

## SAFETY DATA SHEETS

**This SDS packet was issued with item:**

078944633

N/A



<b>SAFETY DATA SHEET</b>		
<b>Company Name:</b>	<b>Strides Pharma Science Limited</b>	<b>SDS Number:</b> SDS/FD-036-00
<b>Section 1: Identification</b>		
<b>Product Identifier</b>		
Product name:	Ursodiol Tablets USP 250mg and 500 mg	
Trade name:	Not Applicable	
Product Code No.:	2006153, 2006161, 2006162	
<b>Relevant identified use of the substance or mixture and use advised against</b>		
Recommended Use:	Ursodiol suppresses hepatic synthesis and secretion of cholesterol, and inhibits intestinal absorption of cholesterol.	
Restrictions on Use:	Use only as directed.	
<b>Details of the supplier of the safety data sheet:</b>		
Manufacturer name:	Strides Pharma Science Ltd	
Address:	Strides Pharma Science Limited Strides House, Bilekahalli, Bannerghatta Road, Bangalore, 560076, India.	
Telephone Number-General:	+918067840307/309	
Emergency Telephone Number:	+918067840307/309	
<b>Note:</b> This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.		
<b>Section 2: Hazard Identification:</b>		
Hazard Classification of chemical mixture	Not classified as Hazardous.	
Hazard Classification of chemical substance	<p><b>OSHA Regulatory Status</b> This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.122) Not a dangerous substance or mixture according to the Globally Harmonized System (GHS) Unknown Acute toxicity, 24.9% of the mixture consists of ingredient(s) of unknown toxicity Over the counter drugs in their solid form are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 20 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limit may be surpassed, than can be considered hazardous</p>	

Signal word	WARNING		
Hazard Statement	Suspected of damaging fertility or the unborn child.		
<b>Additional Hazard Information</b>			
Short Term:	Not Available		
Long Term:	Not Available		
<b>Label elements</b>			
Precautionary statements	<p>The product contains no substances which at their given concentration, are considered to be hazardous to health</p> <p><b>Appearance</b> Tablet</p> <p><b>Physical state</b> Solid</p> <p><b>Odor</b> No information available</p> <p><b>Chemical Name: Ursodiol USP:</b></p> <p><b>Symptoms:</b> Symptoms during therapeutic use may include headache, nausea and dizziness. Other lesser reported symptoms include abdominal irritation and discomfort, diarrhea, gas, vomiting (diarrhea has been associated with overdose), joint and muscle aches and pain, back pain, and upper respiratory, nose and throat irritation, inflammation and infection; allergic or sensitization reactions are reported with pure material. Rare cases of skin eruptions have been reported.</p> <p><b>POVIDONE USP:</b> Possible eye, skin, gastrointestinal and/or respiratory tract irritation. Possible allergic reaction to material if inhaled, ingested or in contact with skin. Overdose effects from ingestion of large amounts include abdominal cramps, flatulence, and fecal impaction.</p> <p><b>Chemical Name: Ursodiol USP:</b></p> <p><b>Medical Conditions Aggravated by Exposure:</b> Patients with complete biliary obstruction and known hypersensitivity or intolerance to Ursodiol or any of the components of the formulation.</p> <p><b>POVIDONE USP:</b> Known hypersensitivity to this medication</p>		
Storage/Disposal	Keep containers tightly closed in a dry, cool and well-ventilated place. Store away from incompatible materials		
EU classification	Not available		
US GHS classification	Not available		
<b>Section 3: Composition/Information on Ingredients</b>			
<b>Mixtures:</b>			
<b>Composition</b>			
<b>Components (Chemical Name)</b>	<b>Identifiers (CAS No.)</b>	<b>% Composition</b>	<b>Classification according to regulations (US GHS/EU EINECS)</b>
Ursodiol USP	128-13-2	*	204-879-3
Microcrystalline Cellulose ((Avicel PH 101))	9004-34-6	*	232-674-9
Sodium Starch Glycolate (Type A)	6833-40-9	*	209-150-3



