

SAFETY DATA SHEET

Section 1: Identification	
Material	Eltrombopag Tablets, 12.5 mg, 25 mg, 50 mg, and 75 mg
Recommended use	Pharmaceutical product
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	
Precautionary Statements - Prevention	Wash face, hands and any exposed skin thoroughly after handling Do not eat, drink or smoke when using this product Wear eye protection/ face protection Do not breathe dust/fume/gas/mist/vapors/spray
Precautionary statements - Response	Get medical advice/attention if you feel unwell IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing Immediately call a POISON CENTER or doctor IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell Rinse mouth
Precautionary Statements - Disposal	Dispose of contents/container to an approved waste disposal plant
Other Information	Very toxic to aquatic life with long lasting effects
Section 3: Composition/Information on Ingredients	
Ingredients	CAS
Eltrombopag Olamine	496775-62-3
Povidone	9003-39-8
Mannitol	69-65-8
Microcrystalline cellulose	9004-34-6
Sodium Starch	9063-38-1
Magnesium stearate	557-04-0
Purified water	NA

Opadry blue	NA
Opadry Pink	NA
Opadry White	NA
Opadry Orange	NA
Section 4: First-Aid Measures	
General advice	Show this safety data sheet to the doctor in attendance. Immediate medical attention is required.
Inhalation	Remove to fresh air. Get medical attention immediately if symptoms occur
Eye contact	Get immediate medical advice/attention. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area
Skin contact	Wash off immediately with soap and plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.
Ingestion	Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Call a physician.
Self-protection of the first aider	Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8).
<u>Most important symptoms and effects, both acute and delayed</u>	
Symptoms	Burning sensation.
<u>Indication of any immediate medical attention and special treatment needed</u>	
Note to physicians	Treat symptomatically.
Section 5: Fire-Fighting Measures	
Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable extinguishing media	CAUTION: Use of water spray when fighting fire may be inefficient
Specific hazards arising from the chemical	No information available.
Explosion data Sensitivity to Mechanical Impact Sensitivity to Static Discharge	None None.
Special protective equipment for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment

Section 6: Accidental Release Measures	
Personal precautions, protective equipment and emergency procedures	
Personal precautions	Avoid contact with skin, eyes or clothing. Use personal protective equipment as required. Ensure adequate ventilation. Evacuate personnel to safe areas.
Other Information	Refer to protective measures listed in Sections 7 and 8.
Environmental precautions	Prevent further leakage or spillage if safe to do so.
Methods and material for containment and cleaning up	
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.
Prevention of secondary hazards	Clean contaminated objects and areas thoroughly observing environmental regulations
Section 7: Handling and Storage	
Precautions for safe handling	
Advice on safe handling	Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Ensure adequate ventilation.
Conditions for safe storage, including any incompatibilities	
Storage Conditions	Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children. Store locked up.
Section 8: Exposure Controls/Personal Protection	
Exposure Limits	The following ingredients are the only ingredients of the product above the cut-off level (or level that contributes to the hazard classification of the mixture) which have an exposure limit applicable in the region for which this safety data sheet is intended or other recommended limit. At this time, the other relevant constituents have no known exposure limits from the sources listed here.
Engineering controls	Showers Eyewash stations Ventilation systems.
Individual protection measures, such as personal protective equipment	
Eye/face protection	Tight sealing safety goggles
Hand protection	Wear suitable gloves
Skin and body protection	Wear suitable protective clothing
Respiratory protection	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required
General hygiene considerations	Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Do not eat, drink or smoke

	when using this product
Section 9: Physical and Chemical Properties	
Physical Form	Tablet
Appearance	<p>12.5 mg tablets are off-white, round, bevel edged biconvex film coated tablets debossed with 'H' on one side and 'E10' on the other side and are available in Bottle of 30 tablets NDC 31722-841-30</p> <p>25 mg tablets are beige colored, round, bevel edged, biconvex film-coated tablets debossed with 'H' on one side and 'E11' on the other side and are available in Bottle of 30 tablets NDC 31722-842-30</p> <p>50 mg tablets are off-white, round, bevel edged, biconvex film-coated tablets debossed with 'H' on one side and 'E12' on the other side and are available in Bottle of 30 tablets NDC 31722-843-30</p> <p>75 mg tablets are off-white to light yellow colored, round, bevel edged biconvex tablets debossed with 'H' on one side and 'E13' on the other side and are available in Bottle of 30 tablets NDC 31722-844-30</p>
Section 10: Stability and Reactivity	
Reactivity	No information available
Chemical stability	Stable under normal conditions
Possibility of hazardous reactions	None under normal processing
Hazardous polymerization	Hazardous polymerization does not occur
Conditions to avoid	None known based on information supplied
Incompatible materials	Strong acids. Strong oxidizing agents.
Hazardous decomposition products	None known based on information supplied

Section 11: Toxicological Information	
Information on likely routes of exposure	
Product Information	
Inhalation	Specific test data for the substance or mixture is not available.
Eye contact	Specific test data for the substance or mixture is not available. Severely irritating to eyes. Causes serious eye damage. May cause burns. May cause irreversible damage to eyes
Skin contact	Specific test data for the substance or mixture is not available. May cause irritation
Ingestion	Specific test data for the substance or mixture is not available. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. Harmful if swallowed. (based on components).
Symptoms related to the physical, chemical and toxicological characteristics	
Symptoms	Redness. Burning. May cause blindness
Numerical measures of toxicity	
Acute toxicity	
The following values are calculated based on chapter 3.1 of the GHS document .	
ATEmix (oral)	500.00 mg/kg
Unknown acute toxicity 100 % of the mixture consists of ingredient(s) of unknown toxicity 0 % of the mixture consists of ingredient(s) of unknown acute oral toxicity 100 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity 100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas) 100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor) 100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)	
Delayed and immediate effects as well as chronic effects from short and long-term exposure	
Skin corrosion/irritation	May cause skin irritation
Serious eye damage/eye irritation	Classification based on data available for ingredients. Causes burns. Risk of serious damage to eyes.
Respiratory or skin sensitization	No information available.
Germ cell mutagenicity	No information available.
Carcinogenicity	No information available.
Reproductive toxicity	No information available
STOT - single exposure	No information available
STOT - repeated exposure	May cause damage to organs.
Aspiration hazard	No information available.

Section 12: Ecological Information	
Ecotoxicity	Avoid release into the environment.
Persistence and degradability	No information available
Bioaccumulation	There is no data for this product.
Other adverse effects	No information available
Section 13: Disposal Considerations	
Waste treatment methods Waste from residues/unused products	Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.
Contaminated packaging	Do not reuse empty containers
Section 14: Transport Information	
DOT	Not regulated
TDG	Not regulated
MEX	Not regulated
ICAO (air)	Not regulated
IATA	Not regulated
IMDG	Not regulated
RID	Not regulated
ADR	Not regulated
ADN	Not regulated
Section 15: Regulatory Information	
International Inventories	
TSCA	Does not comply
DSL/NDSL	Does not comply
EINECS/ELINCS	Does not comply
ENCS	Does not comply
IECSC	Does not comply
KECL	Does not comply
PICCS	Does not comply
AICS	Does not comply
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 which are 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

US State 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

Issue Date : 24-03-2025

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.