

CERTIFICATE FOR SAFETY DATA SHEET

Name of the product: Ibuprofen Tablets USP 400mg, 600mg & 800mg

Product Code: 2005112, 2005113 & 2005214

SDS Number: SDS/D1-029-00

Activity	Department	Name	Sign & Date
Prepared By (FD)	FD	Suyog Pande	<u>Sande</u> 08.06.2018
Reviewed By (FD)	FD	Ranjeet Kumar Mohanty	<u>R</u> 08/06/18
Reviewed By (RA)	Regulatory Affairs	M.M. Akhtar Qureshi	<u>M.Qureshi</u> 09/06/18
Approved By (FD)	FD	Sudarshan Nimbelkar	<u>SA</u> 08/06/18
Authorized By (TSGQA/DQA)	DQ	S. GOPINATH	<u>S.Gopinath</u> 08/06/18

Safety data Sheet		
Company Name:	Strides Shasun Ltd	SDS Number: SDS/D1-029-00
Section 1: Identification		
Product Identifier		
Product name:	Ibuprofen Tablets USP 400mg. Ibuprofen Tablets USP 600mg. Ibuprofen Tablets USP 800mg.	
Trade name:	Not applicable	
Product Code No.:	2005112,2005113 & 2005214	
Relevant identified use of the substance or mixture and use advised against		
Recommended Use:	Non-steroidal anti-inflammatory drugs	
Restrictions on Use:	Use only as directed	
Details of the supplier of the safety data sheet:		
Manufacturer name:	Strides Shasun Limited	
Address:	Strides Shasun Limited UNIT II,R.S.No.32,33&34,PIMS Road, Periyakalapet, Puducherry-605014, India.	
Telephone Number-General:	+914132650900 +914132655697 +914132655698 +914132655951 +914132655952	
Emergency Telephone Number:	91 8067 840307/309	
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).		
Section 2: Hazard Identification:		
Hazard Classification of chemical mixture	Physical	Health
	Not Hazardous	Eye Irritant Category 2A Specific Target Organ toxicity Category 3 (Respiratory irritation)
Signal word	Not available	
Hazard Statement	Harmful if swallowed Suspected of damaging the unborn child. Causes serious eye irritation. May cause respiratory irritation.	
Additional Hazard Information		
Short Term:	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. Acute over dosage and/or chronic abuse of ibuprofen may cause kidney effects.		
Long Term:	Animal studies have shown a potential to cause adverse effects on the fetus.		
Label elements			
Precautionary statements	Avoid breathing dust. Wash hands thoroughly after handling. Use only outdoors or in a well ventilated area. Wear eye protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical attention. IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER or doctor if you feel unwell.		
Storage/Disposal	Dispose in accordance with local and national regulations.		
EU classification	Not available		
US GHS classification	Not available		
Section 3: Composition/Information on Ingredients			
Mixtures:			
Composition			
Components (Chemical Name)	Identifiers (CAS No.)	% Composition	Classification according to regulations (US GHS/EU EINECS)
Ibuprofen	15687-27-1	*	Not available
Colloidal Silicon dioxide	7631-86-9	*	Not available
Microcrystalline Cellulose	9004-34-6	*	Not available
Pregelatinized Starch	9005-25-8	*	Not available
Sodium Starch Glycolate	9063-38-1	*	Not available
Talc	14807-96-6	*	Not available
Magnesium Stearate	557-04-0	*	Not available
Hypromellose	9004-65-3	*	Not available
Titanium dioxide	13463-67-7	*	Not available
Lactose Monohydrate	64044-51-5	*	Not available
Polyethylene glycol	25322-68-3	*	Not available
Sodium citrate	68-04-2	*	Not available
*Percentage composition is not captured due to trade secret.			
Section 4: First aid measures			
General advice:	Not applicable		
Inhalation:	Remove person to fresh air. If irritation occurs or symptoms develop, get medical attention.		
Skin contact:	Wash skin with soap and water. If irritation develops and persists, get medical attention.		

