

Safety data Sheet	
Company Name:	Strides Shasun Ltd SDS Number: SDS/D1-040-00
Section 1: Identification	
Product Identifier	
Product name:	Cinacalcet Tablets 30mg, 60mg and 90mg [Film coated]
Trade name:	Not applicable
Product Code No.:	2005257, 2005258, 2005256
Relevant identified use of the substance or mixture and use advised against	
Recommended Use:	Calcimimetics
Restrictions on Use:	Do not take internally unless instructed by a physician.
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, Periyakalpet, Puducherry-605014, India.
Telephone Number- General:	+914132650900, +914132655697, +914132655698, +914132655951, +914132655952
Emergency Telephone Number:	91 8067 840307/309
<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 available
Signal word	Danger
Hazard Statement	H314 - Causes severe skin burns and eye damage H317 - May cause an allergic skin reaction H371 - May cause damage to organs H373 - May cause damage to organs through prolonged or repeated exposure H410 - Very toxic to aquatic life with long lasting effects
Additional Hazard Information	
Short Term:	Not available
Label elements	
Precautionary statements	P280 - Wear protective gloves/ protective clothing/ eye protection/ face protection

	<p>P303 + P361 + P353 - IF ON SKIN (or hair): Remove/ Take off immediately all contaminated clothing. Rinse skin with water/ shower</p> <p>P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing</p> <p>P310 - Immediately call a POISON CENTER or doctor/ physician</p> <p>P280 - Wear eye protection/ face protection</p> <p>P260 - Do not breathe dust/fume/gas/mist/vapors/spray</p>		
Storage/Disposal	Not available		
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)
Cinacalcet HCl	364782-34-3	*	E11: H318 /Xi: R41
Microcrystalline Cellulose	9004-34-6	*	Not available
Crospovidone	9003-39-8	*	Not available
Colloidal Silicodioxide	7631-86-9	*	Not available
Pregelatinized Starch	9005-25-8	*	Not available
Magnesium stearate	557-04-0	*	Not available
Methylhydroxypropylcellulose	9004-67-5	*	Not available
Titanium dioxide	13463-67-7	*	Not available
Polyethylene glycol	25322-68-3	*	Not available
Carnauba Wax	8015-86-9	*	Not available
*Percentage composition is not captured due to trade secret.			
Section 4: First aid measures			
General advice:	Not applicable		
Inhalation:	Move to fresh air. If symptoms persist, call a physician.		
Skin contact:	Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes. Consult a physician if necessary.		
Eye contact:	In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.		
Ingestion:	Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Consult a physician.		
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	Treat symptomatically.
Special treatment	Not available
Other information	Not available
Section 5: Fire Fighting Measures	
Extinguishing media	
Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable Extinguishing Media	Not available
Firefighting Procedures	As in any fire, wear self-contained breathing apparatus pressure-demand, NIOSH (approved) and full protective gear.
Unusual Fire and Explosion Hazards	Not available
Hazardous combustion products:	Not available
Additional Information	Not available
Section 6: Accidental Release Measures	
Personal precautions, protective equipment and emergency procedures	
Personal Precautions:	Not available
Emergency Procedure	Not available
Methods and material for containment and cleaning up	
Containment/Cleanup measures	Spill Procedures: If material is released or spilled, cordon off spill area. Take proper precautions to minimize exposure by using appropriate personal protective equipment in cleaning up a spill. If in powder form, wet down spilled material to minimize airborne dispersion. Soak up material with absorbent e.g., paper towels, and wash spill area thoroughly with appropriate cleaning materials. Dispose of collected material in accordance with applicable waste disposal regulations. Avoid release to the environment.
Prohibited materials	Not available
Section 7: Handling and Storage	
Precautions for safe handling	
Patients/Consumers:	
Safe handling:	Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke in work areas. Use adequate ventilation to minimize exposure. Wash hands, face and other potentially exposed areas immediately after handling this material. Remove contaminated clothing prior to entering eating areas. Clean protective equipment thoroughly after each use. Store in a well ventilated area.

