

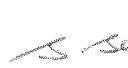




CERTIFICATE FOR SAFETY DATA SHEET
Name of the Product: Triamcinolone Acetonide Ointment USP, 0.05%

Product Code: 2005862

SDS Number: SDS/FD-014-00

Activity	Department	Name	Sign & Date
Prepared By (FD)	FD	Adarsh S. Kulkarni	 29/04/19
Reviewed By (FD)	FD	GATHISH KUMAR B	 29/04/19.
Reviewed By (RA)	RA	S SELVAKUMAR	 29/04/2019
Approved By (FD)	FD	Sudarshan Nimbalkar	 29/04/19
Authorized By (TSGQA/DQA)	DQ	S. GOPINATH	 29/04/19

Safety Data Sheet		
Company Name:	Strides Pharma Science Ltd	SDS Number: SDS/FD-014-00
Section 1: Identification		
Product Identifier		
Product name:	Triamcinolone Acetonide Ointment USP 0.05%	
Trade name:	Not applicable	
Product Code No.:	2005862	
Relevant identified use of the substance or mixture and use advised against		
Recommended Use:	Pharmaceutical product indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses	
Restrictions on Use:	Use only as directed	
Details of the supplier of the safety data sheet:		
Manufacturer name:	Strides Pharma Science Limited	
Address:	Strides Pharma Science Limited No36/7, Suragajakkanahalli, Indlavadi cross, Ankel Taluk, Bengaluru, Karanataka, India - 562106	
Telephone Number- General:	91 8067 840307/309	
Emergency Telephone Number:	91 8067 840307/309	
Note: <i>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	Physical	Health
	Not available	Reproductive toxicity Category 1B Skin corrosion/irritation Category 2 Eye damage/irritation Category 2 Carcinogenicity Category 2 STOT (Repeated Exposure) Category 2 (endocrine system)
Signal word	Danger	
Hazard Statement	H302 - Harmful if swallowed, Suspected of causing cancer.	
Label elements		
Precautionary statements	P264 - Wash hands thoroughly after handling P270 - Do not eat, drink or smoke when using this product P301+ P312 - If swallowed: call a poison center or doctor/physician if you feel unwell P501 - Dispose of contents/container in accordance with all local and national regulations	
Storage/Disposal	Dispose in accordance with local, state, and federal 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)
Triamcinolone Acetonide	76-25-5	*	No data Available
Light mineral Oil	8042-47-5	*	Not classified as dangerous
Heavy Mineral Oil	8042-47-5	*	Not classified as dangerous
White Petrolatum	8009-03-8	*	Not classified as dangerous
Lanolin Alcohol	8027-33-6	*	No data Available
Mineral Wax	8001-75-0	*	Not data Available
Purified water	Not applicable	*	Not applicable
*Percentage composition is not captured due to trade secret.			
Section 4: First aid measures			
General advice:	Not applicable		
Inhalation:	If breathing is difficult, move to fresh air. Watch for signs of respiratory insufficiency and assist ventilations if needed. Monitor for pulmonary edema and treat if necessary		
Skin contact:	After contact with skin, wash immediately with plenty of water. Gently and thoroughly wash the contaminated skin with running water and non-abrasive soap. Be particularly careful to clean folds, crevices, creases and groin. Cover the irritated skin with an emollient. If irritation persists, seek medical attention. Wash contaminated clothing before reusing.		
Eye contact:	Flush with copious amounts of water for at least 15 minutes. Hold eyelids away from eyeball to ensure thorough rinsing. Irrigate each eye continuously with normal saline during transport. Seek medical attention immediately.		
Ingestion:	Toxicity is low after acute ingestion; gastrointestinal decontamination is generally not necessary. Seek medical advice and monitoring/treatment for allergic reactions.		
Most important symptoms and effects both acute and delayed:			
Symptoms:	Not available		
Other hazards	Not available		
Indication of immediate medical attention and special treatment needed			
Notes for the doctor	Not available		
Special treatment	Not available		
Other information	Not available		

Section 5: Fire Fighting Measures	
Extinguishing media	
Suitable Extinguishing Media	Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials..
Unsuitable Extinguishing Media	Not available
Firefighting Procedures	Not available
Unusual Fire and Explosion Hazards	Not available
Fire-fighting equipment/instructions	As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
Hazardous combustion products:	No data available
Flammability of the Product	No data available
Additional Information	Not available
Section 6: Accidental Release Measures	
Small Spill: Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.	
Large Spill: Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.	
Personal precautions, protective equipment and emergency procedures	
Personal Precautions:	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid inhalation of dust from the spilled material. Ensure adequate ventilation. Wear appropriate personal protective equipment
Emergency Procedure	
Methods and material for containment and cleaning up	
Containment/Cleanup measures	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Wash spill site.
Prohibited materials	Not available
Section 7: Handling and Storage	
Precautions for safe handling	
Patients/ Consumers:	Not available
Safe handling:	Keep away from heat. Keep away from sources of ignition. Empty containers pose a fire risk, evaporate the residue under a fume hood. Ground all equipment containing material. Do not ingest. Do not breathe dust. Wear suitable protective clothing If ingested, seek medical advice immediately and show the container or the label.
Fire Prevention	Not available



