SAFETY DATA SHEET

Section 1: Identification	
Material **Recommended use**	Posaconazole Injection 300 mg/16.7 mL (18 mg/mL) Pharmaceutical Use
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	
Classification	Not classified as hazardous
Skin sensitisation	Category 1
Specific target organ toxicity - repeated exposure (Oral)	Category 2 (Adrenal gland, Bone marrow, Kidney, Liver, Nervous system, Reproductive organs)
Short-term (acute) aquatic hazard	Category 3
Long-term (chronic) aquatic hazard	Category 3
Hazard statements	May cause an allergic skin reaction May cause damage to organs (Adrenal gland, Bone marrow, Kidney, Liver, Nervous system, Reproductive organs) through prolonged or repeated exposure if swallowed. Harmful to aquatic life with long lasting effects
Precautionary statements	**Prevention:** Do not breathe mist or vapours Contaminated work clothing should not be allowed out of the workplace Avoid release to the environment Wear protective gloves. **Response:** Wash with plenty of water Get medical help if you feel unwell If skin irritation or rash occurs: Get medical help Take off contaminated clothing and wash it before reuse. **Disposal:** Dispose of contents/ container to an approved waste disposal plant

Other hazards which do not result in classification None known	
Section 3: Composition/Information on Ingredients	
Ingredients	**CAS**
Posaconazole	171228-49-2
Betadex Sulfobutyl Ether Sodium	182410-00-0
Edetate Disodium	6381-92-6
Hydrochloric acid	7647-01-0
Nitrogen	7727-37-9
Sodium Hydroxide	1310-73-2
Water for Injection	NA
Section 4: First-Aid Measures	
General advice	In the case of accident or if you feel unwell, seek medical ad-vice immediately. When symptoms persist or in all cases of doubt seek medical advice.
If inhaled	If inhaled, remove to fresh air. Get medical attention
In case of skin contact	In case of contact, immediately flush skin with soap and plenty of water Remove contaminated clothing and shoes Get medical attention Wash clothing before reuse Thoroughly clean shoes before reuse
In case of eye contact	Flush eyes with water as a precaution Get medical attention if irritation develops and persists
If swallowed	If swallowed, DO NOT induce vomiting Get medical attention Rinse mouth thoroughly with water
Most important symptoms and effects, both acute and delayed	Diarrhoea Fever Headache Nausea Vomiting May cause an allergic skin reaction May cause damage to organs through prolonged or repeated exposure if swallowed.
Protection of first-aiders	First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
Notes to physician	Treat symptomatically and supportively

Section 5: Fire-Fighting Measures	
Suitable extinguishing media	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	None known.
Specific hazards during fire-fighting	Exposure to combustion products may be a hazard to health
Hazardous combustion products	Carbon oxides Sulphur oxides Metal oxides
Specific extinguishing methods	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for firefighters	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment
Section 6: Accidental Release Measures	
Personal precautions, protective equipment and emergency procedures	Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	Soak up with inert absorbent material. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the clean-up of releases. You will need to deter-mine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

Section 7: Handling and Storage	
Technical measures	See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section
Local/Total ventilation	Use only with adequate ventilation.
Advice on safe handling	Do not get on skin or clothing Do not breathe mist or vapours Do not swallow Avoid contact with eyes Wash skin thoroughly after handling Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment
Conditions for safe storage	Keep in properly labelled containers. Store in accordance with the particular national regulations.
Materials to avoid	Do not store with the following product types: Strong oxidizing agents
Section 8: Exposure Controls/Personal Protection	
Engineering measures	Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections). All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Laboratory operations do not require special containment
Personal protective equipment	
Respiratory protection	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection
Filter type	Particulate's type
Hand protection Material	Chemical-resistant gloves
Eye protection	Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a face shield or other full-face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols
Skin and body protection	Work uniform or laboratory coat.

