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SAFETY DATA SHEET

Section 1: Identification	
Material	Mesalamine Rectal Suppositories 1000 mg
Other means of identification Synonyms	None
Recommended use	Pharmaceutical product
Classification	Anti-inflammatory agents.
Manufacturer	**Annora Pharma Private Limited,** Survey No. 261, Annaram Village, Gummadidala Mandal, Sangareddy, Telangana 502313, India (IND)
Distributor	Camber Pharmaceuticals, Inc., Piscatway, NJ 08854
Section 2: Hazard(s) Identification	
Appearance	Suppositories
Physical State	Solid
odor	Not applicable
Therapeutic Target Organ(s)	Rectal

Emergency Overview:
Health Hazards: Accidental ingestion may be harmful. Inhalation and eye contact may cause irritation. In therapeutic use, the most common adverse reactions reported have included headache, nausea, dizziness, fever, rash, acne, and worsening of ulcerative colitis. Additional symptoms related to rectal administration of the drug are not relevant to workplace exposure. Other adverse effects reported have included renal damage and hypersensitivity reactions, including cardiac hypersensitivity reactions.
Flammability Hazards: This product is combustible and may ignite if exposed to high temperature for a prolonged period. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon and nitrogen oxides).
Reactivity Hazards: This product is not reactive.
Environmental Hazards: Large quantities released to the aquatic and terrestrial environment may have an adverse effect.
Other Hazards: No other hazard information currently known.
Emergency Considerations: Emergency responders should wear appropriate protection for situation to which they respond.

Section 3: Composition/Information on Ingredients	
Ingredients	**CAS**
Mesalamine	89-57-6

Section 4: First-Aid Measures	
Protection Of First Aid Responders: First-aid responders should not attempt to treat victims of exposure to this material without adequate personal protective equipment. Rescuers should be taken for medical attention, if necessary	
Description Of First Aid Measures: Upon contact of this material with skin, eyes, or mucous membranes, immediately decontaminate by flushing with water for at least 20 minutes. Remove contaminated clothing and shoes. Take a copy of this SDS to health professional with victim. Wash clothing and thoroughly clean shoes before reuse.	
Inhalation	Due to the form of this product, inhalation is not a likely route of exposure. If somehow this product is inhaled, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention if adverse effect occurs after removal to fresh air.
Skin Exposure	Basic hygiene should prevent any problems. If the product contaminates the skin, and adverse effect occurs, begin decontamination with running water. Minimum flushing is for 20 minutes. Do not interrupt flushing. Remove exposed or contaminated clothing, taking care not to contaminate eyes. Seek medical attention if adverse effect occurs after flushing.
Eye Exposure	If this product enters the eyes, open victim's eyes while under gently running water. Use sufficient force to open eyelids. Have victim "roll" eyes. Minimum flushing is for 20 minutes. Do not interrupt flushing. Seek immediate medical attention after flushing if adverse effect occurs.
Ingestion Exposure	If this product is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, do not induce vomiting. Rinse mouth with water immediately. Victim should drink large quantities of water. If milk is available, victim should drink it after drinking water. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow

Medical Conditions Aggravated By Exposure: In therapeutic use, liver disease, renal impairment, upper gastrointestinal obstruction or cardio conditions such as myocarditis and pericarditis may be aggravated by exposure. Workplace exposure may also aggravate these conditions. Persons who may have hypersensitivity reactions to sulfazines, salicylates or aminosalicylates or other disorders described in Section 11 (Toxicological Information) may experience aggravation upon exposure.

Indication Of Immediate Medical Attention And Special Treatment If Needed: Treat symptoms and eliminate exposure. Persons developing hypersensitivity reactions should receive immediate medical attention. There is no specific antidote for Mesalamine treatment should be symptomatic and supportive. This may include prevention of further gastrointestinal tract absorption, correction of fluid electrolyte imbalance, and maintenance of adequate renal function.

Section 5: Fire-Fighting Measures

Flashpoint: Not determined

Flammable Limits & Method Of Determination (in air by volume, %): Not applicable.

Fire Extinguishing Media: Use extinguishing media appropriate for surrounding fire.

