



CERTIFICATE FOR SAFETY DATA SHEET

Name of the Product: PEG 3350 and Electrolytes for Oral Solution with Orange flavor, USP

Product Code: 2003151

SDS Number: SDS/FD-028-00

Activity	Department	Name	Sign & Date
Prepared By (FD)	FD	Ranjeet Kumar Mohanty	21-04-2020 <input checked="" type="checkbox"/> Ranjeet Kumar Mohanty Signed by: Ranjeet Mohanty
Reviewed By (FD)	FD	Bidhubhusan Dash	21-04-2020 <input checked="" type="checkbox"/> Bidhubhusan Dash Signed by: Bidhubhusan Dash
Reviewed By (RA)	RA	Naresh Kumar T	22-04-2020 <input checked="" type="checkbox"/> NareshKumar.T Signed by: Naresh Kumar T
Approved By (FD)	FD	Sudharshan Nimbalkar	22-04-2020 <input checked="" type="checkbox"/> Sudarshan Nimbalkar Signed by: Sudharshan Nimbalkar
Authorized By (TSGQA/ DQA)	QA	Harish Prasad	22-04-2020 <input checked="" type="checkbox"/> B.S.Harish Prasad Signed by: Harish Prasad

RD/FD/009/F-02/R1



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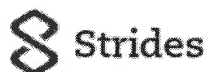
Safety data Sheet		
Company Name:	Strides Pharma Science Ltd	SDS Number : SDS/FD-028-00
Section 1: Identification		
Product Identifier		
Product name:	PEG 3350 and Electrolytes for Oral Solution with Orange flavor, USP	
Trade name:	Not applicable	
Product Code No.:	2003151	
Relevant identified use of the substance or mixture and use advised against		
Recommended Use:	Finished pharmaceutical product- bowel cleansing prior to colonoscopy and barium enema X-ray examination.	
Restrictions on Use:	Gastrointestinal (GI) obstruction, ileus, or gastric retention, Bowel perforation, Toxic colitis or toxic megacolon	
Details of the supplier of the safety data sheet:		
Manufacturer name:	Strides Pharma Science Limited	
Address:	Strides Pharma Science Limited No 36/7, Suragajakkanahalli, Indlavadi Cross, Anekal Taluk, Bengaluru, Karnataka, 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 the chemical mixture:	Fire Hazard: 1	
Signal Word:	Warning	
Hazard Statement:	Eye: May cause mild eye irritation. May cause mechanical irritation. Ingestion: Causes gastrointestinal irritation with nausea, vomiting and diarrhea. Low hazard for usual industrial handling.	
Label elements		
Precautionary statements	Not available	
Storage/Disposal:		
EU Classification:	Not available	
US GHS Classification:	Not available	
Section 3: Composition/Information on Ingredients		

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Mixtures: Material does not meet the criteria of a substance according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS) and EU EINECS.			
Composition			
Components (Chemical Name)	Identifiers (CAS No.)	% Composition	Classification according to regulations (US GHS/EU EINECS)
Polyethylene Glycol 3350	25322-68-3	**	Not applicable
Sodium sulfate(anhydrous)	7757-82-6	**	Not applicable
Sodium Bicarbonate	144-55-8	**	Not applicable
Sodium Chloride	7647-14-5	**	Not applicable
Potassium Chloride	7447-40-7	**	Not applicable
Acesulfame Potassium	55589-62-3	**	Not applicable
Flavour Orange	Not applicable	**	Not applicable
Note: Percentage composition is not captured due to trade secret.			
Section 4: First aid measures			
General Information:			
Inhalation:	Allow the victim to rest in a well-ventilated area. Seek immediate medical attention.		
Skin:	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. Cold water may be used. Cover the irritated skin with an emollient. If irritation persists, seek medical attention. Wash contaminated clothing before reusing.		
Eye:	Immediately flush eyes with running water for at least 15 minutes, keeping eyelids open. Cold water may be used.		
Ingestion:	Do not induce vomiting. Loosen tight clothing such as a collar, tie, belt or waistband. If the victim is not breathing, perform mouth-to-mouth resuscitation. Seek immediate medical attention.		
Most important symptoms and effects both acute and delayed:			
Symptoms:	Nausea, abdominal fullness and bloating		
Other hazards	Abdominal cramps, vomiting and anal irritation occur less Frequently. Isolated cases of urticaria, rhinorrhea, dermatitis and (rarely) anaphylactic reaction have been reported which may represent allergic reactions		
UN GHS/ EU EINECS:			
Effects:	Not available		
Indication of any immediate medical attention and special treatment needed:			
Notes for the doctor:	Not available		
Special treatment:	Not available		
Other information	Not available		

