

## CERTIFICATE FOR SAFETY DATA SHEET

Name of the product: Ibuprofen Tablets USP 400mg, 600mg &800mg Product Code: 2005112, 2005113 & 2005214

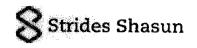
SDS Number: SDS/D1-029-00

Activity	Department	Name	Sign & Date
Prepared By (FD)	FD	Suyog Pande	Sande 08.06.2018
Reviewed By (FD)	FD	Rangeet kumar Mohanty	-P08/06/18
Reviewed By (RA)	Regulation	M.M. Hebitar Qureshi	Manueli 08/06/18
Approved By (FD)	f)	Sudarshan Nimbalkas	Astalis
Authorized By (TSGQA/DQA)	DQ	S. GIOPLWATH	08/06/18

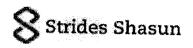
RD/FD/009/F-02/R0



	Safety data Sl	neet				
Company Name:	iny Name: Strides Shasun Ltd SDS Number: SDS/D1-029-00					
Section 1: Identification						
Product Identifier						
Product Identifier	II					
Product name:	Ibuprofen Tablets USP 400mg.					
Floduct name.	Ibuprofen Tablets USP 600mg. Ibuprofen Tablets USP 800mg.					
Trade name:	Not applicable	mg.				
Product Code No.:	2005112,2005113 & 20052	11.1				
	f the substance or mixture a					
Recommended Use:	Non-steroidal anti-inflamm					
Restrictions on Use:	Use only as directed	atory drugs				
Details of the supplier of						
Manufacturer name:	Strides Shasun Limited					
ivianutacturer name.	Strides Shasun Limited					
Address:	UNIT II,R.S.No.32,33&34	PIMS Road				
radioss.	Periyakalapet, Puducherry-	·				
	+914132650900	00501 <del>4</del> , India.				
	+914132655697					
Telephone Number-	+914132655698					
General:	+914132655951					
	+914132655952					
Emergency Telephone						
Number:	91 8067 840307/309					
Note: This safety data she	eet is written to provide safe	y, health and environmental information for				
		ace. It is not intended to provide information				
	of the product (PIL will be app					
Section 2: Hazard Identi	fication:					
	Physical	Health				
Hazard Classification of		Eye Irritant Category 2A				
chemical mixture	Not Hazardous	Specific Target Organ toxicity Category 3				
		(Respiratory irritation)				
Signal word	Not available					
	Harmful if swallowed					
	Suspected of damaging the unborn child.					
Hazard Statement	Causes serious eye irritation.					
	May cause respiratory irritation.					
Additional Hazard	iviay cause respiratory fifth	HOII.				
Information						
Inivi mation	A goldontal in a a sti	avea offects similar to the end of the transfer				
Short Term:	Accidental ingestion may cause effects similar to those seen in clinic use. Individuals sensitive to this chemical or other materials in its					
	use. Individuals sensitive to	this chemical or other materials in its				

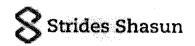


The state of the s	chemical class may develop allergic reactions. Acute over dosage and/or			
	chronic abuse of ibuprofen may cause kidney effects.			
Long Term:	Animal studies have shown a potential to cause adverse effects on the			
-	fetus.			
Label elements	T	•		
	Avoid breathing			
	Wash hands the			
			well ventilated area.	
	Wear eye prote			
Precautionary statements	IF IN EYES: R	inse caution	usly with water for several minutes. Remove	
	contact lenses,	if present a	nd easy to do. Continue rinsing. If eye	
	irritation persis			
	IF INHALED:	Remove pe	rson to fresh air and keep comfortable for	
	breathing. Call	a POISON	CENTER or doctor if you feel unwell.	
Storage/Disposal		rdance wit	h local and national regulations.	
EU classification	Not available			
US GHS classification	Not available	***************************************		
Section 3: Composition/In	formation on In	gredients		
Mixtures:				
Composition				
Components (Chemical	Identifiers	%	Classification according to regulations	
Name)	(CAS No.)	Compos ition	(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	s not captured due	e to trade se	ecret.	
Section 4: First aid measu	res			
General advice:	Not applicable			
Somethin autitee,	Remove person to fresh air. If irritation occurs or symptoms develop,			
	Remove person	to fresh air	. II irritation occurs or symptoms develop	
Inhalation:			r. If irritation occurs or symptoms develop,	
	get medical atte	ntion.	vater. If irritation develops and persists, get	

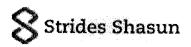


	D.	
	Remove contaminated clothing and wash it before reuse.	
Eve contact:	Immediately flush eyes with water while lifting the upper and lower lids	
Eye contact:	for at least 15 minutes.	
	Get medical attention if irritation persists.	
	Rinse mouth with water. Do not induce vomiting. Never give anything by	
Ingestion:	mouth to a person who is unconscious or convulsing. Get medical	
	attention if large amount is ingested or if symptoms develop.	
Most important sympton	ns and effects both acute and delayed:	
	Causes eye irritation. May cause mild skin irritation. Breathing dust may	
	cause respiratory tract irritation. Swallowing amounts above the	
Symptoms:	recommended dosage may cause gastrointestinal effects, dizziness,	
Symptoms.	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 1	nedical 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 N	Measures	
Extinguishing media	Tousures	
Suitable Extinguishing		
Media	Use carbon dioxide, dry chemical, or water spray.	
Unsuitable Extinguishing		
Media	Not available	
	During all firefighting activities	
Firefighting Procedures	During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.	
Unusual Fire and	morading sen-contained oreading apparatus.	
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	
	1 NOT AVAILABLE	
Section 6: Accidental Rele	ease Measures	
	tective equipment and emergency procedures	
pro-	Wear appropriate protective clothing and equipment as described in	
TD	Section 8 If tablets are damaged requirement as described in	
Personal Precautions:	Section 8. If tablets are damaged, respiratory protection may be required.	
	Avoid generating airborne dust during clean-up. If dust is present,	
Emergency Procedure	eliminate all sources of ignition.  Not available	
	containment and cleaning up	
and material for	containment and cleaning up	