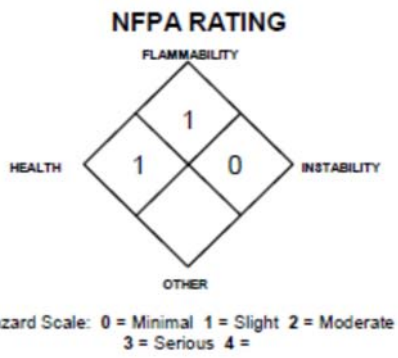
Unsuitable Extinguishing Media: None known

Specific Hazards Arising From The Product:

This product is not combustible and may ignite if exposed to high temperature for a prolonged period. If involved in a fire, the water component may evaporate and the residual may ignite. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon and nitrogen oxides).

Explosion Sensitivity to Mechanical Impact: Not sensitive.

Explosion Sensitivity to Static Discharge: Not Sensitive.



Special protective actions for fire-fighters:

Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus (SCBA) and full protective equipment. If protective equipment is contaminated by this product, it should be thoroughly washed with running water prior to removal of SCBA respiratory protection. Firefighters whose protective equipment becomes contaminated should thoroughly shower with warm, soapy water and should receive medical evaluation if they experience any adverse effects.

Section 6: Accidental Release Measures	
Personal Precautions	
	In the event of a spill, clear the area and protect people. The atmosphere must have levels of components lower than those listed in Section 8, (Exposure Controls and Personal Protective Equipment) if applicable, and have at least 19.5 percent oxygen before personnel can be allowed into the area without Self-Contained Breathing Apparatus (SCBA). Monitor area and confirm levels are bellow exposure limits given in Section 8 (Exposure Controls-Personal Protection), if applicable, before non-response personnel are allowed into the spill area. Spills may be slipper
Protective equipment:	
Small Spills:	For incidental spills (e.g., several suppositories), wear double latex or nitrile disposable gloves and eye protection.
Large Spills:	For large spills (e.g., 1 liter or more), protective apparel should be used with a respirator when there is any danger of aerosols being generated. Minimum Personal Protective Equipment should be rubber gloves, rubber boots, face shield, and Tyvek suit. Minimum level of personal protective equipment for releases in which the level of oxygen is less than 19.5% or is unknown must be Level B: triple-gloves (rubber gloves and nitrile gloves over latex gloves), chemical resistant suit and boots, hard hat, and Self-Contained Breathing Apparatus.
Methods For Cleanup And Containment	
Small Spills:	Absorb up spilled material with damp sponge, polypads or other suitable material.

Large Spills:	Trained personnel following pre-planned procedures should handle non-incidental releases. Access to the spill areas should be restricted. Absorb spilled product carefully, avoiding the generation of aerosols onto polypads or other non-reactive absorption.
All Spills:	Decontaminate the area of the spill thoroughly using detergent and water. Place all spill residue in an appropriate container and seal. Do not mix with wastes from other materials. If necessary, discard contaminated response equipment or rinse with soapy water before returning such equipment to service. Dispose of in accordance with applicable international, national, state, and local procedures (see Section 13, Disposal Considerations).
Environmental precautions	
	Prevent material from entering sewer or confined spaces, waterways, soil or public waters. Do not flush to sewer. For spills on water, contain, minimize dispersion and collect.
Section 7: Handling and Storage	
Product Preparation Instructions For Medical Personnel	Handle this material following standard medical practices and following the recommendations presented on the Package Insert.
Precautions for safe handling	All employees who handle this product should be trained to handle it safely. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this compound, and during patient administration. As with all chemicals, avoid getting this product ON YOU or IN YOU. Wash thoroughly after handling this product or equipment and containers that contain this product. Do not eat or drink while using this product. Avoid breathing airborne mists or spray generated by this product. Ensure this product is used with adequate ventilation (refer to Section 8, Exposure Controls-Personal

