



HETERO LABS LIMITED

"Hetero Corporate", 7-2-A2, Industrial Estates, Sanath Nagar, Hyderabad - 500 018, A.P., INDIA.
Tel : 91-40-23704923/24/25, Fax : 91-40-23704926, 23714250
e-mail : contact@heterodrugs.com URL : http://www.heterodrugs.com

SAFETY DATA SHEET

Section 1: Identification	
Material	Itraconazole Oral Solution 10 mg/mL
Other means of identification	Itraconazole Oral Solution
Recommended use	Pharmaceutical product
Recommended restrictions	NA
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	
Hazard Classification:	Not Classified as Hazardous under GHS.
Label Elements (Hazcom 2012)	This product is not classified as hazardous in accordance with the GHS criteria (29 CFR 1910.1200). No labelling required.
P264	Wash hands thoroughly after handling product
P302+P352	If ON SKIN: wash with plenty of soap and water.
P332+P313	If skin irritation or rash occurs: Get medical attention or advice.
P305+P351+P338	If IN EYES: Rinse continuously with water for several minutes. Remove contacts if present and easy to do. Get medical attention or advice.
P304+P341	If INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a comfortable position for breathing
P273	Avoid release to the environment.
Section 3: Composition / Information on Ingredients	
Active Ingredient	
Itraconazole	
CAS	84625-61-6
Section 4: First-Aid Measures	
Product is not likely to present problems during normal handling, but in case of excessive exposure the following measures may be required;	
Ingestion	In the event of accidental ingestion, seek medical advice. Do Not Induce Vomiting.
Skin Contact	In the event of occupational skin contact, remove contaminated clothing and rinse off exposed area with water.
Eye Contact	In case of eye contact, rinse immediately with water for 15 minutes and seek medical advice.
Inhalation	Move individual to fresh air. Seek medical advice.
Measures-General Advice	Consult a physician or poison control center. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.



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Most important symptoms/effects, acute and delayed	The most important known symptoms and effects are described in the labelling.
Indication of any immediate medical attention and special treatment needed	Evidence of accidental or purposeful ingestion overdose requires immediate medical attention.
Section 5: Fire-Fighting Measures	
Suitable extinguishing media	Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
Specific hazards arising from the chemical	Carbon oxides
Advice for firefighters	Wear self-contained breathing apparatus for firefighting if necessary.
Further information	No data available
Section 6: Accidental Release Measures	
Personal precautions, protective equipment and emergency procedures	Use personal protective equipment. Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. For personal protection see section 8.
Environmental precautions	Do not let product enter drains.
Methods and materials for containment and cleaning up	Pick up and arrange disposal without creating dust. Mop up. Keep in suitable, closed containers for disposal.
Reference to other sections	For disposal see section 13.
Section 7: Handling and Storage	
Precautions for safe handling	Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed.
Conditions for safe storage, including any incompatibilities	Store locked up. Keep container tightly closed in a dry and well-ventilated place. Recommended storage temperature: room temperature
Specific end use(s)	Itraconazole Oral Solution, 10 mg/mL is an antifungal pharmaceutical preparation.
Section 8: Exposure Controls/Personal Protection	
Exposure controls	
Appropriate engineering controls	Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday. Follow approved Good Manufacturing Practices. Local exhaust ventilation normally not required.
Personal protective equipment	
Eyel/face protection	Safety glasses with side-shields.
Skin Protection	Handle with gloves to prevent skin contact and product contamination. Product components may be absorbed through the skin.
Body Protection	Wear appropriate covering to prevent dusting and contamination of work clothing.



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Respiratory protection	Use approved respirators and components when mixing, formulating or packaging product.
This recommendation is advisory only and must be evaluated by an industrial hygienist and safety officer familiar with the specific situation of anticipated use. This SDS is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. Patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.	
Control of environmental exposure	Do not let product enter drains.
Section 9: Physical and Chemical Properties	
Information on basic physical and chemical properties	
Appearance	Oral Solution
Physical State	Liquid
Description	Clear, colorless to yellowish brown liquid having cherry flavor filled in Amber glass bottle 150 mL Bottle in Carton NDC 31722-006-31
Section 10: Stability and Reactivity	
Reactivity	No data available
Chemical stability	Stable under normal use and storage conditions.
Possibility of hazardous reactions	No data available
Conditions to avoid	No data available
Incompatible materials	Strong oxidizing agents
Hazardous decomposition products	No data available
Section 11: Toxicological Information	
Information on toxicological effects (based on Itraconazole)	
Acute toxicity	
LD50 Oral-rat	>320 mg/kg
LD50 Oral-mouse	>320 mg/kg
LD50 Oral-dog	> 200 mg/kg
LD50 Oral-Gpig	>160 mg/kg
Skin corrosion/irritation	No data available for the formulated product.
Serious eye damage/eye irritation	May be Irritating to eyes (based on Itraconazole)
Respiratory or skin sensitization	May cause skin or respiratory irritation (based on Itraconazole)
Germ cell mutagenicity	Product not classified
Carcinogenicity	No data available for the formulated product.
Reproductive toxicity	No data available for formulated product. Itraconazole is classified as Reprotox Cat 2.
Specific target organ toxicity - single exposure	No data available for formulated product.
Specific target organ toxicity - repeated exposure	No data available for formulated product.



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Aspiration hazard	No data available for the formulated product.
Additional Information	No data available.
Section 12: Ecological Information	
Toxicity	No data available on formulated product
Persistence and degradability	No data is available.
Bioaccumulative potential	No data available.
Mobility in soil	No data available.
Results of PBT and vPvB assessment	PBT/vPvB assessment not available as chemical safety assessment not required/not conducted
Other adverse effects	No data available.
Section 13: Disposal Considerations	
Waste treatment methods	Dispose in accordance with local, state and federal regulations. Do not dispose in sanitary waste sewer. Ensure product waste disposal follows FDA guidelines.
Contaminated packaging	Dispose of as unused product.
Section 14: Transport Information	
DOT (US)	Not dangerous goods
IMDG	Not dangerous goods
IATA	Not dangerous goods
Product is a FDA regulated product: follow proper FDA regulations for packaging and transport of product.	
Section 15: Regulatory Information	
This product is a FDA regulated pharmaceutical product that may not be classified, regulated or is exempt from certain requirements contained in 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200). Consult product packaging insert for additional health and safety information on dosage and potential side effects from use of this product.	
Section 16: Other Information, including date of preparation or last revision	
Issue Date: 21-08-2020	
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.	