

SAFETY DATA SHEET

Section 1: Identification	
Material	Mesalamine Delayed Release Tablets USP, 1.2 g
Recommended use	Topical anti-inflammatory effect
Manufacturer	Annora Pharma Private Limited, Survey No. 261, Annaram Village, Gummadidala Mandal, Sangareddy, Telangana 502313, India (IND)
Distributor	Camber Pharmaceuticals, Inc., Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
Health Hazards	Not classified.
Physical Hazards	Not classified.
OSHA Regulatory Status	Over the counter drugs in their solid final form (e.g. tablets or pills) are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limits may be surpassed, they can be considered hazardous.
Hazards not otherwise classified (HNOC)	Not applicable.
Other information	Not available.
Section 3: Composition/Information on Ingredients	
Active Ingredient	CAS
Mesalamine	89-57-6
Colloidal silicon dioxide	112926-00-8
Ferric oxide	1309-37-1
Hypromellose	9004-65-3
Magnesium stearate	557-04-0
Methacrylic acid and methyl methacrylate copolymer	25086-15-1
Microcrystalline cellulose	9004-34-6
Polyethylene glycol	25322-68-3
Sodium starch glycolate	9063-38-1
Talc	14807-96-6
Titanium dioxide	13463-67-7

Triethyl citrate	77-93-0
Ammonium hydroxide	1336-21-6
Black iron oxide	1309-38-2
Propylene glycol	57-55-6
Shellac	9000-59-3
Section 4: First-Aid Measures	
Eye Contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin Contact	Wash skin with soap and water.
Ingestion	Clean mouth with water and drink afterwards plenty of water.
Inhalation	Remove to fresh air.
Symptoms	Symptoms of salicylate toxicity may be possible, such as: tinnitus, vertigo, headache, confusion, drowsiness, sweating, hyperventilation, vomiting, diarrhea, hypothermia, dehydration, disruption of electrolyte balance and blood pH.
Note to Physicians	Treat symptomatically.
Section 5: Fire-Fighting Measures	
Suitable extinguishing media	Water spray jet, dry powder, foam, carbon dioxide.
Unsuitable Extinguishing Media	No information available.
Specific hazards arising from the chemical	Unknown. May release toxic fumes of carbon oxides and nitrogen oxides.
Sensitivity to Mechanical Impact	None.
Sensitivity to Static Discharge	None.
Protective equipment and precautions for firefighters	As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

Section 6: Accidental Release Measures	
Personal Precautions	Ensure adequate ventilation, especially in confined areas.
Methods for Containment	Prevent further leakage or spillage if safe to do so.
Methods for Cleaning Up	Pick up and transfer to properly labeled containers.
Section 7: Handling and Storage	
Advice on Safe Handling	Handle in accordance with good industrial hygiene and safety practice.
Storage Conditions	Store at 20°C to 25°C (68°F to 77°F) [see USP Controlled Room Temperature].
Incompatible materials	Not available.
8. Exposure controls / personal protection	
Exposure Guidelines	Based on a review of animal and clinical literature, there is no Occupational Exposure Limit (OEL) recommended as an 8-hour TWA for Mesalamine.
Chemical name	Magnesium stearate, NF 557-04-0
ACGIH TLV	TWA: 10 mg/m ³ except stearates of toxic metals
OSHA PEL	-
NIOSH IDLH	-
Engineering Controls	None required for consumer use. In laboratories or industrial settings, handle material under adequate ventilation (e.g., chemical fume hood, vented balance enclosure [VBE]). Keep container tightly closed. Minimize the amount of material handled at any one time.
Eye/Face Protection	None required for consumer use. In laboratory, medical or industrial settings, safety glasses with side shields are recommended. The use of goggles or full-face protection may be required depending on the industrial exposure setting. Contact a health and safety professional for specific information.

Skin and Body Protection	None required for consumer use. In laboratory, medical or industrial settings, gloves and lab coats are recommended. The use of additional personal protective equipment such as shoe coverings, gauntlets, and hood or head coverings may be necessary. Contact a health and safety professional for specific information.
Respiratory Protection	None required for consumer use. Respirators may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where the exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. All respirators must conform to specifications for efficiency and performance. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA Standard 29 CFR 1910.134. Contact a health and safety professional or manufacturer for specific information.
General Hygiene Considerations	Handle in accordance with good industrial hygiene and safety practice.

Section 9: Physical and Chemical Properties	
Physical State	Solid
Description	<p>Mesalamine delayed-release tablets, USP are available as reddish-brown, oval-shaped, enteric-coated tablets containing 1.2 g mesalamine is imprinted with “M19” in black color on one side and plain on other side supplied in:</p> <p>HDPE Bottle with a child-resistant closure of 120 delayed-release tablets NDC 31722-043-12</p> <p>HDPE Bottle with a child-resistant closure of 500 delayed-release tablets NDC 31722-043-05</p> <p>Store at 20°C to 25°C (68°F to 77°F) [see USP Controlled Room Temperature].</p>
Section 10: Stability and Reactivity	
Reactivity Stable at normal conditions.	Not available.
Chemical stability	Mesalamine is unstable in the presence of water and light.
Possibility of hazardous	None under normal processing.
Hazardous Polymerization	Not available.
Conditions to avoid	Not available.
Incompatible materials	Not available.
Hazardous decomposition	May include nitrogen oxides and carbon oxides.
Section 11: Toxicological Information	
Acute Toxicity	<p>Mesalamine:</p> <p>Oral LD50 = 2000-4594 mg/kg (Rat)</p> <p>= 3000 mg/kg (Monkey)</p> <p>Dermal LD50 - > 5 g/kg (Rabbit)</p>
Section 12: Ecological Information	
Ecotoxicity	Mesalamine is not inhibitory to sludge micro-organisms and is not considered to present a risk to aquatic micro-organisms.
Persistence and degradability	Mesalamine has been shown to be readily biodegradable.
Bioaccumulation	Mesalamine does not meet the criteria for persistent bioaccumulation.
Mobility	Unknown.
Section 13: Disposal Considerations	
Waste treatment methods	Disposal should be in accordance with applicable regional, national and local laws and regulations.

Section 14: Transport Information

DOT	The product is not hazardous when shipping via air (IATA), ground (DOT), or sea (IMDG).
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Section 15: Regulatory Information

International Inventories	
TSCA	Complies
DSL/NDSL	Complies
EINECS/ELINCS	Does not comply
ENCS	Complies
IECSC	Complies
KECL	Complies
PICCS	Complies
AICS	Complies

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
 DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
 EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
 ENCS - Japan Existing and New Chemical Substances
 IECSC - China Inventory of Existing Chemical Substances
 KECL - Korean Existing and Evaluated Chemical Substances
 PICCS - Philippines Inventory of Chemicals and Chemical Substances
 AICS - Australian Inventory of Chemical Substances

US Federal Regulations

SARA 313
 Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

US State Regulations**California Proposition 65**

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

This product does not contain any substances regulated by state right-to-know regulations.

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable.

Section 16: Other Information, including date of preparation or last revision**Issue Date: 10-04-2024****Version: 01****Further information****Revision date: 10-04-2024****Revision note: 1. 14 section updated.**

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.