	Protection). Remove contaminated clothing immediately. Keep container tightly closed when not in use. Open containers slowly on a stable surface in areas that have been designated for use of this product. Wipe down areas in which this product is used, so that product does not accumulate. Empty containers may contain residual material; therefore, empty containers should be handled with care.
Conditions For Safe Storage	Containers of this product must be properly labeled. Store containers in a cool, dry location, away from direct sunlight, sources of intense heat or other sources of ignition or where freezing is possible. Store below 25ºC (77ºF), may be refrigerated. Keep away from direct heat, light or humidity. Product should be stored in secondary containers or in a diked area, as appropriate. Store away from incompatible materials (see Section 10, Stability and Reactivity).
Specific End Use(s)	This product is a human pharmaceutical. Follow all industry standards for use of this product
Protective practices during maintenance of contaminated equipment	When cleaning non-disposable equipment, wear latex or butyl rubber (double gloving is recommended), goggles, and lab coat. Wash equipment with soap and water. Wipe equipment down with damp sponge or polypad.
Section 8: Exposure Controls/Personal Protection	
Exposure limits/control parameters:	
Ventilation and Engineering Controls:	Use with adequate ventilation. Follow standard medical product handling procedures. During decontamination of work surfaces, workers should wear the same equipment recommended in Section 6 (Accidental Release Measures) of this SDS.

Occupational/Workplace Exposure Limits/Guidelines:

Chemical Name	CAS #	Exposure limits in air							
		ACGIH-TLVs		OSHA-PELs		NIOSH-RELs		NIOSH	OTHER
		TWA mg/m^3	STEL mg/m^3	TWA mg/m^3	STEL mg/m^3	TWA mg/m^3	STEL mg/m^3	IDLH mg/m^3	mg/m^3
Mesalamine	89-57-6	NE	NE	NE	NE	NE	NE	NE	Allergan OEL: 800 $\mu g/m^3$
Hard Fat (mixture of triglycerides)		NE	NE	NE	NE	NE	NE	NE	NE

NE = Not Established

International Occupational Exposure Limits:	Currently, the no additional exposure limits have been established by various countries for components of this product. The exposure limits given may not be the most current; individual country authorities should be contacted to check on more current limits.
PERSONAL PROTECTIVE EQUIPMENT	
	Use of personal protective equipment must be in compliance with U.S. OSHA 29 CFR Subpart I (beginning at 1910.132), Canadian CSA Standards Z94.4-02 and Z94.3-02, EU EN 529:2005, CEN/TR 15419:2006, and CR 13464:1999. Please reference applicable regulations and standards for relevant details.
Respiratory Protection	A respirator is not required for routine conditions of use with adequate engineering controls. A full-face Air-Purifying Respirator with high-efficiency particulate filter or a Supplied-Air Respirator must be worn during operations where engineering controls are not sufficient, large spill cleanup, or when processing generates airborne aerosols. If respiratory protection is needed, use only respiratory protection authorized under appropriate regional regulations
Eye Protection	During operations in which mists or sprays may be generated, splash goggles or safety glasses

	should be considered.
Hand Protection	During manufacture or other similar industrial operations, wear the appropriate hand protection for the process. Use double gloves for spill response, as stated in Section 6 (Accidental Release Measures) of this SDS.
Body Protection	Use appropriate protective clothing for the task (e.g., lab coat, etc.)
Section 9: Physical and Chemical Properties	
Appearance	Suppositories
Color	As per Description
Physical State	Solid
Description	Mesalamine suppositories, 1000 mg for rectal administration are available as bullet shaped, light tan to grey suppositories containing 1000 mg mesalamine packed in PVC/PE molds. They are suppled as follows: Carton of 30 rectal suppositories (5 strips of 6 suppositories) NDC 31722-005-30 Carton of 42 rectal suppositories (7 strips of 6 suppositories) NDC 31722-005-31
Section 10: Stability and Reactivity	
Chemical stability	Store below 25ºC (77ºF), may be refrigerated. Keep away from direct heat, light or humidity
Hazardous Decomposition Products	
Combustion	If exposed to extremely high temperatures, the products of thermal decomposition may include irritating fumes and toxic gases (e.g., carbon and nitrogen oxides). **Hydrolysis*:*** None known.
Incompatible materials	This compound is incompatible with strong oxidizers, strong acids.
Possibility of hazardous reactions/ polymerization	No data available.
Conditions to avoid	Avoid heat, light, and contact with incompatible chemicals
Section 11: Toxicological Information	
Symptoms of exposure by route of exposure: The health hazard information provided below is pertinent to employee handling in an occupational setting. The following paragraphs describe the symptoms of exposure by route of exposure	

