SAFETY DATA SHEET

Section 1: Identification	
Material **Recommended use**	Voriconazole for Injection 200 mg/vial Pharmaceutical product used as antifungal agent
Manufacturer	Aspiro Pharma Limited, Sy. No. 321, Biotech Park, Phase-III, Karkapatla Village, Markook Mandal, Telangana (S), Siddipet (Dist.)-502281, India.
Distributor	**Camber Pharmaceuticals, Inc.**, Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
Hazardous	Not listed
Statement of Hazard:	Harmful if swallowed.
Additional Hazard Information: **Short Term:**	May produce slight eye irritation, Active ingredient is not a skin irritant , Accidental ingestion may cause effects similar to those seen in clinical use.
Long Term:	Adverse reproductive effects seen in repeat-dose animal studies are consistent with the pharmacologic action of this drug and are expected to be relevant to humans. Animal studies indicate that this material may cause adverse effects on the liver, the developing fetus.
EU Risk Phrases	R40 - Limited evidence of a carcinogenic effect. R43 - May cause sensitization by skin contact. R61 - May cause harm to the unborn child.
This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.	

Section 3: Composition/Information on Ingredients	
Ingredients	CAS
Voriconazole	137234-62-9
Sulfobutyl ether beta-cyclodextrin sodium	182410-00-0
Section 4: First-Aid Measures	
Eye Contact:	Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.
Skin Contact:	Wash skin with soap and water. Remove contaminated clothing and shoes. If irritation occurs or persists, get medical attention.
Ingestion:	Get medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.
Inhalation:	Remove to fresh air. If not breathing, give artificial respiration. Get medical attention immediately.
Section 5: Fire-Fighting Measures	
Extinguishing Media:	Use carbon dioxide, dry chemical, or water spray.
Hazardous Combustion Products:	Carbon monoxide, carbon dioxide, nitrogen oxides and fluorine-containing compounds
Fire Fighting Procedures:	During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
Fire / Explosion Hazards:	Fine particles (such as dust and mists) may fuel fires/ explosions.
Section 6: Accidental Release Measures	
Health and Safety Precautions	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting:	Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.
Measures for Environmental Protections:	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Additional Consideration for Large Spills:	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.
Section 7: Handling and Storage	
General Handling:	Avoid generating airborne dust. Avoid contact with eyes, skin and clothing. Avoid breathing dust. Wash thoroughly after handling.
Storage Conditions:	Store as directed by product packaging.
Section 8: Exposure Controls/Personal Protection	
Analytical Method:	Analytical method available for Voriconazole and Sulfobutyl ether b-cyclodextrin sodium. Contact Pfizer Inc for further information.
Engineering Controls:	Engineering controls should be used as the primary means to control exposures. Local and general ventilation should be used as necessary, when handling this material in bulk.
Personal Protective Equipment	
Hands:	Rubber gloves
Eyes:	Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.
Skin:	Not required for the normal use of this product. Wear protective clothing when working with large quantities.
Respiratory protection:	Not required for the normal use of this product. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

Section 9: Physical and Chemical Properties	
Physical Form	Lyophilized cake or powder
Colour	White to off white
Description	Voriconazole for injection is supplied in a single-dose vial as a sterile, white to off white lyophilized cake or powder equivalent to 200 mg voriconazole and 3,200 mg sulfobutyl ether beta-cyclodextrin sodium (SBECD). It does not contain preservatives and is not made with natural rubber latex. Individually packaged vials of 200 mg Voriconazole for Injection. NDC 31722-224-31
Section 10: Stability and Reactivity	
Stability:	Stable at ambient temperatures
Conditions to Avoid:	Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers.
Hazardous Decomposition Products:	Thermal decomposition products include oxides of nitrogen, carbon monoxide, carbon dioxide and halogen containing gases.
Polymerization:	Will not occur
Section 11: Toxicological Information	
General Information:	The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Voriconazole

Rat/Mouse	Oral	LD50	<	300 mg/kg
Rat/Mouse	Oral	LD min.	>	100 mg/kg
Rat	IV	LD50	>	100 mg/kg
Rat	Dermal	LD50	>	2000 mg/kg

Sulfobutylether b-cyclodextrin sodium (SBECD)

Rat Oral LD50 > 2000 mg/kg

Rat/Mouse IV LD50 > 2000 mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Voriconazole

Skin Irritation Rabbit Non-irritating
Skin Sensitization - GPMT Guinea Pig Negative
Eye Irritation Rabbit Minimal

Sulfobutylether b-cyclodextrin sodium (SBECD)

Eye Irritation Rabbit Non-irritating
Skin Irritation Rabbit Non-irritating
Skin Sensitization - GPMT Guinea Pig Positive