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Section 5: Fire Fighting Measures	
Extinguishing media	
Suitable Extinguishing Media:	Use DRY chemical powder. Use water spray, fog or foam. Do not use water jet.
Unsuitable Extinguishing Media:	Not available
Firefighting Procedures:	Fight fire with normal precautions from a reasonable distance. Wear self-contained breathing apparatus.
Unusual Fire and Explosion Hazards:	Combustible. Vapours can form explosive mixtures with air.
Hazardous Combustion Products:	In case of fire may be liberated: carbon monoxide (CO), carbon dioxide (CO ₂)
Additional information:	Not available
Section 6: Accidental Release Measures	
Personal precautions, protective equipment and emergency procedures	
Personal Precautions:	Use safety goggle with side protection. Wear suitable gloves. Chemical protection gloves are suitable, which are tested according to EN 374. Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended. Respiratory protection necessary at: Aerosol or mist formation. Type: A (against organic gases and vapours with a boiling point of > 65 °C, colour code: Brown).
Emergency Procedures:	Not applicable
Methods and material for containment and cleaning up	
Containment/Cleanup Measures:	Covering of drains, Place in appropriate containers for disposal.
Prohibited Materials:	Not applicable
Section 7: Handling and Storage	
Precautions for safe handling	
Protective measures:	
Safe Handling:	Provide adequate ventilation. Wash hands before breaks and after work.
Fire prevention:	Not available
Dust generation preventions:	Use local and general ventilation.
Environmental precautions:	Keep away from drains, surface and ground water.
Conditions for safe storage, including any incompatibilities:	Keep container tightly closed. Observe hints for combined storage.
Technical measures and storage conditions:	Recommended storage temperature: 15 - 25 °C.
Special Packaging Materials:	Not available

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Requirement for storage rooms and assembly: Not available			
Incompatible Materials or Ignition Sources: Not available			
Section 8: Exposure Controls and personal protection			
Control Parameters:			
National limit values, Occupational exposure limit values (Workplace Exposure Limits), Relevant DNELs/DMELs/PNECs and other threshold levels			
Exposure Limits/ Guidelines: Refer to the occupational exposure limits / guidelines for the individual product components.			
Exposure Limits			
Component Name	Result	OSHA	Other agency information
Polyethylene Glycol 3350	TWAs/STELs/ WEEL	No data available	10 mg/m ³
Sodium sulfate(anhydrous)	TWAs/STELs	5 mg/m ³	Dust – 5 mg/m ³
Sodium Bicarbonate	TWAs/STELs	Not available	Dust – 5 mg/m ³
Sodium Chloride	TWAs/STELs	Not available	Not available
Potassium Chloride	TWAs/STELs	Not available	Not available
Acesulfame Potassium	TWAs/STELs	15 mg/m ³	Not available
Flavour Orange	TWAs/STELs	Not available	Not available
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:	Safety glasses. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Gloves. 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.		
Hands:			
Eyes:			
Skin:			
Respiratory protection:			
Special requirements for PPE :			
Section 9: Physical and Chemical properties			
Information on physical and chemical Properties			
Material Description:			
Physical form	Powder		