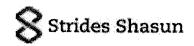
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			70.4			
	_	methods that avoid the generation				
Containment/Cleanup		tablets (scoop up carefully) and place in appropriate container for				
measures		an area thoroughly. If dust is pre	esent, do not use vacuum			
	unless explosi	on-proof.				
Prohibited materials	Not available					
Section 7: Handling ar						
Precautions for safe ha	andling					
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 gen	eration of dust.				
Environmental precautions	Not available					
Conditions for safe sto	rage, including an	y incompatibilities	**************************************			
	and	Store as indicated on product packaging in a secure location.				
Special Packaging Materials	Not available	e				
		· · · · · · · · · · · · · · · · · · ·				
Section 8: Exposure C	ontrols and persor	nal protection				
Exposure Limits/Guid						
Component Name	Result	OSHA	Other agency Information			
Ibuprofen	TWA	No data available	2000 ug/m3 TWA Perrigo OEB1			
Colloidal	PEL/TWA	6mg/m³	$2 \text{ mg/ m}^3$			
Silicon dioxide		15 mg/m (Total dust) 5 mg/m³ (Respirable)	,			
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 2						



Magnesium Stearate	TWA/PEL	5 mg/m3 (Respirable fraction	10 mg/m3			
		for nuisance dusts)				
		15 mg/m3 Total dust				
Hypromellose	TWA	10 mg/ m <sup>3</sup>	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				
<b>Note:</b> The exposure limit	(s) listed for solid	components are only relevant if of	dust or mist may be			
generated.						
<b>Exposure Controls</b>						
<b>Engineering Controls</b>		ation normally adequate				
Personal protective equ						
Hands:	Not available					
Eyes:	Chemical safet	ty goggles recommended for hand	dling damaged tablets or			
	tablets.					
Skin:	Impervious glo	oves recommended for handling of	damaged tablets.			
	None needed	under normal use conditions.	If exposure limits are			
		VIOSH approved particulate res				
Respiratory protection:	Selection of respiratory protection depends on the contaminant type, form					
	and concentrat	ion. Select in accordance with O	SHA 1910.134 and good			
	Industrial Hyg	Industrial Hygiene practice.				
Special requirements for	Not available					
PPE:						
Section 0. Dhysical and	Chamical	4	- HAWARI			
Section 9: Physical and						
Information on physical Material Description:	and chemical Pr	operues				
Physical Form:	Calid T-1-1-4					
Color:	Solid, Tablet White					
Odour:						
	Not available					
General Properties:	) Y / 'I 11	N. 4. 11.1				
Boiling point	Not available					
Melting point:	Not available					
Water solubility:	Not available					
Solvent solubility:		Not available.				
Specific gravity / Relativ	Not available.					
density:						
pH	Not available.					
Decomposition						
temperature:						
Viscosity		Not available.				
Density: Not available.						
Partition coefficient: Not available.						



X 7 1 ('1') 1			
Volatility and	Not available.		
Flammability			
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 I	Reactivity		
Reactivity	Not reactive under normal conditions of use.		
Chemical stability under			
Chemical stability under normal ambient	This product is expected to be stable.		
	This product is expected to be stable.		
normal ambient Temperature Possibility of hazardous			
normal ambient Temperature	This product is expected to be stable.  Not available		
normal ambient Temperature Possibility of hazardous			
normal ambient Temperature Possibility of hazardous reactions	Not available		
normal ambient Temperature Possibility of hazardous reactions Conditions to avoid	Not available  Not available		

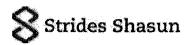
## Section 11: Toxicological information

Information on toxicological effects

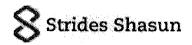
products

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Components					
Components	CAS No	Acute toxicity			
Components		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
Wicroci ystamile Centrose		Rat	Oral	LD50	> 2000 mg/kg
Pregelatinized Starch	9005-25-8	Mouse	Intraperiton eal	LD50	6600 mg/kg
Corn starch	9005-25-8	Mouse	Intraperiton eal	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
iviagnosium sicaraic		Rat	Inhalation	LC 50	>2000mg/m <sup>3</sup>



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				1
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 irritating to h		on with rednes	s and tearing.	Ibuprofen is
Skin contact:	Contact may		irritation.		
Section 12: Ecological In  Toxicity	Ibuprofen: LC50 fish (lepomis 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 Cor	siderations			<u>, , , , , , , , , , , , , , , , , , , </u>	
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 in	formation				
UN Number	Not available	<u>,                                      </u>		····	
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 Inf				
			tion specific for the substance or mixture	
Component Name	CAS numb	<u>er                                     </u>	CERCLA/SARA Emission Reporting	
Ibuprofen	15687-27-1		Not Listed	
Colloidal	7631-86-9		Not Listed	
Silicon dioxide				
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 informa	tion			
Reason for revision: (Include Change			data about propored	
control number)		New Safety data sheet prepared		
Revision date:		08/06/2018		
Version Number:		00		