

SAFETY DATA SHEET		
Company Name:	Strides Pharma Science Limited	SDS Number: SDS/FD-038-00
Section 1: Identification		
Product Identifier		
Product name:	Hydrocortisone Tablets USP 5mg, 10mg and 20 mg	
Trade name:	Not Applicable	
Product Code No.:	2006647, 2006648 & 2006649	
Relevant identified use of the substance or mixture and use advised against		
Recommended Use:	Anti-inflammatory	
Restrictions on Use:	Use only as directed.	
Details of the supplier of the safety data sheet:		
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	
<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 classified as Hazardous.	
Hazard Classification of chemical substance	GHS Classification Reproductive toxicity - Category 2	
Signal word	WARNING	
Hazard Statement	Suspected of damaging the unborn child.	
Additional Hazard Information		
Short Term:	Not available	
Long Term:	Not available	
Label elements		
Precautionary statements	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood.	

	Use personal protective equipment as required. Store locked up. IF exposed or concerned: Get medical attention/advice. Store locked up. Dispose of contents/container in accordance with all local and national regulations.		
Storage/Disposal	Store as directed by product packaging		
	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release. Dispose of waste in accordance with all applicable laws and regulations		
EU classification	Not available		
US GHS classification	GHS - Classification Reproductive Toxicity: Category 2		
Section 3: Composition/Information on Ingredients			
Mixtures:			
Composition			
Components (Chemical Name)	Identifiers (CAS No.)	% Composition	Classification according to regulations (US GHS/EU EINECS)
Hydrocortisone	50-23-7	*	Eye Irritation (Category 2B) Toxic to Reproduction (Category 2) Sensitization - Respiratory (Category 1) Sensitization - Skin (Category 1) Specific Target Organ Toxicity - Repeated Exposure (Category 2) - (endocrine system)
Microcrystalline Cellulose	9004-34-6	*	232-674-9
Colloidal Silicon Dioxide	7631-86-9	*	Acute Tox oral 5
Lactose Monohydrate	10039-26-6	*	Not available
Magnesium Stearate	557-04-0	*	Not available
*Percentage composition is not captured due to trade secret.			
Section 4: First aid measures			
General advice:	Not applicable		
Inhalation:	Remove to fresh air and keep patient at rest. Seek medical attention immediately.		
Skin contact:	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.		
Eye contact:	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.		

Ingestion:	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
Most important symptoms and effects both acute and delayed:	
Symptoms:	For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 - Toxicological Information.
Other hazards	An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).
Indication of immediate medical attention and special treatment needed	
Notes for the doctor	None
Special treatment	Not available
Other information	Text of CLP/GHS Classification abbreviations mentioned in Section 3 Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child
Section 5: Fire Fighting Measures	
Extinguishing media	
Suitable Extinguishing Media	Extinguish fires with CO ₂ , extinguishing powder, foam, or water.
Unsuitable Extinguishing Media	No information available
Firefighting Procedures	During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
Unusual Fire and Explosion Hazards	Fine particles (such as dust and mists) may fuel fires/explosions.
Hazardous combustion products:	Formation of toxic gases is possible during heating or fire. May include oxides of carbon.
Additional Information	During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
Section 6: Accidental Release Measures	
Personal precautions, protective equipment and emergency procedures	
Personal Precautions:	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
Emergency Procedure	Not available
Methods and material for containment and cleaning up	
Containment/Cleanup measures	Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.
Prohibited materials	Not available
Section 7: Handling and Storage	

Precautions for safe handling			
Patients/Consumers:			
Safe handling:	Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.		
Fire Prevention	Not available		
Dust generation Preventions	Avoid the generation of dust.		
Environmental precautions	Avoid release to the environment.		
Conditions for safe storage, including any incompatibilities			
Technical measures and Storage Conditions:	Store as directed by product packaging		
Special Packaging Materials	Not available		
Section 8: Exposure Controls and personal protection			
Exposure Limits/Guidelines			
Component Name	Result	OSHA	Other agency Information
Hydrocortisone	No data available	No data available	No data available
Microcrystalline Cellulose	TWA: 10 mg/m ³	TWA: 15 mg/m ³ total dust TWA: 5 mg/m ³ respirable fraction (vacated) TWA: 15 mg/m ³ total dust	NIOSH IDLH: TWA: 10 mg/m ³ total dust TWA: 5 mg/m ³ respirable dust TWA: 1 mg/m ³
Colloidal Silicon Dioxide	TWAs/ STELs/NIOSH/ TWA OSHA PEL	20mppcf TWA (80) / (% SiO ₂) mg/m ³ TWA	6 mg/m ³ TWA
Lactose Monohydrate	TWAs/STELs	No data available	No data available
Magnesium Stearate	TWA: 10 mg/m ³ inhalable particulate matter TWA: 3 mg/m ³ respirable particulate matter TWA: 10 mg/m ³ inhalable particulate	No data available	No data available