Inhalation	Although unlikely due to the form of the product, inhalation of airborne aerosols generated by this product may irritate the nose, throat, and lungs. Some available information indicates penicillums can cause respiratory sensitization and allergic reaction.
Skin Contact	Contact with the skin may cause irritation. Prolonged or repeated skin contact may cause dermatitis (dry, red skin).
Eye Contact	Contact with the eyes of aerosols generated by this product may cause irritation, redness, and tearing
Skin Absorption	No specific data is available on potential absorption of this material through intact skin.
Ingestion	Ingestion is not a significant route of occupational exposure. Symptoms of acute ingestion may include those described under 'Other Health Effects'.
Injection	Though not anticipated to be a significant route of exposure for this product, injection (via punctures or lacerations by contaminated objects) may cause redness at the site of injection. Symptoms may also include those described under 'Other Health Effects'
Other potential health effects-therapeutic doses: In therapeutic use, the most common adverse reactions reported have included headache, nausea, dizziness, fever, rash, acne, and worsening of ulcerative colitis. Additional symptoms related to rectal administration of the drug are not relevant to workplace exposure. Other adverse effects reported have included renal damage and hypersensitivity reactions, including cardiac hypersensitivity reactions. In therapeutic use the following additional adverse effects described by body system have included:	
Blood System	Acute failure of bone marrow to make new blood cells, including white blood cells, blood platelet decrease.
Body as a Whole	Drug fever, fatigue, lupus-like syndrome (auto-immune disorder).
Cardiovascular System	Inflammation of heart muscle, and pericardium (sac surrounding heart), fluid around the heart.

Central Nervous and Peripheral System	Dizziness, headache, Guillain-Barre syndrome, peripheral neuropathy, inflammatory disease causing injury to the spinal cord with varying degrees of weakness, sensory alterations, and autonomic dysfunction (the part of the nervous system that controls involuntary activity, such as the heart, breathing, the digestive system, and reflexes).
Eyes	Eye swelling.
Gastrointestinal Disorders	Abdominal cramps, abdominal distension, anal itching, ano-rectal discomfort, constipation, discolored feces, flatulence, frequent bowel movements, gastrointestinal bleeding, mucus in stools, nausea, painful defecation, pancreatitis, severe, episodic, rectal and digestive system pain, rectal discharge, feeling that you need to have a bowel movement, stomach discomfort, vomiting.
Liver	Cholestatic jaundice, hepatitis, jaundice, Kawasaki-like syndrome including changes in liver enzymes, liver necrosis, liver failure.
Renal System	Interstitial nephritis (form of kidney disease).
Reproductive Disorders	Reversible low sperm concentration.
Respiratory System	Hypersensitivity pneumonitis (including allergic inflammation of the alveoli, white blood cell disorder causing respiratory infection, pneumonitis causing progressive scarring of both lungs).
Skin	Hair loss, tissue swelling, tender, red bumps (nodules) under the skin, itching, rash, hives, red, scaly skin, pyoderma gangrenosum (skin condition, causing tissue to become necrotic, leading to deep ulcers that usually occur on the legs).
Health Effects Or Risks From Exposure: An Explanation in Lay Terms. Exposure to this product may cause the following health effects:	
Acute	Prolonged contact with this product may cause

