
Exposure Limits/Guidelines			
Component Name	Result	OSHA	Other agency Information
Piroxicam	TWA-8-Hr	0.1 mg/m ³	NA
Starch	-	15 mg/m ³ TWA total 5 mg/m ³ TWA	NA
	-	-	ACGIH Threshold Limit Value (TWA) - 10 mg/m ³ TWA
	-	-	Australia TWA - 10 mg/m ³ TWA

Magnesium stearate	-	-	ACGIH Threshold Limit Value (TWA) - 10 mg/m ³ TWA except stearates of toxic metals
	-	-	Australia TWA - 10 mg/m ³ TWA
Sodium lauryl sulfate	TWA-8-Hr	0.3 mg/m ³	-
Note: The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated.			
Exposure Controls			
Engineering Controls	Engineering controls should be used as the primary means to control exposures.		
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:	Not required for the normal use of this product. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.		
Special requirements for PPE:	Not applicable		
Section 9: Physical and Chemical properties			
Information on physical and chemical Properties			
Material Description:			
Physical Form:	Capsule		
Color:	Maroon / Blue (10 mg) ; Maroon (20 mg)		
Odour:	Odorless		
General Properties:			
Boiling point	Not applicable		
Melting point:	Not applicable		
Water solubility:	Not applicable		
Solvent solubility:	Not applicable		
Specific gravity / Relative density:	Not applicable		
pH	Not applicable		
Decomposition temperature:	Not applicable		
Viscosity	Not applicable		
Density:	Not applicable		
Partition coefficient:	Not applicable		
Volatility and Flammability	Not applicable		
Vapor pressure:	Not applicable		

Vapor density	Not applicable				
Evaporation rate:	Not applicable				
Flash Point	Not applicable				
Upper Exposure limit:	Not applicable				
Lower Exposure limit:	Not applicable				
Flammability (solid, gas):	Not applicable				
Section 10: Stability and Reactivity					
Reactivity					
Chemical stability under normal ambient Temperature	Stable				
Possibility of hazardous reactions	Not applicable				
Conditions to avoid	None Known				
Incompatible materials	Strong oxidizers				
Hazardous decomposition products	Not applicable				
Section 11: Toxicological information					
Information on toxicological effects					
General Information: The information included in this section describes the potential hazards of the individual ingredients.					
Components					
Components	CAS No	Acute toxicity			
		Species	Route	End Point	Dose
Starch	9005-25-8	Mouse	IP	LD50	6600 mg/Kg
Magnesium stearate	557-04-0	Rat	Oral	LD 50	>2000mg/Kg
		Rat	Inhalation	LC 50	>2000mg/m ³
Sodium lauryl sulfate	151-21-3	Rat	Oral	LD 50	>1288mg/Kg
Piroxicam	36322-90-4	Mouse	Oral	LD50	360 mg/Kg
		Rat	Oral	LD 50	270 mg/Kg
		Mouse	IP	LD50	360 mg/Kg
		Rat	IP	LD 50	220 mg/Kg
		Dog	Oral	LD 50	>700 mg/Kg
FD & C Red No. 3 (E 127)	16423-68-0	Rat	Oral	LD 50	1840 mg/Kg
		Mouse	Oral	LD50	1264 mg/Kg
Potential health effects					
Inhalation:	Not applicable				
Ingestion:	Not applicable				
Eye contact:	Sodium lauryl sulfate: Severe irritant in rabbits Piroxicam: Nonirritant in rabbits. No eye irritation was seen upon repeated installation of a 10 mg/ml solution of piroxicam, 10 times per day for 7 days or installation of 0.5 ml of a 1% solution for 21 days.				

Skin contact:	Sodium lauryl sulfate: Severe irritant in rabbits	
	Piroxicam: Nonirritant in rabbits. No skin irritation was observed for piroxicam when 500 mg of a 10% ointment was applied once or up to 500 mg of a 1% ointment was applied twice a day for one month.	
Section 12: Ecological Information		
Toxicity	Not applicable	
Persistence and degradability	Not applicable	
Bio accumulative potential	Not applicable	
Mobility in Soil	Not applicable	
Other adverse effects	Not applicable	
Section 13: Disposal Considerations		
Product waste	Dispose of waste in accordance with all applicable laws and regulations.	
Packaging waste	Dispose of waste in accordance with all applicable laws and regulations.	
Section 14: Transport information		
Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.		
UN Number	Not applicable	
UN shipper name	Not applicable	
Transport hazard class:	Not applicable	
Environmental hazards	Not applicable	
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable	
Section 15: Regulatory Information		
Safety, health and environmental regulations/legislation specific for the substance or mixture		
Component Name	CAS number	CERCLA/SARA Emission Reporting
Piroxicam	36322-90-4	Not applicable
Lactose monohydrate	64044-51-5	Not applicable
Starch	9005-25-8	Not applicable
Magnesium stearate	557-04-0	Not applicable
Sodium lauryl sulfate	151-21-3	Not applicable
FD & C Red No. 3 (E 127)	16423-68-0	Not applicable
FD & C Blue No. 1	3844-45-9	Not applicable
Section 16: Other information		
Reason for revision: (Include Change control number)	New Safety data sheet prepared	
Revision date:	03/04/2018	
Version Number:	00	