

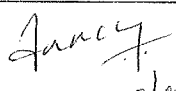
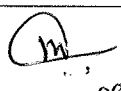
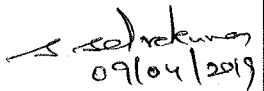
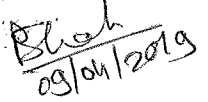
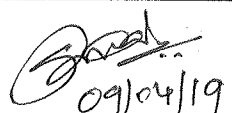


CERTIFICATE FOR SAFETY DATA SHEET

Name of the Product: Ethosuximide Capsules USP 250mg [Soft gelatin]

Product Code: 2004653

SDS Number: SDS/FD-010-00

Activity	Department	Name	Sign & Date
Prepared By (FD)	FD	RAMA RAI CHOWDARY	 09/04/19
Reviewed By (FD)	FD	B. M. Shivraj	 09/04/19
Reviewed By (RA)	RA	S. SELVAKUMAR	 09/04/2019
Approved By (FD)	FD	Punit Shah	 09/04/2019
Authorized By (TSGQA/DQA)	DR	S. GOPINATH	 09/04/19

RD/FD/009/F-02/R1

Safety Data Sheet		
Company Name:	Strides Pharma Science Ltd	SDS Number: SDS/FD-010-00
Section 1: Identification		
Product Identifier		
Product name:	Ethosuximide Capsules USP 250mg [Soft gelatin]	
Trade name:	Not applicable	
Product Code No.:	2004653	
Relevant identified use of the substance or mixture and use advised against		
Recommended Use:	Pharmaceutical product used as anticonvulsant	
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	
<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	Physical	Health
	Not available	Not available
Signal word	Danger	
Hazard Statement	H360D - May damage the unborn child H341 - Suspected of causing genetic defects	
Label elements		
Precautionary statements	P202 - Do not handle until all safety precautions have been read and understood P281 - Use personal protective equipment as required P308 + P313 - IF exposed or concerned: Get medical attention/advice P405 - Store locked up P501 - Dispose of contents/container in accordance with all local and national regulations	
Storage/Disposal	Store as directed by product packaging	
EU classification	EU Indication of danger: Harmful Toxic to Reproduction: Category 2 Mutagenic: Category 3	

	EU Risk Phrases: R22 - Harmful if swallowed. R61 - May cause harm to the unborn child. R68 - Possible risk of irreversible effects.		
US GHS classification	Germ cell mutagenicity: Category 2 Reproductive toxicity: Category 1B		
Section 3: Composition/Information on Ingredients			
Mixtures:			
Composition			
Components (Chemical Name)	Identifiers (CAS No.)	% Composition	Classification according to regulations (US GHS/EU EINECS)
Ethosuximide	77-67-8	*	GHS classification - Acute Tox. 4, H302; Repr. 1B, H360D; Muta. 2, H341 EU classification : Xn, R22; Repr. Cat.2,R61; Mut. Cat.3,R68
Macrogols / Polyethylene Glycol 400	25322-68-3	*	Not Listed
Gelatin	9000-70-8	*	232-554-6
Glycerin	56-81-5	*	200-289-5
Sorbitol Solution	12441-09-7, 50-70-4	*	235-671-0, 200-061-5
FD & C Red #3	16423-68-0	*	240-474-8
D & C Yellow #10	8004-92-0	*	Not listed
Purified Water	7732-18-5	*	231-791-2
Medium chain triglyceride	73398-61-5	*	Not listed
Isopropyl Alcohol	67-63-0	*	200-661-7
Printing Ink White IH- Edible Oil	NA	*	Not Listed
Lecithin (soyalecithin)	8002-43-5	*	232-307-2
*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:	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 carbon dioxide, dry chemical, or water spray.
Unsuitable Extinguishing Media	Not available
Firefighting Procedures	During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus
Unusual Fire and Explosion Hazards	Not available
Hazardous combustion products:	Formation of toxic gases is possible during heating or fire.
Additional Information	Not available
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. Minimize exposure.
Emergency Procedure	Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure.
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:	Not available
Safe handling	If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. Wash thoroughly after handling. 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	Not available		
Environmental precautions	Not available		
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
Ethosuximide	OEL TWA-8 Hr	No data available	2 mg/m ³
Macrogols / Polyethylene Glycol 400	OEL- TWA	No data available	Austria OEL - MAKs 1000 mg/m ³ Germany - TRGS 900 - TWAs 1000 mg/m ³ Germany (DFG) - MAK 1000 mg/m ³ average molecular weight 200-600 Switzerland OEL -TWAs 1000 ppm
Gelatin	TWA	No data available	No data available
Glycerin	TWA	5 mg/m ³	Australia TWA – 10 mg/m ³ Belgium OEL – TWA – 10 mg/m ³ OSHA - Final PELs – TWAs - 15 mg/m ³
Sorbitol Solution	TWA	No data available	No data available
FD & C Yellow #10	TWA	No data available	No data available
FD & C Red #3	TWA	No data available	No data available
Purified Water	TWA	No data available	No data available
Medium chain triglycerides	PEL/TWA	No data available	No data available
Isopropyl Alcohol	TWA	400 ppm	200ppm, 400ppm
Printing Ink White IH-Edible Oil	TWA	No data available	No data available
Lecithin (soya lecithin)	TWA	No data available	No data available
Note: The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated.			