	irritation via skin or eye contact.
Chronic	Repeated skin contact may cause dermatitis (dry, red skin). Chronic exposure may cause adverse symptoms as described under 'Other Health Effects'
Target Organs	
Acute	*Industrial Exposure*: Skin, eyes. *Therapeutic Doses*: Gastrointestinal system.
Chronic	*Industrial Exposure*: Skin. *Therapeutic Doses*: Systems given under "Other Potential Health Effects
Irritancy Of Product: This product may irritate contaminated tissue if contact is prolonged.	
Sensitization To The Product: In therapeutic use, Mesalamine-induced cardiac hypersensitivity reactions (myocarditis and pericarditis) have been reported, especially in persons with hypersensitivity to sulfasalazine. Additionally, reports of facial and extremity swelling, itching, hives and hair loss have occurred.	
Toxicity data: Currently the following toxicity data are available for the active ingredient. Additional data are available, for excipients, but are not presented in this SDS. Contact Allergan for more information.	
MESALAMINE: TDLo (Oral-Woman) 8760 mg/kg/1 year-intermittent: Behavioral: anorexia (human), muscle weakness; Kidney/Ureter/Bladder: changes in tubules (including acute renal failure, acute tubular necrosis) TDLo (Oral-Woman) 5400 mg/kg/90 days-intermittent: Gastrointestinal: changes in structure or function of endocrine pancreas TDLo (Oral-Woman) 80 mg/kg/1 days-intermittent: Cardiac: pulse rate; Vascular: BP lowering not characterized in autonomic section TDLo (Oral-Woman) 21,800 mg/kg/39 weeks-intermittent: Lungs, Thorax, or Respiration: fibrosis, focal (pneumoconiosis), respiratory depression; Blood: eosinophilia	TDLo (Oral-Woman) 8 mg/kg: Behavioral: headache; Gastrointestinal: hypermotility, diarrhea; Nutritional and Gross Metabolic: body temperature increase TDLo (Oral-Man) 321 mg/kg/15 days-intermittent: Skin and Appendages: photosensitivity (after systemic exposure) TDLo (Oral-Man) 6857 mg/kg/17 weeks-intermittent: Gastrointestinal: nausea or vomiting; Liver: jaundice, cholestatic TDLo (Oral-Man) 51 mg/kg/5 days-intermittent: Gastrointestinal: hypermotility, diarrhea; Skin and Appendages: dermatitis, other (after systemic exposure); Nutritional and Gross Metabolic: body temperature increase
MESALAMINE (continued): TDLo (Oral-Man) 2057 mg/kg/17 weeks-intermittent: Blood: agranulocytosis; Nutritional and Gross Metabolic: body temperature increase TDLo (Oral-Man) 6.86 gm/kg/16 weeks-intermittent:	**MESALAMINE (continued):** LD50 (Intraperitoneal-Rat) 100 mg/kg: Behavioral: analgesia LD50 (Intraperitoneal-Rat) 1 gm/kg: Behavioral: convulsions or effect on seizure

Gastrointestinal: nausea or vomiting; Liver: jaundice (or hyperbilirubinemia) hepatocellular; Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: multiple enzyme effects TDLo (Oral-Man) 503 mg/kg/26 weeks-intermittent: Gastrointestinal: other changes; Blood: changes in serum composition (e.g. TP, bilirubin, cholesterol); Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: multiple enzyme effects TDLo (Oral-Child) 20 mg/kg: Blood: changes in serum composition (e.g. TP, bilirubin, cholesterol) TDLo (Unreported-Child) 400 mg/kg/10 days-continuous: Gastrointestinal: nausea or vomiting; Skin and Appendages: dermatitis, allergic (after systemic exposure); Nutritional and Gross Metabolic: body temperature increase LD50 (Oral-Rat) 2800 mg/kg: Behavioral: somnolence (general depressed activity), food intake (animal); Gastrointestinal: other changes LD50 (Oral-Mouse) 3370 mg/kg LD50 (Skin-Rabbit) > 5 gm/kg	threshold; Kidney/Ureter/Bladder: other changes in urine composition; Skin and Appendages: hair LD50 (Intraperitoneal-Mouse) 469 mg/kg LDLo (Oral-Monkey) 3 gm/kg: Sense Organs and Special Senses (Eye): ptosis; Behavioral: somnolence (general depressed activity); Kidney/Ureter/Bladder: hematuria TDLo (Oral-Rat) 36,400 mg/kg/13 weeks-intermittent: Kidney/Ureter/Bladder: urine volume increased, changes in bladder weight; Blood: normocytic anemia TDLo (Oral-Mouse) 525 mg/kg/7 days-intermittent: Biochemical: Metabolism (Intermediary): effect on inflammation or mediation of inflammation TDLo (Rectal-Rat) 840 mg/kg/1 weeks-intermittent: Gastrointestinal: other changes; Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: other oxidoreductases, Metabolism (Intermediary): effect on inflammation or mediation of inflammation TDLo (Rectal-Rat) 2100 mg/kg/3 weeks-intermittent: Gastrointestinal: other changes

