



# SAFETY DATA SHEET

Version 1.0

Revision Date 09/18/2018

## 1. PRODUCT AND COMPANY IDENTIFICATION

### 1.1 Product identifiers

Product name : Itraconazole Oral Solution, 10 mg/ml

Product codes : 087

### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses : Pharmaceutical preparation

Uses advised against : All other uses

### 1.3 Details of the supplier of the safety data sheet

Company : Amneal Pharmaceuticals  
1 New England Avenue  
Piscataway, NJ 08854  
USA

Telephone : +1 732-645-3030

### 1.4 Emergency telephone number

Emergency Phone # (24hrs) : CHEMTREC 1-800-424-9300 CCN796801 [US and Canada]  
+1 703-527-3887 (collect calls accepted)

## 2. HAZARDS IDENTIFICATION

### 2.1 Classification of the substance or mixture

#### GHS Classification in accordance with 29 CFR 1910 (OSHA HCS)

Not classified as hazardous under GHS.

### 2.2 GHS Label elements, including precautionary statements

No GHS Label required.

Signal Word: None 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.

**2.3 Hazards not otherwise classified (HNOC) or not covered by GHS – none****3. COMPOSITION/INFORMATION ON INGREDIENTS****3.1 Substances**

Active Ingredient	CAS Number	GHS* Classification Active Ingredient	%
Itraconazole, USP	84625-61-6	Acut tox, oral Cat 4 Skin corrosion/irritation Cat 2 Reproductive toxicity Cat 2 Eye irritation Cat 2 STOT-SE Cat 3 (respiratory effects)	<0.1
Excipients/Additives	CAS Number	GHS Classification	%
Propylene Glycol, USP	57-55-6	Not classified GHS	9.4
Hydroxypropyl beta cyclodextrin	NA-mixture	Not classified GHS, combustible dust-powder	34-35
Sodium saccharin, USP	6155-57-3	Not classified GHS	0.04
Cherry Flavor FV 7379	NA-mixture	Not classified GHS	0.1
Art Caramel Flavor FV 8873	NA-mixture	Not classified GHS	<0.3
Sorbitol Solution 70%	50-70-4	Not classified GHS, combustible dust-powder	15.4
Hydrochloric acid 37% NF	7647-01-0	Skin corrosion/irritation Cat 1B	0.1-0.2
Purified Water, USP	7732-18-5	Not classified GHS	>25

\* based on active ingredient

**4. FIRST AID MEASURES****4.1 Description of first aid**

**INHALATION:** Move individual to fresh air. Seek medical advice.

**SKIN:** In the event of occupational skin contact, remove contaminated clothing and rinse off exposed area with water.

**EYES:** In case of eye contact, rinse immediately with water for 15 minutes and seek medical advice.

**INGESTION:** In the event of accidental ingestion, seek medical advice. Do Not Induce Vomiting.

**4.2 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.

**4.3 Most important symptoms and effects, both acute and delayed**

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

**4.4 Indication of any immediate medical attention and special treatment needed**

Evidence of accidental or purposeful ingestion overdose requires immediate medical attention.

**5. FIREFIGHTING MEASURES****5.1 Extinguishing media  
Suitable extinguishing**

**media**

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

**5.2 Special hazards arising from the substance or mixture**

Carbon oxides

**5.3 Advice for firefighters**

Wear self-contained breathing apparatus for firefighting if necessary.

**5.4 Further information**

No data available

**6. ACCIDENTAL RELEASE MEASURES****6.1 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.

**6.2 Environmental precautions**

Do not let product enter drains.

**6.3 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.

**6.4 Reference to other sections**

For disposal see section 13.

**7. HANDLING AND STORAGE****7.1 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.

**7.2 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 or refrigerated

**7.3 Specific end use(s)**

Itraconazole Oral Solution, 10 mg/ml is an antifungal pharmaceutical preparation.

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION****8.1 Control parameters****Components with workplace control parameters**

Component	CAS Number	OSHA
Hydrochloric acid	7674-01-0	5 ppm-C (gas)

**8.2 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****Eye/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.

### 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.

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## 9. PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

a) Appearance	Brownish solution
b) Odor	Cherry, caramel
c) Odor Threshold	No data available
d) pH	No data available
e) Melting point/freezing point	No data available
f) Initial boiling point and boiling range	No data available
g) Flash point	No data available
h) Evaporation rate	No data available
i) Flammability (solid, gas)	No data available
j) Upper/lower flammability or explosive limits	No data available
k) Vapor pressure	No data available
l) Vapor density	No data available
m) Relative density	No data available
n) Water solubility	No data available
o) Partition coefficient: n- octanol/water	No data available
p) Auto-ignition temperature	No data available
q) Decomposition temperature	No data available
r) Viscosity	No data available
s) Explosive properties	No data available
t) Oxidizing properties	No data available

### 9.2 Other safety information

No data available

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## 10. STABILITY AND REACTIVITY

### 10.1 Reactivity

No data available

### 10.2 Chemical stability

Stable under normal use and storage conditions.

### 10.3 Possibility of hazardous reactions

No data available

### 10.4 Conditions to avoid

No data available

**10.5 Incompatible materials**

Strong oxidizing agents

**10.6 Hazardous decomposition products**

No data available

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**11. TOXICOLOGICAL INFORMATION****11.1 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.

**Aspiration hazard**

No data available for the formulated product.

**Additional Information**

No data available.

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**12. ECOLOGICAL INFORMATION****12.1 Toxicity**

No data available on formulated product

**12.2 Persistence and degradability**

No data available

**12.3 Bioaccumulative potential**

No data available

**12.4 Mobility in soil**

No data available

**12.5 Results of PBT and vPvB assessment**

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

**12.6 Other adverse effects**

No data available

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**13. DISPOSAL CONSIDERATIONS****13.1 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.

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**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.

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**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.

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**16. OTHER INFORMATION**

**The above information is presented in good faith and believed to be accurate as of the date indicated. No warranty, expressed or implied is granted by Amneal Pharmaceuticals in regard to this information. Amneal Pharmaceuticals shall not be held liable for any damage resulting from improper handling or misuse of the above product.**

**Preparation Information**

Amneal Pharmaceuticals  
Regulatory Affairs  
Version: 1.0

Revision Date: 09/18/2018