Exposure Controls	
Engineering Controls	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
Personal protective equipment	
Hands:	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations
Eyes:	Wear safety glasses or goggles if eye contact is possible
Skin:	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Respiratory protection:	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.
Special requirements for PPE:	Not available
Section 9: Physical and Chemical properties	
Information on physical and chemical Properties	
Material Description:	
Physical Form:	Soft gelatin capsules
Color:	Orange
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	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	Not available	
Chemical stability under normal ambient Temperature	Stable under normal conditions of use.	
Possibility of hazardous reactions	Not known	
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	Not 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
Ethosuximide	77-67-8	Mouse Oral LD50 1530 mg/kg Rat Oral LD50 1950mg/kg Mouse Intravenous LD50 780mg/kg Mouse Intravenous LD50 1070mg/kg
Macrogols / Polyethylene Glycol 400	25322-68-3	LD 50 oral Rat = 28g/kg LD 50 Dermal rabbit >20gm/kg
Gelatin	9000-70-8	LD50 oral Rat > 3750 mg/kg LD50 Dermal Rabbit > 3600 mg/kg
Glycerin	56-81-5	Mouse Oral LD50 4090 mg/kg Rat Oral LD50 12.6 g/kg Rabbit Dermal LD50 > 10 g/kg Rat Inhalation LC50 1hr > 570 mg/m3 Rat Dermal LD 50 > 21.9 g/kg
Sorbitol Solution	12441-09-7, 50-70-4	LD50 IV mouse > 7100 mg/kg LD50 oral mice > 23.3g/kg LD50 oral rat > 15900 mg/kg
FD & C Red #3	16423-68-0	Rat Oral LD50 1840 mg/kg Mouse Oral LD50 1264mg/kg
D & C Yellow #10	8004-92-0	Rat Oral LD50 2000 mg/kg
Purified Water	7732-18-5	No Data Available
Medium chain triglyceride	73398-61-5	LD60 oral Rat > 5000mg/kg
Isopropyl Alcohol	67-63-0	LD50 oral mouse >3600mg/kg

Printing Ink White IH-Edible Oil	NA	No Data Available
Lecithin (soyalecithin)	8002-43-5	No Data Available
Potential health effects		
Inhalation:	Not Available	
Ingestion:	Not Available	
Eye contact:	Not Available	
Skin contact:	Not Available	
Section 12: Ecological Information		
Aquatic Toxicity: (Species, Method, End Point, Duration, Result)	Oncorhynchus mykiss (Rainbow Trout) LD50 96 Hours 50 mg/L Daphnia magna (Water Flea) EC50 24 Hours >500 mg/L A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.	
Persistence and degradability	No data is available.	
Bio accumulative potential	No data is available.	
Mobility in Soil	No data is available.	
Other adverse effects	No data is 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
Ethosuximide	77-67-8	Not Listed
Macrogols / Polyethylene Glycol 400	25322-68-3	Not Listed
Gelatin	9000-70-8	Not Listed
Glycerin	56-81-5	Not Listed
Sorbitol Solution	12441-09-7, 50-70-4	Not Listed
FD & C Red #3	16423-68-0	Not Listed
D & C Yellow #10	8004-92-0	Not Listed
Purified Water	7732-18-5	Not Listed
Medium chain triglyceride	73398-61-5	Not Listed
Isopropyl Alcohol	67-63-0	Not Listed
Printing Ink White IH-Edible Oil	NA	Not Listed
Lecithin (soyalecithin)	8002-43-5	Not Listed
Section 16: Other information		
Reason for revision: (Include Change control number)	New Safety Data Sheet prepared	
Revision date:	08/04/2019	
Version Number:	00	