Dust generation Preventions	Not available		
Environmental precautions	Not available		
Conditions for safe storage, including any incompatibilities			
Technical measures and Storage Conditions:	Keep container dry. Keep in a cool place. Ground all equipment containing material. Keep container tightly closed. Keep in a cool, well-ventilated place. Combustible materials should be stored away from extreme heat and away from strong oxidizing agents.		
Special Packaging Materials	Not available		
Section 8: Exposure Controls and personal protection			
Exposure Limits/Guidelines			
Component Name	Result	OSHA	Other agency Information
Triamcinolone Acetonide	Dust (TWA)	Dust (TWA) 5 mg/m ³ Respirable fraction. 15 mg/m ³ - Total dust. 50 mppcf - Total dust. 15 mppcf -Respirable fraction. 10 mg/m ³ - Inhalable particles	No data available
Light mineral Oil	Mist: OSHA PEL: 5 mg/m ³ Mist: OSHA ACGIH TLV: Oil Mist: OSHA TWA	As Oil Mist: OSHA PEL: 5mg/m ³ As Oil Mist: OSHA ACGIH TLV: 5 mg/m ³ As Oil Mist: OSHA TWA: 5 mg/m ³	No data available
Heavy Mineral Oil	Mist: OSHA PEL: 5 mg/m ³ Mist: OSHA ACGIH TLV: Oil Mist: OSHA TWA	As Oil Mist: OSHA PEL: 5mg/m ³ As Oil Mist: OSHA ACGIH TLV: 5 mg/m ³ As Oil Mist: OSHA TWA: 5 mg/m ³	No data available
White Petrolatum	No data available	No data available	No data available
Lanolin Alcohol	No data available	No data available	No data available
Mineral Wax	TWA 2 mg/m ³ ; NIOSH	No data available	No data available
Purified water	Not applicable	Not applicable	Not applicable
Note: The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated.			
Exposure Controls			
Engineering Controls	Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.		

Personal protective equipment	
Hands:	Chemically compatible gloves. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy
Eyes:	Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area
Skin:	Avoid unintended skin contact. Wear gloves impervious to conditions of use. Additional protection may be necessary to prevent skin contact including the use of an apron, face shield, boots, or full body protection. A safety shower should be located in the work area.
Respiratory protection:	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134)
Personal Protection	Safety glasses. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Gloves.
Personal Protection in Case of a Large Spill	Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self-contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.
Special requirements for PPE:	Not available
Section 9: Physical and Chemical properties	
Information on physical and chemical Properties	
Material Description:	
Physical Form:	Solid
Color:	White to pale yellow Ointment
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	10 Pa.s - 60Pa.s
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 of use.	
Possibility of hazardous reactions	Not known	
Conditions to avoid	Avoid heat and Flame	
Incompatible materials	Acids, caustics, and other chemicals that could affect its performance should be avoided.	
Hazardous decomposition products	Under fire conditions, thermal decomposition may generate irritating and/or toxic fumes or gases (i.e. carbon oxides and hydrogen fluoride).	
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
Triamcinolone Acetonide	76-25-5	Rat Oral LD50: 6,300 mg/kg, 1,451 mg/kg Mouse Oral LD50 : 5,000 mg/kg, 2,168 mg/kg
Light mineral Oil	8042-47-5	Oral LD50 >5000 mg/kg (Rat) LD50 Dermal >3000 mg/kg (Rabbit)
Heavy mineral Oil	8042-47-5	Oral LD50 >5000 mg/kg (Rat) LD50 Dermal >3000 mg/kg (Rabbit)
White Petrolatum	8009-03-8	Acute dermal toxicity (LD50): 3600 mg/kg [Rabbit (LOLI)].
Lanolin Alcohol	8027-33-6	Acute oral toxicity (LD50): >5000 mg/kg [Rat (from LOLI)]; >26000 mg/kg [Rat]
Mineral Wax	8001-75-0	No data available
Purified water	Not applicable	Not applicable
Potential health effects		

Inhalation:	Although unlikely due to form of product, inhalation of vapors may slightly irritate the nose, throat, and lungs. Symptoms are generally alleviated upon breathing fresh air.	
Ingestion:	Ingestion is not a significant route of occupational overexposure. Acute ingestion of large quantities of this product or chronic ingestion caused by poor hygiene practices may cause adverse symptoms. Symptoms of ingestion overexposure may include nausea, vomiting, and diarrhea.	
Eye contact:	No data Available	
Skin contact:	Skin contact may cause burning sensation, stinging, prickling, itching, and tingling. Corticosteroids (such as Triamcinolone Acetonide) may cause allergic contact dermatitis. This is usually diagnosed by observing a failure to heal rather than a clinical exacerbation. Eye contact may cause irritation and tearing.	
Section 12: Ecological Information		
Toxicity	Avoid release into the environment. Runoff from fire control or dilution water may cause pollution.	
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.	
Packaging waste	Dispose of waste in accordance with all applicable laws and regulations.	
Section 14: Transport information		
UN Number	Not applicable	
UN shipper name	Not applicable	
Transport hazard class:	Not dangerous goods	
Environmental hazards	Not dangerous goods	
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
Triamcinolone Acetonide	76-25-5	Not Listed
Light mineral Oil	8042-47-5	Not Listed
Heavy mineral Oil	8042-47-5	Not Listed
White Petrolatum	8009-03-8	Not Listed
Lanolin Alcohol	8027-33-6	Not Listed



Mineral Wax	8001-75-0	Not Listed
Purified water	Not applicable	Not Listed
Section 16: Other information		
Reason for revision: (Include Change control number)	New Safety Data Sheet prepared	
Revision date:	29/04/2019	
Version Number:	00	