Povidone USP (K-29-32)	9003-39-8	*	238-877-9
Sodium Lauryl Sulphate	151-21-3	*	NA
Tromethamine USP	77-86-1	*	NA
Polyethylene glycol 3350	25322-68-3	*	NA
Magnesium Stearate NF	557-04-0	*	NA
*Percentage composition is not captured due to trade secret.			
<b>Section 4: First aid measures</b>			
<b>General advice:</b>	Not applicable		
Inhalation:	Remove to fresh air.		
Skin contact:	Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.		
Eye contact:	Rinse immediately with plenty of water and seek medical advice.		
Ingestion:	Consult a physician if necessary.		
<b>Most important symptoms and effects both acute and delayed:</b>			
Symptoms:	Not available		
Other hazards	Not available		
<b>Indication of immediate medical attention and special treatment needed</b>			
Notes for the doctor	Not available		
Special treatment	Not available		
<b>Other information</b>	Not available		
<b>Section 5: Fire Fighting Measures</b>			
Extinguishing media			
Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.		
Unsuitable Extinguishing Media	None known.		
<b>Specific hazards arising from the chemical</b>	Fire may produce irritating, corrosive and/or toxic gases.		
<b>Explosion data</b> <b>Sensitivity to Mechanical Impact</b> <b>Sensitivity to Static Discharge</b>	Not impact sensitive.  Fine dust dispersed in air, in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.		
<b>Protective equipment and precautions for firefighters</b>	As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full		



	protective gear		
<b>Section 6: Accidental Release Measures</b>			
<b>Personal precautions, protective equipment and emergency procedures</b>			
Personal Precautions:	Use personal protection recommended in Section 8. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.		
Emergency Procedure	See Section 12 for additional ecological information.		
<b>Methods and material for containment and cleaning up</b>			
Containment/Cleanup measures	Prevent further leakage or spillage if safe to do so. Use personal protective equipment as required. Cover powder spill with plastic sheet or tarp to minimize spreading and keep powder dry. Take up mechanically, placing in appropriate containers for disposal. Avoid creating dust. Clean contaminated surface thoroughly		
Prohibited materials	Not available		
<b>Section 7: Handling and Storage</b>			
<b>Precautions for safe handling</b>			
<b>Patients/Consumers:</b>			
Safe handling:	Avoid contact with skin, eyes or clothing. Avoid generation of dust. Do not eat, drink or smoke when using this product.		
Fire Prevention	Not available		
Environmental precautions	Avoid release to the environment.		
<b>Conditions for safe storage, including any incompatibilities</b>			
Technical measures and Storage Conditions:	Store at 20°C to 25°C (68°F to 77°F). Dispense in a tight container using a child-resistant closure.		
Special Packaging Materials	Not available		
<b>Section 8: Exposure Controls and personal protection</b>			
<b>Exposure Limits/Guidelines</b>			
<b>Component Name</b>	<b>Result</b>	<b>OSHA</b>	<b>Other agency Information</b>
Ursodiol USP,	OEL 800 ug/m3	No data available	No data available
Microcrystalline Cellulose (Avicel PH 101)	TWA: 10 mg/m3	TWA: 15 mg/m3 total dust TWA: 5 mg/m3 respirable fraction (vacated) TWA: 15 mg/m3 total dust	<b>NIOSH IDLH</b> : TWA: 10 mg/m3 total dust TWA: 5 mg/m3 respirable dust TWA: 1 mg/m3
Sodium Starch Glycolate (Type-A)	NA	NA	NA
Povidone USP (K-29-32)	Not Available	Not Available	Not Available
Sodium Lauryl Sulphate	Not Available	Not Available	Not Available