Color	White to almost white
Odor	Not available
General Properties:	
Boiling Point	Not available
Melting Point	56°C (132.8°F)
Water Solubility	Easily soluble in cold water. Soluble in hot water
Solvent solubility	Not available
Specific Gravity/Relative Density	1.0926 (Water = 1)
pH	6 [Acidic.] (1% soln/water)
Decomposition Temperature	Not available
Viscosity	Not available
Density	Not available
Partition co-efficient	Not available
Volatility and Flammability:	
Vapor Pressure	Not relevant
Vapor Density	Not relevant
Evaporation Rate	Not available
UEL (Upper exposure Limit)	Not available
Flash Point	Not available
LEL (Lower Exposure Limit)	Not available
Flammability (Solid, Gas)	Not available
Section 10: Stability and Reactivity	
Reactivity:	Not available
Chemical Stability under normal ambient temperature:	The product is stable
Possibility of Hazardous Reactions:	Not available
Any stabilizer requirement on storage:	Not available
Conditions to Avoid:	Not available
Incompatible materials:	Not available
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
Polyethylene Glycol 3350	25322-68-3	Skin - LD50, Rabbit, > 20,000 mg/kg Ingestion - LD50, Rat, >10,000 mg/kg (estimated)
Sodium sulfate(anhydrous)	7757-82-6	Acute oral toxicity (LD50): 5989 mg/kg [Mouse].
Sodium Bicarbonate	144-55-8	Acute oral toxicity (LD50): 3360 mg/kg [Mouse].
Sodium Chloride	7647-14-5	Acute oral toxicity (LD50): 3000 mg/kg [Rat]. Acute dermal toxicity (LD50): >10000 mg/kg [Rabbit]. Acute toxicity of the dust (LC50): >42000 mg/m ³ 1 hours [Rat].
Potassium Chloride	7447-40-7	Acute oral toxicity (LD50): 1500 mg/kg [Mouse].
Acesulfame Potassium	55589-62-3	Acute oral toxicity (LD50): 7431 mg/kg [Rat].
Flavour Orange	Not applicable	Not available
Potential Health Effects		
Inhalation		
Acute (Immediate):	Slightly hazardous	
Chronic (Delayed):	Not available	
Skin		
Acute (Immediate):	Slightly hazardous in case of skin contact (irritant, permeator)	
Chronic (Delayed):	Not available	
Eye		
Acute (Immediate):	Not available	
Chronic (Delayed):	Not available	
Ingestion		
Acute (Immediate):	Slightly hazardous	
Chronic (Delayed):	Not available	
Section 12: Ecological Information		
Toxicity:	Not available	
Persistence and degradability:	Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.	
Bio accumulative potential:	The products of degradation are more toxic.	



Mobility in Soil:	Not available	
Other adverse effects:	Not available	
Section 13: Disposal Considerations		
Product Waste:	Not available	
Packaging Waste:	Not available	
Section 14: Transport information		
UN Number	(Four digit number) Not a DOT controlled material (United States).	
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 available	
Section 15: Regulatory Information		
Safety, health and environmental regulations/legislation specific for the substance or mixture		
Component	CAS No.:	CERCLA/SARA Emission Reporting
Polyethylene Glycol 3350	25322-68-3	Not listed
Sodium sulfate(anhydrous)	7757-82-6	Not listed
Sodium Bicarbonate	144-55-8	Not listed
Sodium Chloride	7647-14-5	Not listed
Potassium Chloride	7447-40-7	Not listed
Acesulfame Potassium	55589-62-3	Not listed
Flavour Orange	Not applicable	Not listed
Note: Superfund Amendments and Reauthorization Act Or Superfund or Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA)		
Section 16: Other information		
Reason for revision: (Include Change control number)	New safety data sheet prepared.	
Revision date :	21/04/2020	
Version Number:	00	

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