	<p>matter except stearates of toxic metals TWA: 3 mg/m³ respirable particulate matter except stearates of toxic metals</p>		
<p>Note: The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated.</p>			
<p>Exposure Controls</p>			
<p>Engineering Controls</p>	<p>Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.</p>		
<p>Personal protective equipment</p>			
<p>Eyes:</p>	<p>Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)</p>		
<p>Skin & Body:</p>	<p>Wear impervious protective clothing to prevent skin contact – consider use of disposable clothing where appropriate. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)</p>		
<p>Respiratory protection:</p>	<p>Under normal conditions of use, 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 (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)</p>		
<p>Special requirements for PPE:</p>	<p>Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.</p>		
<p>Section 9: Physical and Chemical properties</p>			
<p>Information on physical and chemical Properties</p>			
<p>Material Description:</p>			
<p>Physical Form:</p>	<p>Tablets</p>		
<p>Color:</p>	<p>White to off-white</p>		
<p>Odour:</p>	<p>Odorless</p>		
<p>General Properties:</p>			
<p>Boiling point:</p>	<p>Not available</p>		
<p>Melting point:</p>	<p>Not available</p>		

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	No data available				
Chemical stability under normal ambient Temperature	Stable under normal conditions.				
Possibility of hazardous reactions	No data available				
Conditions to avoid	Fine particles (such as dust and mists) may fuel fires/explosions.				
Incompatible materials	As a precautionary measure, keep away from strong oxidizers				
Hazardous decomposition products	No data available				
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
Hydrocortisone	50-23-7	Rat	Oral	LD50	5000 mg/kg

Microcrystalline Cellulose	9004-34-6	Data Not Available			
Colloidal Silicon Dioxide	7631-86-9	Rat	Oral	LD50	>7900 mg/kg
Lactose Monohydrate	10039-26-6	Rat	Oral	LD50	>10000mg/kg
Magnesium Stearate	557-04-0	Data Not Available			
Potential health effects					
Inhalation:	May be harmful if swallowed				
Ingestion:	Ingestion of this material may cause effects similar to those seen in clinical use including nausea, vomiting, muscle cramps, weakness, nervousness, restlessness, trouble sleeping Clinical use has resulted in changes in electrolytes and/or blood chemistry changes. Drugs of this class may cause Cushing's syndrome, manifested by moon face, obesity, headache, acne, thirst, increased urination, impotence, menstrual irregularities, facial hair growth, and mental changes. Clinical use may cause an increase in blood pressure (hypertension).				
Eye contact:	May cause minimal eye irritation (based on animal data).				
Skin contact:	May be harmful if absorbed through the skin.				
Section 12: Ecological Information					
Toxicity	No data available				
Persistence and degradability	No data available				
Bio accumulative potential	No data available				
Mobility in Soil	No data available				
Other adverse effects	No data available				
Section 13: Disposal Considerations					
Product waste	Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.				
Packaging waste	Not available				
Section 14: Transport information					
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.	
Section 15: Regulatory Information		
Safety, health and environmental regulations/legislation specific for the substance or mixture		
Component Name	CAS number	CERCLA/SARA Emission Reporting
Hydrocortisone	50-23-7	Not Listed
Microcrystalline Cellulose	9004-34-6	Group 3
Colloidal Silicon Dioxide	7631-86-9	Not Listed
Lactose Monohydrate	10039-26-6	Not Listed
Magnesium Stearate	557-04-0	Group 3
Section 16: Other information		
Reason for revision: (Include Change control number)	New Safety data sheet prepared	
Revision date:	NA	
Version Number:	00	