SAFETY DATA SHEET

Vancomycin Hydrochloride Capsules, USP 125 mg and 250 mg

1. IDENTIFICATION

Product identifier: Vancomycin Hydrochloride Capsules, USP 125 mg and 250 mg
Product Codes: 0121-1032-20, 0121-1033-20, 0121-1032-50, 0121-1033-50

Supplier Name and Address:	PAI Pharma 1700 Perimeter Road Greenville, SC 29605
Telephone number:	(864) 277-7282
Emergency phone number:	CHEMTREC 800-424-9300

Recommended use: Human drug
Restrictions on use: Prescription use only

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Not hazardous	Not hazardous

Not hazardous in accordance with the GHS and OSHA Hazcom 2024.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Amount
Vancomycin Hydrochloride	1404-93-9	125 or 250 mg/capsule
Polyethylene glycol	25322-68-3	Proprietary
Gelatin capsule	NOT Applicable	Proprietary

The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST-AID MEASURES

Inhalation: Remove person to fresh air. If irritation or other symptoms occur, get medical attention.
Skin contact: In the case of contact with crushed or broken capsules, remove contaminated clothing. Wash skin with soap and water. If irritation develops, get medical attention. Launder clothing before reuse..
Eye contact: Immediately flush eyes with water while lifting the upper and lower lids. Get medical attention if irritation persists**.**
Ingestion: In the case of unintentional ingestion or overdosage, rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to a person who is unconscious or convulsing. Get medical attention.

Most important symptoms/effects, acute and delayed: May cause mild eye and skin irritation. Swallowing may cause effects as seen in clinical use including nausea, abdominal pain, vomiting, diarrhea, skin rash and mucosal lesions.

Indication of immediate medical attention and special treatment, if necessary: Medical attention is recommended for unintended ingestion or overdosage.

5. FIRE-FIGHTING MEASURES

Extinguishing media: Use any media that is suitable for the surrounding fire.

Specific hazards arising from the chemical: Capsules are not a fire hazard but may burn under fire conditions. Fine dust from crushed capsules will present a dust explosion hazard.

Special protective equipment and precautions for fire-fighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, and emergency procedures: Wear appropriate protective clothing and equipment as described in Section 8. If capsules are damaged, respiratory protection may be required. Avoid generating airborne dust during cleanup. If dust is present, eliminate all sources of ignition.

Environmental Precautions: Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

Methods and materials for containment and cleaning up: Collect using methods that avoid the generation of dust and damage to capsules (scoop up carefully) and place in appropriate container for disposal. Clean area thoroughly. If dust is present, do not use vacuum unless explosion-proof.

7. HANDLING AND STORAGE

Precautions for safe handling: Avoid the generation of dust. If capsules are damaged, avoid contact with eyes, skin and clothing and avoid breathing dust. Wash thoroughly with soap and water after handling.

Conditions for safe storage, including any incompatibilities: Store as indicated on product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure guidelines:

Vancomycin Hydrochloride	None Established
Polyethylene glycol	None Established
Gelatin capsule	None Established

Appropriate engineering controls: Use with adequate general or local exhaust ventilation to minimize exposure levels.

Individual protection measures:
Respiratory protection: None needed under normal use conditions. If exposure limits are excessive and for handling damaged capsules a NIOSH approved particulate respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.
Skin protection: None required for normal use. Impervious gloves recommended for manufacturing operations and spill cleanup.
Eye protection: None required for normal use. Chemical safety goggles recommended for manufacturing operations and spill cleanup.
Other: None known.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Solid (capsules)	**pH:** Not applicable
Odor: None	**Color:** No data available
Melting point/freezing point: Not applicable	**Boiling Point:** Not determined
Flash point: Not applicable	**Particle Characteristics:** No data available
Flammability: Not flammable	**VOC:** Not applicable
Flammable limits: LEL: None	**UEL:** None
Vapor pressure: Not applicable	**Relative vapor density:** Not applicable
Relative density: Not applicable	**Solubility(ies):** Partially soluble
Partition coefficient: n-octanol/water: Not available	**Auto-ignition temperature:** Not available
Decomposition temperature: Not available	**Kinematic Viscosity:** Not applicable

10. STABILITY AND REACTIVITY

Reactivity: Not reactive under normal conditions of use.
Chemical stability: Stable.
Possibility of hazardous reactions: None known.
Conditions to avoid: None known.
Incompatible materials: Avoid oxidizing agents.
Hazardous decomposition products: Thermal decomposition may yield carbon oxides and chlorine compounds.

11. TOXICOLOGICAL INFORMATION

Acute effects of exposure:
Inhalation: Inhalation of dust may cause irritation of the mucous membranes and upper respiratory tract and possibly symptoms similar to ingestion

Ingestion: Swallowing may cause effects as seen in clinical use including nausea, abdominal pain, vomiting, diarrhea, skin rash and mucosal lesions.
Skin contact: May cause mild irritation.
Eye contact: May cause mild irritation with redness and tearing.
Chronic Effects: None known.
Sensitization: Components are not known to be sensitizers.
Germ Cell Mutagenicity: Components are not classified as germ cell mutagens. At concentrations up to 1,000 mcg/mL, vancomycin had no mutagenic effect *in vitro* in the mouse lymphoma forward mutation assay or the primary rat hepatocyte unscheduled DNA synthesis assay.
Reproductive Toxicity: Components are not classified as reproductive toxins. Vancomycin did not cause fetal malformation when administered intravenously during organogenesis to pregnant rats (gestation days 6 to 15) and rabbits (gestation days 6 to 18) at the equivalent recommended maximum human dose of 200 mg/kg/day to rats or 120 mg/kg/day to rabbits. No effects on fetal weight or development were seen in rats at the highest dose tested or in rabbits given 80 mg/kg/day. Maternal toxicity was observed in rats at doses 120 mg/kg and above and rabbits at 80 mg/kg and above.
Carcinogenicity: None of the components are listed as carcinogens or suspected carcinogens by IARC, NTP, or OSHA.

Acute Toxicity Values: Acute Oral Toxicity Estimate (ATE) calculated: >10000 mg/kg
Vancomycin Hydrochloride: Oral rat LD50 >10,000 mg/kg

12. ECOLOGICAL INFORMATION

Environmental properties have not been evaluated. Releases to the environment should be avoided.
Ecotoxicity values: No data available.
Persistence and degradability: No data available.
Bioaccumulative potential: No data available.
Mobility in soil: No data is available.
Other adverse effects: None known.

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all local, state and federal regulations.

14. TRANSPORT INFORMATION

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
DOT		Not Regulated			
TDG		Not Regulated			
IMDG		Not Regulated			
IATA		Not Regulated			

Transport in bulk according to IMO instruments: Not applicable – product is transported only in packaged form.

Special precautions: None known.

15. REGULATORY INFORMATION

Safety, health, and environmental regulations specific for the product in question.

CERCLA: This product is not subject to CERCLA release reporting. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

SARA Hazard Category (311/312): Not Hazardous

EPA SARA 313: This product contains the following chemicals regulated under SARA Title III, section 313:
None

EPA TSCA Inventory: This product is a drug and not subject to TSCA**.**

California Proposition 65: This product is not known to contain regulated chemicals.

CANADA:
Canadian CEPA: This product is a drug and not subject to CEPA regulations.

16. OTHER INFORMATION

Issue Date: 03/24/2026
Revision Number: 01
Revision Date: New SDS
SDS Revision History: New SDS

Disclaimer : The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.