OTHER ANIMAL TOXICITY DATA: Toxicology studies of Mesalamine were conducted in rats, mice, rabbits and dogs, and the kidney was the main target organ of toxicity. In rats, adverse renal effects were observed at a single oral dose of 600 mg/kg (about 3.2 times the recommended human intra-rectal dose, based on body surface area) and at IV doses of >214 mg/kg (about 1.2 times the recommended human intra-rectal dose, based on body surface area). In a 13-week oral gavage toxicity study in rats, papillary necrosis and/or multifocal tubular injury were observed in males receiving 160 mg/kg (about 0.86 times the recommended human intra-rectal dose, based on body surface area) and in both males and females at 640 mg/kg (about 3.5 times the recommended human intra-rectal dose, based on body surface area). In a combined 52-week toxicity and 127-week carcinogenicity study in rats, degeneration of the kidneys and hyalinization of basement membranes and Bowman's capsule were observed at oral doses of 100 mg/kg/day (about 0.54 times the recommended human intra-rectal dose, based on body surface area) and above. In a 14-day rectal toxicity study of Mesalamine suppositories in rabbits, intra-rectal doses up to 800 mg/kg (about 8.6 times the recommended human intra-rectal dose, based on body surface area) was not associated with any adverse effects. In a six-month oral toxicity study in dogs, doses of 80 mg/kg (about 1.4 times the recommended human intra-rectal dose, based on body surface area) and higher caused renal pathology similar to that described for the rat. In a rectal

toxicity study of Mesalamine suppositories in dogs, a dose of 166.6 mg/kg (about 3.0 times the recommended human intra-rectal dose, based on body surface area) produced chronic nephritis and pyelitis. In the 12-month eye toxicity study in dogs, keratoconjunctivitis sicca (KCS) occurred at oral doses of 40 mg/kg (about 0.72 times the recommended human intra-rectal dose, based on body surface area) and above.	
Carcinogenic Potential: The following information is available for the active ingredient.	
	Mesalamine was not carcinogenic at dietary doses of up to 480 mg/kg/day in rats and 2000 mg/kg/day in mice, which are about 2.9 and 6.1 times the maximum recommended maintenance dose of Mesalamine of 1.6 g/day or 26.7 mg/kg/day, based on 60 kg body weight, respectively, based on body surface area. The remaining component is not found on the following lists: U.S. EPA, U.S. NTP, U.S. OSHA, U.S. NIOSH, GERMAN MAK, IARC, or ACGIH and therefore are neither considered to be nor suspected to be cancer-causing agents by these agencies.
Reproductive Toxicity Information: There are no adequate and well-controlled studies of Mesalamine in pregnant women; however, when administered therapeutically, Mesalamine is not expected to cause fetal harm when administered to a pregnant woman. In formulated products this material is rated by the FDA for therapeutic risk as Pregnancy Risk Category B (Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women OR Animal studies have shown an adverse effect, but adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus in any trimester).	
Mutagenicity	Mesalamine was negative in the Ames assay for mutagenesis, negative for induction of sister chromatid exchanges (SCE) and chromosomal aberrations in Chinese hamster ovary cells *in vitro*, and negative for induction of micronuclei (MN) in mouse bone marrow polychromatic erythrocytes
Embryotoxicity/Teratogenicity	*Human Data:* Limited published human data on Mesalamine show no increase in the overall rate of congenital malformations. Some data show an increased rate of preterm birth, stillbirth, and low birth weight; however, these adverse pregnancy outcomes are also associated with active inflammatory bowel disease. Furthermore, all pregnancies, regardless of drug exposure, have a background rate of 2 to 4% for major malformations, and 15 to 20% for pregnancy loss. Mesalamine crosses the placenta. In prospective and retrospective