	Remove contaminated clothing and wash it before reuse.
Eye contact:	Immediately flush eyes with water while lifting the upper and lower lids for at least 15 minutes. Get medical attention if irritation persists.
Ingestion:	Rinse mouth with water. Do not induce vomiting. Never give anything by mouth to a person who is unconscious or convulsing. Get medical attention if large amount is ingested or if symptoms develop.
Most important symptoms and effects both acute and delayed:	
Symptoms:	Causes eye irritation. May cause mild skin irritation. Breathing dust may cause respiratory tract irritation. Swallowing amounts above the recommended dosage may cause gastrointestinal effects, dizziness, headache, nervousness, increased bleeding time, rash and tinnitus. May increase the risk of gastrointestinal bleeding, ulceration and heart attack and stroke.
Other hazards	Not available
Indication of immediate medical attention and special treatment needed	
Notes for the doctor	Immediate medical attention is recommended for overdose.
Special treatment	Not available
Other information	Not available
Section 5: Fire Fighting Measures	
Extinguishing media	
Suitable Extinguishing Media	Use carbon dioxide, dry chemical, or water spray.
Unsuitable Extinguishing Media	Not available
Firefighting Procedures	During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
Unusual Fire and Explosion Hazards	No unusual fire or explosion hazards noted
Hazardous combustion products:	Formation of toxic gases is possible during heating or fire
Additional Information	Not available
Section 6: Accidental Release Measures	
Personal precautions, protective equipment and emergency procedures	
Personal Precautions:	Wear appropriate protective clothing and equipment as described in Section 8. If tablets are damaged, respiratory protection may be required. Avoid generating airborne dust during clean-up. If dust is present, eliminate all sources of ignition.
Emergency Procedure	Not available
Methods and material for containment and cleaning up	

Containment/Cleanup measures	Collect using methods that avoid the generation of dust and damage to tablets (scoop up carefully) and place in appropriate container for disposal. Clean area thoroughly. If dust is present, do not use vacuum unless explosion-proof.		
Prohibited materials	Not available		
Section 7: Handling and Storage			
Precautions for safe handling			
Patients/Consumers:			
Safe handling:	If tablets are damaged, avoid contact with eyes, skin and clothing and avoid breathing dust. Wash thoroughly with soap and water after handling.		
Fire Prevention	Not available		
Dust generation Preventions	Avoid the generation of dust.		
Environmental precautions	Not available		
Conditions for safe storage, including any incompatibilities			
Technical measures and Storage Conditions:	Store as indicated on product packaging in a secure location.		
Special Packaging Materials	Not available		
Section 8: Exposure Controls and personal protection			
Exposure Limits/Guidelines			
Component Name	Result	OSHA	Other agency Information
Ibuprofen	TWA	No data available	2000 ug/m3 TWA Perrigo OEB1
Colloidal Silicon dioxide	PEL/TWA	6mg/m ³ 15 mg/m (Total dust) 5 mg/m ³ (Respirable)	2 mg/ m ³
Microcrystalline Cellulose	PEL/TWA	15 mg/m3 (Total dust) 5 mg/m3 (respirable fraction of dust)	10 mg/m3 (TWA)
Pregelatinized Starch	TWA ACGIH TLV/ TWA OSHA PEL	10 mg/m3 5 mg/m3 (respirable) 15 mg/m3 (total dust)	No data available
Corn starch	TWA ACGIH TLV/ TWA OSHA PEL	10 mg/m3 5 mg/m3 (respirable) 15 mg/m3 (total dust)	No data available
Sodium Starch Glycolate	TWAs	No available	No available
Talc	PEL/TWA	20 mppcf	2 mg/m3

Magnesium Stearate	TWA/PEL	5 mg/m3 (Respirable fraction for nuisance dusts) 15 mg/m3 Total dust	10 mg/m3
Hypromellose	TWA	10 mg/ m³	No data available
Titanium dioxide	PEL	15 mg/m3	10 mg/m3
Lactose Monohydrate	TWAs/STELs	Not available	Not available
Polyethylene glycol	WEEL	No Data	10 mg/m3
Sodium citrate	Not available	Not available	Not available
Note: The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated.			
Exposure Controls			
Engineering Controls	General ventilation normally adequate		
Personal protective equipment			
Hands:	Not available		
Eyes:	Chemical safety goggles recommended for handling damaged tablets or tablets.		
Skin:	Impervious gloves recommended for handling damaged tablets.		
Respiratory protection:	None needed under normal use conditions. If exposure limits are exceeded, a NIOSH approved particulate respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.		
Special requirements for PPE:	Not available		
Section 9: Physical and Chemical properties			
Information on physical and chemical Properties			
Material Description:			
Physical Form:	Solid, Tablet		
Color:	White		
Odour:	Not available		
General Properties:			
Boiling point	Not available		
Melting point:	Not available		
Water solubility:	Not available		
Solvent solubility:	Not available.		
Specific gravity / Relative density:	Not available.		
pH	Not available.		
Decomposition temperature:	Not available.		
Viscosity	Not available.		
Density:	Not available.		
Partition coefficient:	Not available.		