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 containers tightly closed in a cool, well-ventilated place		
Special Packaging Materials	Not available		
Section 8: Exposure Controls and personal protection			
Exposure Limits/Guidelines			
Component Name	Result	OSHA	Other agency Information
Cinacalcet HCl	-	Not available	Amgen's Hazard Classification System as an Occupational Exposure Band 3 compound (20 µg/m ³ - 100 µg/m ³)
Magnesium Stearate	TWA/PEL	5 mg/m ³ (Respirable fraction for nuisance dusts) 15 mg/m ³ Total dust	10 mg/m ³
Crospovidone	TWA	5 mg/m ³	No Data
Colloidal Silicon Dioxide	PEL/TWA	6mg/m ³ 15 mg/m (Total dust) 5 mg/m ³ (Respirable)	2 mg/ m ³
Pregelatinized Starch	TWAs/STELs	15 mg/m ³	10 mg/m ³
Microcrystalline Cellulose	PEL/TWA	15 mg/m ³ (Total dust) 5 mg/m ³ (respirable fraction of dust)	10 mg/m ³ (TWA)
Methyl hydroxypropylcellulose	TWA	10 mg/ m ³	No data available
Titanium dioxide	PEL	15 mg/m ³	10 mg/m ³
Polyethylene glycol	WEEL	No Data	10 mg/m ³
Carnauba Wax	-	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	Not available		
Personal protective equipment			
Hands:	Wash hands, face and other potentially exposed areas after handling material (especially before eating, drinking or smoking). Clean protective equipment thoroughly after each use.		

Eyes:	Wear safety glasses with side shields, chemical splash goggles, or safety glasses with side shields and a full-face shield to prevent contact with eyes. The choice of protection should be based on the job activity and potential for exposure to the eyes and face.
Skin:	Use gloves or other appropriate personal protective equipment if skin contact with formulation is possible. Wear lab coat or other protective over garment if splashing is possible. The choice of protection should be based on the job activity and potential for skin contact.
Respiratory protection:	When possible, handle material in enclosed processes or containers. If it is properly handled with effective local exhaust ventilation or containment, respiratory protection may not be needed. For procedures involving larger quantities or dust/aerosol generating procedures such as weighing or a large transfer of liquids, an air-purifying respirator with NIOSH approval for dusts and mists may be needed. The choice of protection should be based on the job activity and the potential for exposure.
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: Green

Odour: Not available.

General Properties:

Boiling point: 178-184 °C (Cinacalcet HCl)

Melting point: Not available.

Water solubility: Approx. 1,500 mg/L at pH 5; <10 mg/L at pH 7

Solvent solubility: Not available.

Specific gravity / Relative density: Not available.

pH: 5.1 - pH of aqueous solution (saturated at 25 o C)

Decomposition temperature: Not available.

Viscosity: Not available.

Density: Not available.

Partition coefficient: Log Pow value 4.79 (log Kow)

Volatility and Flammability: Not available.

Vapor pressure: Not available.

Vapor density: Not applicable

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					
Chemical stability under normal ambient Temperature	No information available				
Possibility of hazardous reactions	No information available				
Conditions to avoid	No information available				
Incompatible materials	No information available				
Hazardous decomposition products	No information 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
Cinacalcet HCl	364782-34-3	Rat	Oral	LD50	>1,500 mg/kg body weight.
Crospovidone	9003-39-8	Rat	Oral	LD50	5000 mg/kg
Colloidal Silicon Dioxide	7631-86-9	Rat	Oral	LD 50	3160 mg/kg
Pregelatinized Starch	9005-25-8	No data available			
Microcrystalline Cellulose	9004-34-16	Rabbit	Dermal	LD50	> 2000 mg/kg
		Rat	Oral	LD50	> 2000 mg/kg
Magnesium stearate	557-04-0	Rat	Oral	LD 50	>2000mg/Kg
		Rat	Inhalation	LC 50	>2000mg/m ³
Methylhydroxypropylcellulose	9004-67-5	Rat	Oral	LD50	> 10000 mg/kg
Titanium dioxide	13463-67-7	Rat	Oral	LD50	> 7500 mg/kg
Polyethylene glycol	25322-68-3	Rat	Oral	LD50	44,200 mg/kg
Carnauba Wax	8015-86-9	Not available			
Potential health effects					
Inhalation:	Not available				
Ingestion:	Not available				
Eye contact:	Not available				
Skin contact:	Not available				
Section 12: Ecological Information					
Toxicity	Ecotoxicity effects: Cinacalcet HCl is very toxic in acute and chronic studies evaluating its effects on aquatic organisms and invertebrates.				