	studies of over 600 women exposed to Mesalamine during pregnancy, the observed rate of congenital malformations was not increased above the background rate in the general population. Some data show an increased rate of preterm birth, stillbirth, and low birth weight, but it is unclear whether this was due to underlying maternal disease, drug exposure, or both, as active inflammatory bowel disease is also associated with adverse pregnancy outcomes.
	Animal Data: No evidence of fetal harm was observed in animal reproduction studies of Mesalamine in rats and rabbits at oral doses approximately 1.9 times (rat) and 3.9 times (rabbit) the recommended human dose. Reproduction studies with Mesalamine were performed during organogenesis in rats and rabbits at oral doses up to 480 mg/kg/day. These Mesalamine doses were about 1.9 times (rat) and 3.9 times (rabbit) the recommended human dose, based on body surface area.
Reproductive Toxicity	Mesalamine, at oral doses up to 480 mg/kg/day (about 1.9 times the recommended human treatment dose on a body surface area basis), was found to have no effect on fertility or reproductive performance of male and female rats. Mesalamine and its N-acetyl metabolite are present in human milk. In published lactation studies, maternal Mesalamine doses from various oral and rectal formulations and products ranged from 500 mg to 3 g daily. The concentration of Mesalamine in milk ranged from non-detectable to 0.11 mg/L. The concentration of the N-acetyl-5-aminosalicylic acid metabolite ranged from 5 to 18.1 mg/L. Based on these concentrations, estimated infant daily doses for an exclusively breastfed infant are 0 to 0.017 mg/kg/day of Mesalamine and 0.75 to 2.72 mg/kg/day of N-acetyl-5-aminosalicylic acid. Because of the potential for serious adverse reactions in nursing infants, nursing mothers should be advised of these effects and the appropriate action should be taken to prevent exposure.
ACGIH Biological Exposure Indices (BEIs): Currently, ACGIH Biological Exposure Indices (BEIs) have not been determined for the components of this product.	

12. ECOLOGICAL INFORMATION	
All work practices must be aimed at eliminating environmental contamination. Some values for the active ingredient are available for the active ingredient, but are not presented in this SDS. Contact Allergan for more information.	
Mobility In Soil:	This product has not been tested for mobility in soil.
Persistence and biodegradability	This product has not been tested for persistence or biodegradability. Due to high level of organic glycerides, that portion of the product is expected to degrade.
Bio-accumulative potential:	This product is not expected to present a hazard of bioconcentration.
Ecotoxicity:	No data is available for this product. All releases to terrestrial, atmospheric and aquatic environments should be avoided.
Results of PBT and vPvB assessment	No Data Available. PBT and vPvB assessments are part of the chemical safety report required for some substances in European Union Regulation (EC) 1907/2006, Article 14.
Other adverse effects	This material has no known ozone depletion potential.
Environmental exposure controls	Controls should be engineered to prevent release to the environment, including procedures to prevent spills, atmospheric release and release to waterways.
13. DISPOSAL CONSIDERATIONS	
Waste treatment/disposal methods	Waste disposal must be in accordance with appropriate Federal, State, and local regulations. Waste containers should be handled with uncontaminated gloves. Reusable equipment should be decontaminated using 0.05M Boric acid solution adjusted to pH 9 with 10 N sodium hydroxide followed by a detergent wash and then clean water rinse or by using a bleach solution (triple wash) and a detergent solution followed by clean water rinse.
Precautions To Be Followed During Waste Handling	Wear proper protective equipment when handling waste materials
U.S. EPA waste number	Not applicable
14. TRANSPORT INFORMATION	
U.S. Department Of Transportation:	This product is NOT classified as dangerous

	goods, per U.S. DOT regulations, under 49 CFR 172.101.

15. REGULATORY INFORMATION

UNITED STATES REGULATIONS:

U.S. SARA Reporting Requirements: The components of this product are not subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act.

U.S. SARA Threshold Planning Quantity (TPQ): There are no specific Threshold Planning Quantities for any component of this product. The default Federal SDS submission and inventory requirement filing threshold of 10,000 lb (4,540 kg) therefore applies, per 40 CFR 370.20.

U.S. CERCLA Reportable Quantities (RQ): Not applicable

U.S. TSCA Inventory Status: This product is regulated under Food and Drug Administration standards; it is not subject to requirements under TSCA.

Other U.S. Federal Regulations: Regulations of the FDA under the Federal Food, Drug and Cosmetic Act are applicable when this material is used in pharmaceutical preparations. Under the Hazard Communication Standard (HCS), Section (b)(5)(ii) drugs are subject to labeling requirements by the FDA under the Federal Food, Drug and Cosmetic Act and are exempt from labeling provisions of the HCS; this section of the HCS exempts only labeling requirements and not requirements for a Safety Data Sheet for drugs.

California Safe Drinking Water and Toxic Enforcement Act (Proposition 65): No component of this product is on the California Proposition 65 Lists.

16. OTHER INFORMATION

Issue Date : 30-07-2020

Version : 00

Further information

Revision date: New issue

Revision note: New issue

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose. Annora Pharma Private Limited shall not be held liable for any damage resulting from handling or from contact with the above product. Annora Pharma Private Limited reserves the right to revise this SDS.