Tromethamine USP	Not Available	Not Available	Not Available
Polyethylene glycol 3350	Not Available	Not Available	Not Available
Magnesium Stearate NF	TWA: 10 mg/m <sup>3</sup> inhalable particulate matter TWA: 3 mg/m <sup>3</sup> respirable particulate matter TWA: 10 mg/m <sup>3</sup> inhalable particulate matter except stearates of toxic metals TWA: 3 mg/m <sup>3</sup> respirable particulate matter except stearates of toxic metals	Not Available	Not Available
<b>Note:</b> Not applicable			
<b>Exposure Controls</b>			
<b>Engineering Controls</b>	The health hazard risks of handling this material are dependent on factors, such as physical form and quantity. Site specific risk assessments should be conducted to determine the appropriate exposure control measures. Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.		
<b>Personal protective equipment</b>			
Eye/Face:	No eye protection is normally needed during medical administration of this product. During operations in which dusts of the product may be generated, safety glasses should be considered.		
Skin & Body:	During medical administration of this product, medical latex or nitrile gloves should be worn to avoid absorption of the product. Use appropriate protective clothing for the task (e.g., lab coat, etc.).		
Respiratory protection:	Respiratory protection is generally not needed during routine conditions of use of this product. If respiratory protection is needed, use only respiratory protection authorized under appropriate regional regulations.		
Special requirements for PPE:	Not available		
<b>Section 9: Physical and Chemical properties</b>			

<b>Information on physical and chemical Properties</b>	
<b>Material Description:</b>	
Physical Form:	Solid
Color:	Off-white
Odour:	Odorless
<b>General Properties:</b>	
Boiling point:	Not available
Melting point:	It melts about 202°C
Water solubility:	Ursodeoxycholic Acid is slightly soluble in water, freely soluble in alcohol, slightly soluble in acetone and methylene chloride
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:	5.0
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.
<b>Section 10: Stability and Reactivity</b>	
<b>Reactivity</b>	Not defined as Reactive substance
Chemical stability under normal ambient Temperature	Stable under normal conditions.
Possibility of hazardous reactions	None under normal processing.
Conditions to avoid	Aerosol formation.
Incompatible materials	None known based on information supplied.
Hazardous decomposition products	None known based on information supplied.

<b>Section 11: Toxicological information</b>				
Information on toxicological effects				
General Information: The information included in this section describes the potential hazards of the individual ingredients.				
<b>Components</b>				
<b>Components</b>	<b>CAS No</b>	<b>Acute toxicity</b>		
		<b>Oral LD50 Dermal LD50 Inhalation LC50</b>	<b>Oral LD50 Dermal LD50 Inhalation LC50</b>	<b>Oral LD50 Dermal LD50 Inhalation LC50</b>
Ursodiol USP	128-13-2	4600 mg/kg (Rat)	4600 mg/kg (Rat)	4600 mg/kg (Rat)
Microcrystalline Cellulose (Avicel PH 101)	9004-34-6	NA	NA	NA
Sodium Starch Glycolate (Type-A)	6833-40-9	> 5 g/kg (Rat) > 2 g/kg (Rabbit) > 5800 mg/m <sup>3</sup> (Rat) 4 h	> 5 g/kg (Rat) > 2 g/kg (Rabbit) > 5800 mg/m <sup>3</sup> (Rat) 4 h	> 5 g/kg (Rat) > 2 g/kg (Rabbit) > 5800 mg/m <sup>3</sup> (Rat) 4 h
Povidone USP (K-29-32)	9003-39-8	100 g/kg (Rat)	= 100 g/kg (Rat)	= 100 g/kg (Rat)
Sodium Lauryl Sulphate	151-21-3	1288 mg/kg [Rat.]	NA	NA
Tromethamine USP	77-86-1	NA	NA	NA
Polyethylene glycol 3350	25322-68-3	Acute: 4000 mg/kg [Rat].	Acute: 20000 mg/kg [Rabbit].	NA
Magnesium Stearate NF	557-04-0	NA	NA	NA
<b>Delayed and immediate effects as well as chronic effects from short and long-term exposure</b>				
<b>Chemical Name Germ cell mutagenicity Carcinogenicity Reproductive Toxicity Effects on or via lactation</b>	<b>Chemical Name Germ cell mutagenicity Carcinogenicity Reproductive Toxicity Effects on or via lactation</b>	<b>Chemical Name Germ cell mutagenicity Carcinogenicity Reproductive Toxicity Effects on or via lactation</b>	<b>Chemical Name Germ cell mutagenicity Carcinogenicity Reproductive Toxicity Effects on or via lactation</b>	<b>Chemical Name Germ cell mutagenicity Carcinogenicity Reproductive Toxicity Effects on or via lactation</b>
Ursodiol USP, micronized not genotoxic in the Ames	Ursodiol USP, micronized not genotoxic in the	Ursodiol USP, micronized not genotoxic in the	Ursodiol USP, micronized not genotoxic in	Ursodiol USP, micronized not