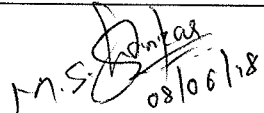
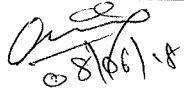

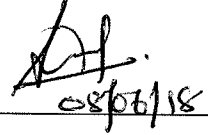

	<p>The 96-hour LC50 value in fathead minnow under static conditions for cinacalcet was 0.085mg/L, with most of the mortality occurring within the first 24 hours. At the lowest concentration tested (0.063 mg/L), 1/20 or 5% of the test animals died at the 96-hour interval. No NOEC was achieved, although the 0.063 mg/L was the EC05 or LOEC for the study.</p> <p>In daphnia magna, the 24-hour and 48-hour EC50 for Cinacalcet HCl are 0.42 mg/L and 0.33 mg/L based on nominal concentrations and 0.23 and 0.16 mg/L based on measured concentrations, respectively. The NOEC was 0.11 mg/L based on nominal concentrations and 0.049 mg/L based on measured concentrations.</p> <p>An acute algal inhibition study produced the following values:</p> <ul style="list-style-type: none"> • 72- and 96-hr EC50 – 0.0191 and 0.0175 mg/L (cell numbers) • 72- and 96-hour EC50 – 0.0203 and 0.0191 mg/L (area under the growth curve) • 72- and 96-hour EC50 - 0.0330 and 0.0320 mg/L (growth rates) <p>In a chronic daphnia reproductive study, the 21-day LC50 for mortality in the parents was 0.14 mg/L. The LOEC and NOEC for parent mortality were 0.20 mg/L and 0.10 mg/L. The LOEC and NOEC for reproductive effects were 0.050 mg/L and 0.025 mg/L, respectively.</p> <ul style="list-style-type: none"> • 72- and 96-hour LOEC and NOEC - 0.0250 and 0.0125 mg/L (cell numbers, area under the growth curve and growth rate).
Persistence and degradability	Cinacalcet HCl is not considered to be biodegradable based on the results of a screening respirometer test and a sealed vessel CO2 production test. An aerobic and anerobic biodegradation test in sediment suggests that if cinacalcet gets into the environment, it would irreversibly bind and remain in the sediment.
Bio accumulative potential	In an activated sludge respiratory inhibition study, the 3-hour EC50 and EC20 were 35.6mg/L and 15.4 mg/L, respectively. The NOEC from the nominal concentration data and effects observed was approximately 1 mg/L.
Mobility in Soil	No information available.
Other adverse effects	No information available.
Section 13: Disposal Considerations	
Product waste	Dispose of any waste according to prescribed federal, state, local and competent authority guidelines.
Packaging waste	Not available
Section 14: Transport information	
This product is not regulated as a hazardous material/dangerous good under US DOT, Canada TDG, IATA, IMDG or EU ADR/RID.	
UN Number	UN Number 3077

UN shipper name	Environmentally Hazardous Substance, solid, n.o.s. (Cinacalcet HCl)	
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 available	
Section 15: Regulatory Information		
Safety, health and environmental regulations/legislation specific for the substance or mixture		
Component Name	CAS number	CERCLA/SARA Emission Reporting
Cinacalcet HCl	364782-34-3	Not Listed
Microcrystalline Cellulose	9004-34-6	Not Listed
Crospovidone	9003-39-8	Not Listed
Colloidal Silicodioxide	7631-86-9	Not Listed
Pregelatinized Starch	9005-25-8	Not Listed
Magnesium stearate	557-04-0	Not Listed
Methylhydroxypropylcellulose	9004-67-5	Not Listed
Titanium dioxide	13463-67-7	Not Listed
Polyethylene glycol	25322-68-3	Not Listed
Carnauba Wax	8015-86-9	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	

CERTIFICATE FOR SAFETY DATA SHEET
Name of the product: Cinacalcet Tablets 30mg, 60mg and 90mg [Film coated]

Product Code: 2005257, 2005258, 2005256

SDS Number: SDS/D1-040-00

Activity	Department	Name	Sign & Date
Prepared By (FD)	FD	M.S. SHANKAR	 08/06/18
Reviewed By (FD)	FD	Chirag Naval	 08/06/18
Reviewed By (RA)	Regulatory Affairs	M.M. Akhtar Qureshi	 08/06/18
Approved By (FD)	FD	Sudarshan Nimbalkar	 08/06/18
Authorized By (TSGQA/DQA)	DQ	S. GOPINATH	 08/06/18