Hygiene measures	If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place When using do not eat, drink or smoke Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before re-use The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.
Section 9: Physical and Chemical Properties	
Physical Form	Injection
Description	Posaconazole injection is available as a clear, colorless to yellow sterile liquid in single-dose Type I glass vials closed with serum rubber stopper and flip off seal. NDC 31722-370-31 - containing 300 mg of posaconazole in 16.7 mL of solution (18 mg of posaconazole per mL).
Section 10: Stability and Reactivity	
Reactivity	Not classified as a reactivity hazard
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	Can react with strong oxidizing agents
Conditions to avoid	None known.
Incompatible materials	Oxidizing agents
Hazardous decomposition products	No hazardous decomposition products are known
Section 11: Toxicological Information	
Information on likely routes of exposure	Inhalation Skin contact Ingestion Eye contact
Acute toxicity	Not classified based on available information
Components: **.beta.-Cyclodextrin, sulfobutyl ethers, sodium salts:** Acute oral toxicity : LD50 (Rat): > 8,800 mg/kg	

Posaconazole:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
LD50 (Mouse): > 3,000 mg/kg
Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg

Skin corrosion/irritation

Not classified based on available information

Components:

Posaconazole:

Species : Rabbit

Result : No skin irritation

Serious eye damage/eye irritation
Not classified based on available information

Components:

Posaconazole:

Species : Rabbit
Result : Mild eye irritation

Respiratory or skin sensitisation

Skin sensitisation

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified based on available information

Components:

.beta.-Cyclodextrin, sulfobutyl ethers, sodium salts:

Assessment : Probability or evidence of skin sensitisation in humans

Posaconazole:
Test Type : Magnusson-Kligman-Test
Exposure routes : Skin contact
Species : Guinea pig
Result : negative

Germ cell mutagenicity

Not classified based on available information

Components:

Posaconazole:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Test Type: Chromosomal aberration
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse
Cell type: Bone marrow
Application Route: Intravenous
Result: negative

Carcinogenicity

Not classified based on available information.

Components:
Posaconazole:
Species : Rat
Application Route : oral (feed)
Exposure time : 2 Years
Result : positive
Remarks : The mechanism or mode of action is not relevant in humans

Species : Mouse
Application Route : Oral
Exposure time : 2 Years
Result : positive
Remarks : The mechanism or mode of action is not relevant in humans

Reproductive toxicity

Not classified based on available information

Components:
.beta.-Cyclodextrin, sulfobutyl ethers, sodium salts:
Effects on fertility : Test Type: Fertility
Species: Rat
Application Route: Intravenous injection

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Intravenous injection
Result: negative

Posaconazole: Effects on fertility : Test Type: Fertility/early embryonic development Species: Rat, male General Toxicity - Parent: NOAEL: 180 mg/kg body weight Symptoms: No effects on mating performance Result: negative Test Type: Fertility/early embryonic development Species: Rat, female General Toxicity - Parent: NOAEL: 45 mg/kg body weight Symptoms: No effects on mating performance Result: negative	
Effects on foetal development	Test Type: Embryo-foetal development Species: Rat, female Application Route: Oral Developmental Toxicity: LOAEL: 29 mg/kg body weight Result: Fetotoxicity, Malformations were observed Test Type: Embryo-foetal development Species: Rabbit, female Developmental Toxicity: LOAEL: 40 mg/kg body weight Result: Fetotoxicity
Reproductive toxicity Assessment	Some evidence of adverse effects on development, based on animal experiments.
STOT - single exposure Not classified based on available information	
STOT - repeated exposure May cause damage to organs (Adrenal gland, Bone marrow, Kidney, Liver, Nervous system, Reproductive organs) through prolonged or repeated exposure if swallowed.	
Components: **Posaconazole:** Exposure routes : Ingestion Target Organs : Adrenal gland, Bone marrow, Kidney, Liver, Reproductive organs, Nervous system Assessment : Causes damage to organs through prolonged or repeated exposure.	
Repeated dose toxicity **Components:** **Posaconazole:** Species : Rat, female LOAEL : 5 mg/kg Application Route : Oral Exposure time : 6 Months Target Organs : Adrenal gland, Lungs, Heart, Liver, spleen, Kidney, Ovary Species : Dog LOAEL : 3 mg/kg Application Route : Oral	