	Ames and the Chinese hamster bone marrow cell chromosome aberration test.	Ames increased incidence of pheochromocytomas of the adrenal medulla in females of the highest dose group. .On the other hand, in a 32-week rat study, Ursodiol at a daily dose of 240mg/kg (1,440 mg/m <sup>2</sup> , 2.6 times the maximum recommended human dose based on body surface area) suppressed the colonic carcinogenic effect of another known carcinogen azoxymethane.	the Ames human dose (based on body surface area) and have revealed no evidence of impaired fertility or harm to the fetus due to Ursodiol.	genotoxic in the Ames
POVIDONE USP	information available. Not suspected of being a	information available. Not suspected of being a	information available. Not suspected of being a	information available. Not suspected of being a
<b>Numerical measures of toxicity - Product Information</b>	24.9% of the mixture consists of ingredient(s) of unknown toxicity			
<b>Unknown Acute Toxicity</b>	May cause respiratory irritation.			
<b>ATE mix (oral)</b>	6977 mg/kg			
<b>ATE mix (dermal)</b>	9288 mg/kg			
<b>ATE mix (inhalation-dust/mist)</b>	26.9 mg/l			
<b>Section 12: Ecological Information</b>				



Toxicity	77.47% of the mixture consists of components(s) of unknown hazards to the aquatic environment	
Persistence and degradability	No information available	
Bio accumulative potential	No information available	
Mobility in Soil	No information available	
Other adverse effects	No information available	
<b>Section 13: Disposal Considerations</b>		
Product waste	Disposal should be in accordance with applicable regional, national and local laws and regulations.	
Packaging waste	Do not reuse container. Dispose of contents/containers in accordance with local regulations.	
<b>Section 14: Transport information</b>		
UN Number	Not available	
UN shipper name	Not available	
Transport hazard class:	Not available	
Environmental hazards	Not available	
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable.	
<b>Section 15: Regulatory Information</b>		
<p><b>Carcinogenicity</b> The table below indicates whether each agency has listed any ingredient as a carcinogen. This product contains one or more substances which are classified by IARC as carcinogenic to humans (Group I), probably carcinogenic to humans (Group 2A) or possibly carcinogenic to humans (Group 2B)</p>		
<b>Component Name</b>	<b>CAS number</b>	<b>IARC/CERCLA/SARA Emission Reporting</b>
Microcrystalline Cellulose	9004-34-6	Group 3
Sodium Starch Glycolate	6833-40-9	Group 3
Povidone USP (K-29-32)	9003-39-8	Group 3
Sodium Lauryl Sulphate	151-21-3	Not Available
Tromethamine USP	77-86-1	Not Available
Polyethylene glycol 3350	25322-68-3	Not Available
Magnesium Stearate NF	557-04-0	Group 3
<p><b>IARC (International Agency for Research on Cancer)</b>  <i>Not classifiable as a human carcinogen</i></p>		



<b>Section 16: Other information</b>	
Reason for revision: (Include Change control number)	New Safety data sheet prepared
Revision date:	NA
Version Number:	00