SAFETY DATA SHEET

Voriconazole Injection

1. IDENTIFICATION

Product identifier: Voriconazole Injection
NDC Numbers: 0121-1091-55

Distributor 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 – treatment of serious fungal infections
Restrictions on use: Prescription use only.

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Not hazardous	Skin Sensitization Category 1 Carcinogen Category 2 Reproductive Toxicity Category 1B Specific Target Organ Toxicity Repeated Exposure Category 2 (liver)

Label Elements:
Danger!

Hazard statement(s)
May cause an allergic skin reaction.
Suspected of causing cancer.
May damage the unborn child.
May cause damage to the liver through prolonged or repeated exposure.

Precautionary statement(s)
Do not breathe mists.
Contaminated clothing must not be allowed out of the workplace.

Precautionary statement(s)
Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Wear protective clothing and gloves.
IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical attention. Take off contaminated clothing and wash it before reuse.
IF exposed or concerned: Get medical attention.
Store locked up.
Dispose in accordance with local and national regulations.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Amount
Voriconazole	137234-62-9	1%
Heptakis-1-(4-sulfonylbutyl)-cyclodextrine, sodium salt	182410-00-0	15-20%
Water	7732-18-5	80-85%

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 occurs, get medical attention.
Skin contact: Remove contaminated clothing. Wash skin with soap and water. If irritation or rash 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: 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. Repeated skin contact may cause an allergic skin reaction. Swallowing may cause visual disturbances, liver effects, elevation of liver function tests and skin rash. May cause photosensitivity. Suspected of causing cancer. May cause harm to the unborn child.

Indication of immediate medical attention and special treatment, if necessary: Medical attention is recommended for ingestion. Refer to the product insert and your poison center for treatment information.

5. FIRE-FIGHTING MEASURES

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

Specific hazards arising from the chemical: Product is not classified as flammable or combustible but will burn in a fire after the water has evaporated.

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. Cool fire exposed containers with water.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, and emergency procedures: Wear appropriate protective clothing and equipment as described in Section 8. Use caution – spill may be a slip hazard.

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: Contain and collect with an inert absorbent material. Place in appropriate container for disposal. Clean area thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling: Avoid the generation of mists. Avoid contact with eyes, skin and clothing. 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:

Voriconazole	None Established
Heptakis-1-(4-sulfonylbutyl)-cyclodextrine, sodium salt	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 exceeded, 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 and clothing recommended for manufacturing operations.
Eye protection: None required for normal use. Chemical safety goggles recommended for manufacturing operations.
Other: None known.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Liquid	**Color:** Colorless
Odor: Odorless	**pH:** 5-7
Melting point/freezing point: No data available	**Boiling Point:** No data available
Flash point: No data available	**Particle Characteristics:** Not applicable
Flammability: Not applicable	**VOC:** No data available
Flammable limits: LEL: Not applicable	**UEL:** Not applicable
Vapor pressure: Same as water	**Relative vapor density:** Same as water
Relative density: No data available	**Solubility(ies):** Soluble in water
Partition coefficient: n-octanol/water: No data available	**Auto-ignition temperature:** No data available
Decomposition temperature: No data available	**Kinematic Viscosity:** No data available

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 and nitrogen oxides.

11. TOXICOLOGICAL INFORMATION

Acute effects of exposure:
Inhalation: Inhalation of mists may cause irritation of the mucous membranes and upper respiratory tract and effects similar to ingestion.
Ingestion: Swallowing may cause visual disturbances, liver effects, elevation of liver function tests and skin rash. May cause photosensitivity.
Skin contact: May cause mild irritation. Repeated skin contact may cause an allergic skin reaction.
Eye contact: May cause mild irritation with redness and tearing.
Chronic Effects: May damage the unborn child. Suspected of causing cancer.
Sensitization: Heptakis-1-(4-sulfonylbutyl)-cyclodextrine, sodium salt is a skin sensitizer.
Germ Cell Mutagenicity: Components are not classified as germ cell mutagens. Voriconazole was not genotoxic in the Ames assay, CHO HGPRT assay, the mouse micronucleus assay or the *in vivo* DNA repair test (Unscheduled DNA Synthesis assay).
Reproductive Toxicity: May damage the unborn child. Voriconazole was administered orally to pregnant rats during organogenesis (gestation days 6 to 17) at 10, 30, and 60 mg/kg/day. Voriconazole was associated with increased incidences of the malformations hydroureter and hydronephrosis at 10 mg/kg/day or greater and cleft palate at 60 mg/kg. Reduced ossification of sacral and caudal vertebrae, skull, pubic, and hyoid bone, supernumerary ribs, anomalies of the sternebrae, and dilatation of the ureter/renal pelvis were also observed at doses of 10 mg/kg or greater. There was no evidence of maternal toxicity at any dose. Voriconazole was administered orally to pregnant rabbits during the period of organogenesis (gestation days 7 to 19) at 10, 40, and 100 mg/kg/day. Voriconazole was associated with increased post-implantation loss and decreased fetal body weight, in association with maternal toxicity (decreased body weight gain and food consumption) at 100 mg/kg/day. Fetal skeletal variations (increases in the incidence of cervical rib and extra sternebral ossification sites) were observed at 100 mg/kg/day.
Carcinogenicity: Voriconazole is classified by IARC as a human carcinogen (group 1). Two-year carcinogenicity studies were conducted in rats and mice. Rats were given oral doses of 6, 18 or 50 mg/kg voriconazole. Hepatocellular adenomas were detected in females at 50 mg/kg and hepatocellular carcinomas were found in males at 6 and 50 mg/kg. Mice were given oral doses of 10, 30 or 100 mg/kg voriconazole. In mice, hepatocellular adenomas were detected in males and females and hepatocellular carcinomas were detected in males.
Acute Toxicity Values: Acute Oral Toxicity Estimate (ATE) calculated: 5000 mg/kg
Voriconazole: Oral LD50 100-<300 mg/kg, Dermal rat LD50 >2000 mg/kg
Heptakis-1-(4-sulfonylbutyl)-cyclodextrine, sodium salt: Oral LD50 >2000 mg/kg, Dermal LD50 >2000 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 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): Refer to Section 2 for the OSHA hazard classification.

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: 04/13/2026
Revision Number: 01
Revision Date: N/A
SDS Revision History: N/A

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.