Exposure time : 392 Days
Target Organs : Lungs, Liver, Brain, small intestine, Adrenal gland, Spinal cord, lymphoid tissue

Species : Monkey
LOAEL : 15 mg/kg
Application Route : Oral
Exposure time : 1 Months
Target Organs : Bone marrow, Adrenal gland, Lymph nodes, Blood

Species : Dog
LOAEL : 3 mg/kg
Application Route : Oral
Exposure time : 56 Weeks
Target Organs : Adrenal gland, Bone marrow, Kidney, Nervous system, spleen, thymus gland, Testis, lymphoid tissue

Species :Monkey
LOAEL : 180 mg/kg
Application Route : Oral
Exposure time : 12 Months
Target Organs : Blood, Gastrointestinal tract, spleen

Species : Monkey
LOAEL : 8 mg/kg
Application Route : Intravenous
Exposure time : 1 Months
Target Organs : Cardio-vascular system, Lungs, Adrenal gland, Blood

Aspiration toxicity
Not classified based on available information
Experience with human exposure
Components:
Posaconazole:
Ingestion : Symptoms: Cough, Headache, Nausea, Vomiting, Fever, Liver effects, Rash, pruritis, Diarrhoea, hypertension, neutropenia, electrolyte imbalance

Section 12: Ecological Information

Ecotoxicity
Components:
.beta.-Cyclodextrin, sulfobutyl ethers, sodium salts:
Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 220 mg/l
Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 96 mg/l
Exposure time: 48 h
Toxicity to algae/aquatic plants : EC50 (Selenastrum capricornutum (green algae)): > 100 mg/l
Exposure time: 72 h

Posaconazole: Toxicity to fish	LC50 (Oncorhynchus mykiss (rainbow trout)): > 0.95 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 Remarks: No toxicity at the limit of solubility
Toxicity to daphnia and other aquatic invertebrates	EC50 (Daphnia magna (Water flea)): 0.276 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	EC50 (Pseudokirchneriella subcapitata (green algae)): > 0.509 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 NOEC (Pseudokirchneriella subcapitata (green algae)): 0.041 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
M-Factor (Acute aquatic toxicity)	1
Toxicity to microorganisms	EC50 (Natural microorganism): > 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209
Toxicity to fish (Chronic toxicity)	NOEC: 0.206 mg/l Exposure time: 33 d Species: Pimephales promelas (fathead minnow) Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	NOEC: 0.244 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211 Remarks: No toxicity at the limit of solubility
M-Factor (Chronic aquatic toxicity)	1

Persistence and degradability
<u>Components</u>:
Posaconazole:
Biodegradability : Result: Not readily biodegradable
Biodegradation: 50 %
Exposure time: 28 h
Method: OECD Test Guideline 314
Stability in water : Degradation half life (DT50): > 30 d
Method: OECD Test Guideline 111

Bioaccumulative potential
Components:

Posaconazole:
Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): 20
Method: OECD Test Guideline 305
Partition coefficient: n-octanol/water : log Pow: 4.15
Mobility in soil
Components:
Posaconazole:
Distribution among environmental compartments : log Koc: 5.52
Other adverse effects
No data available

Section 13: Disposal Considerations

Disposal methods	Do not dispose of waste into sewer.
Waste from residues	Dispose of in accordance with local regulations
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product

Section 14: Transport Information

International Regulations

UNRTDG
Not regulated as a dangerous good
IATA-DGR
Not regulated as a dangerous good
IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to IMO instruments
Not applicable for product as supplied.

Special precautions for user
Not applicable

Section 15: Regulatory Information

Safety, health and environmental regulations/legislation specific for the substance or mixture

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

Section 16: Other Information

Issue Date : 12-03-2025

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.

Aspiro Pharma Private Limited shall not be held liable for any damage resulting from handling or from contact with the above product. Aspiro Pharma Private Limited reserves the right to revise this SDS.