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Voriconazole

1 Month(s) Rat Oral 30 mg/kg/day NOAEL Liver
6 Month(s) Rat Oral 3 mg/kg/day NOAEL Liver, Kidney 12 Month(s) Dog Oral 8 mg/kg/day NOAEL Liver
6 Month(s) Rat Intravenous 10 mg/kg/day NOAEL Liver 6 Month(s) Dog Oral 6 mg/kg/day NOAEL Liver

Sulfobutylether b-cyclodextrin sodium (SBECD)

6 Month(s) Rat Intravenous 600 mg/kg/day NOAEL Kidney, Liver
1 Month(s) Rat Intravenous 160 mg/kg/day NOAEL Kidney
6 Month(s) Dog Intravenous 600 mg/kg/day NOAEL Kidney
1 Month(s) Dog Intravenous 120 mg/kg/day NOAEL Kidney

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Voriconazole

Reproductive & Fertility Rat Oral 3 mg/kg/day NOAEL Fetotoxicity
Embryo / Fetal Development Rat Oral 10 mg/kg/day LOAEL Teratogenic

Sulfobutylether b-cyclodextrin sodium (SBECD)

Fertility and Embryonic Development Rat Intravenous 1500 mg/kg/day NOAEL No effects at maximum dose
Embryo / Fetal Development Rabbit Intravenous 1500 mg/kg/day NOAEL Not Teratogenic
Prenatal & Postnatal Development Rat Intravenous 600 mg/kg/day NOAEL Maternal Toxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)
Voriconazole
Bacterial Mutagenicity (Ames) Bacteria Negative
In Vitro Human Lymphocytes Equivocal
In Vivo Micronucleus Mouse Negative
Sulfobutylether b-cyclodextrin sodium (SBECD)
Bacterial Mutagenicity (Ames) Salmonella , E. coli Negative
In Vitro Chromosome Aberration Human Lymphocytes Negative
Mammalian Cell Mutagenicity Chinese Hamster Ovary (CHO) cells HGPRT Negative
In Vivo Micronucleus Mouse Bone Marrow Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))
Voriconazole
2 Year(s) Rat Oral 18 mg/kg/day NOEL Benign tumors, Liver
2 Year(s) Mouse Oral 30 mg/kg/day NOAEL Malignant tumors, Liver
Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Section 12: Ecological Information

Environmental Overview:	In the environment, the active ingredient in this formulation is expected to remain in water or migrate through the soil to groundwater and degrade slowly Harmful effects to aquatic organisms could occur.
Mobility, Persistence and Degradability:	The active ingredient in this formulation is water soluble and is expected to remain primarily in water and degrade slowly
Bioaccumulation and Toxicity:	Moderate acute toxicity to aquatic organisms could occur. The active ingredient in this formulation has low potential to bioaccumulate and long-term adverse effects to aquatic organisms are not expected. No toxicity to wastewater treatment microorganisms is expected. See the aquatic toxicity data for the active ingredient in the table, below.

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Voriconazole

Mysid Shrimp NPDES LC50 48 Hours 62 mg/L

Red Algae IC50 73 mg/L

Skeletonema Algae NPDES IC-50 48 Hours 74.7 mg/L

Green Algae OECD EbC50/72hr (OECD) EC50 72 Hours > 97 mg/L

Rainbow Trout OECD LC50 96 Hours 110 mg/L

Sulfobutylether b-cyclodextrin sodium (SBECD) Rainbow Trout OECD LC50 96 Hours > 220 mg/L Daphnia magna OECD EC-50 48 Hours > 96 mg/L Green algae OECD IC50 72 Hours > 100 mg/L	
Aquatic Toxicity Comments:	A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.
Bacterial Inhibition: (Species, Method, End Point, Duration, Result) **Voriconazole** Activated sludge OECD EC50 3 Hours > 810 mg/L Polytox MIC 24 Hours > 100 mg/L	
Section 13: Disposal Considerations	
Disposal Procedures:	Dispose of waste in accordance with all applicable laws and regulations.
Section 14: Transport Information	
Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations	
Section 15: Regulatory Information	
EU Symbol:	T
EU Indication of danger:	Toxic to Reproduction: Category 2 Carcinogenic: Category 3 Irritant
EU Risk Phrases:	R40 - Limited evidence of a carcinogenic effect. R43 - May cause sensitization by skin contact. R61 - May cause harm to the unborn child.
EU Safety Phrases:	S22 - Do not breathe dust. S36/37 - Wear suitable protective clothing and gloves. S53 - Avoid exposure - obtain special instructions before use.
Canada - WHMIS: Classifications **WHMIS hazard class:** Class D, Division 2, Subdivision A **Voriconazole** **Standard for the Uniform Scheduling for Drugs and Poisons:** Schedule 4 **Sulfobutylether b-cyclodextrin sodium (SBECD)** **Inventory - United States TSCA - Sect. 8(b)** Present **Australia (AICS):** Present **EU EINECS List** 231-493-2	

Section 16: Other Information

Issue Date : 12-06-2024

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.

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