Volatility and Flammability	Not available.				
Vapor pressure:	Not available.				
Vapor density	Not available.				
Evaporation rate:	Not available.				
Flash Point	Not available.				
Upper Exposure limit:	Not available.				
Lower Exposure limit:	Not available.				
Flammability (solid, gas):	Not available.				
Section 10: Stability and Reactivity					
Reactivity	Not reactive under normal conditions of use.				
Chemical stability under normal ambient Temperature	This product is expected to be stable.				
Possibility of hazardous reactions	Not available				
Conditions to avoid	Not available				
Incompatible materials	Avoid oxidizing agents.				
Hazardous decomposition products	Thermal decomposition may yield carbon oxides.				
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
Ibuprofen	15687-27-1	Rat	Oral	LD 50	636 mg/kg
Colloidal Silicon dioxide	7631-86-9	Rat	Oral	LD50	3160 mg/kg
Microcrystalline Cellulose	9004-34-6	Rabbit	Dermal	LD50	> 2000 mg/kg
		Rat	Oral	LD50	> 2000 mg/kg
Pregelatinized Starch	9005-25-8	Mouse	Intraperitoneal	LD50	6600 mg/kg
Corn starch	9005-25-8	Mouse	Intraperitoneal	LD50	6600 mg/kg
Sodium Starch Glycolate	9063-38-1	Rat	Oral	LD50	> 5000 mg/kg
Talc	14807-96-6	Rat	Oral	LD50	1600 mg/kg
Magnesium Stearate	557-04-0	Rat	Oral	LD 50	>2000mg/Kg
		Rat	Inhalation	LC 50	>2000mg/m³

Hypromellose	9004-65-3	Rat	Oral	LD50	10000 mg/kg
Titanium dioxide	13463-67-7	Rat	Oral	LD50	44200 mg/kg
Lactose Monohydrate	64044-51-5	Rat	Oral	LD50	10000 mg/kg
Polyethylene glycol	25322-68-3	Rat	Oral	LD50	44,200 mg/kg
Sodium citrate	68-04-2	Not available			
Potential health effects					
Inhalation:	Inhalation of dust from damaged tablets may cause irritation of the mucous membranes and upper respiratory tract.				
Ingestion:	Swallowing amounts above the recommended dosage may cause gastrointestinal effects, dizziness, headache, nervousness, increased bleeding time, rash and tinnitus. May increase the risk of gastrointestinal bleeding and ulceration.				
Eye contact:	Contact may cause irritation with redness and tearing. Ibuprofen is irritating to human eyes.				
Skin contact:	Contact may cause slight irritation.				
Section 12: Ecological Information					
Toxicity	Ibuprofen: LC50 fish (Iepomis macrochirus) 173 mg/L/96 hr; EC50 daphnia magna 29.6 mg/L/48 hr, NOEC daphnia magna 20 mg/L/21 d.; ErC50 algae (scenedesmus subspicatus) 315 mg/L/72 hr.				
Persistence and degradability	Ibuprofen: not readily biodegradable.				
Bio accumulative potential	Ibuprofen: log Kow 3.87				
Mobility in Soil	Not available				
Other adverse effects	None known				
Section 13: Disposal Considerations					
Product waste	Dispose in accordance with all local, state and federal regulations. No specific disposal method is recommended.				
Packaging waste	Not available				
Section 14: Transport information					
UN Number	Not available				
UN shipper name	Not available				
Transport hazard class:	This product is not regulated as a hazardous material/dangerous good under US DOT, IATA, IMDG or EUADR.				
Environmental hazards	Not available				

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
Ibuprofen	15687-27-1	Not Listed
Colloidal Silicon dioxide	7631-86-9	Not Listed
Microcrystalline Cellulose	9004-34-6	Not Listed
Pregelatinized Starch	9005-25-8	Not Listed
Corn starch	9005-25-8	Not Listed
Sodium Starch Glycolate	9063-38-1	Not Listed
Talc	14807-96-6	Not Listed
Magnesium Stearate	557-04-0	Not Listed
Hypromellose	9004-65-3	Not Listed
Titanium dioxide	13463-67-7	Not Listed
Lactose Monohydrate	64044-51-5	Not Listed
Polyethylene glycol	25322-68-3	Not Listed
Sodium citrate	68-04-2	Not Listed
Section 16: Other information		
Reason for revision: (Include Change control number)	New Safety data sheet prepared	
Revision date:	08/06/2018	
Version Number:	00	