

# Scientific Documentation

## Itraconazole, Micronized, USP

Not appropriate for regulatory submission.

Please visit [www.spectrumchemical.com](http://www.spectrumchemical.com) or contact Tech Services for the most up-to-date information contained in this information package.

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# Specification for Itraconazole, Micronized, USP (I2662)

Item Number	I2662
Item	Itraconazole, Micronized, USP
CAS Number	84625-61-6
Molecular Formula	$C_{35}H_{38}Cl_2N_8O_4$
Molecular Weight	705.64
MDL Number	
Synonyms	Oriconazole

Test	Specification	
	Min	Max
ASSAY (DRIED BASIS)	98.5	101.5 %
OPTICAL ROTATION, [α] 20D	-0.10° to +0.10°	
RESIDUE ON IGNITION		0.1 %
LOSS ON DRYING		0.5 %
ORGANIC IMPURITIES	TO PASS TEST	
ELEMENTAL IMPURITIES	AS REPORTED	
IDENTIFICATION	TO PASS TEST	
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS	TO PASS TEST	

## *Spectrum Chemical Mfg Corp*

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769 Jersey Ave.	14422 S. San Pedro St.
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## Certificate Of Analysis

Item Number	I2662	Lot Number	4KC0002
Item	Itraconazole, Micronized, USP	Manufacturer Lot	ITR/002/02/21M
CAS Number	84625-61-6	Manufacturer Code	15058
Molecular Formula	C <sub>35</sub> H <sub>38</sub> Cl <sub>2</sub> N <sub>8</sub> O <sub>4</sub>	Molecular Weight	705.64

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (DRIED BASIS)	98.5	101.5 %	99.6 %
OPTICAL ROTATION, [α] 20D	-0.10° to +0.10°		0.00
RESIDUE ON IGNITION		0.1 %	0.06 %
LOSS ON DRYING		0.5 %	0.0 %
ORGANIC IMPURITIES	TO PASS TEST		PASSES TEST
ELEMENTAL IMPURITIES	AS REPORTED		COMPLIES WITH STANDARD
IDENTIFICATION	TO PASS TEST		PASSES TEST
EXPIRATION DATE			31-DEC-2025
DATE OF MANUFACTURE			01-JAN-2021
APPEARANCE			WHITE POWDER
RESIDUAL SOLVENTS	TO PASS TEST		.
CLASS 2 (solvent) / N,N-DIMETHYLFORMAMIDE			NMT 880 PPM
CLASS 2 (SOLVENT) / METHANOL			NMT 3000 PPM
CLASS 2 (solvent) / TOLUENE			NMT 890 PPM

Certificate of Analysis Results Entered By:

AWILLIAMS  
Allison Williams  
25-MAR-21 09:57:39

Certificate of Analysis Results Approved By:

AWILLIAMS  
Allison Williams  
25-MAR-21 09:58:13

Spectrum Chemical Mfg Corp  
777 Jersey Avenue  
New Brunswick 08901 NJ



**All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.**

**Read and understand label and SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personnel only. It is the customer's responsibility to provide adequate hazardous material training and ensure that appropriate Personal Protective Equipment (PPE) is used before handling any chemical.**

The Elemental Impurities standards implemented by USP and other Pharmaceutical Compendia reflect a growing understanding of the toxicology of trace levels of elemental impurities that can remain in drug substances originating from either raw materials or manufacturing processes. Identifying and quantifying impurities can be critical to predicting the best possible patient outcomes. Elemental Impurities has been a requirement of all products meeting USP/NF, EP and BP monographs since January 1, 2018. More information can be found in USP sections <232> Elemental Impurities – Limits and <233> Elemental Impurities – Procedures. Data for drug substances furnished by Spectrum Chemical Mfg. Corp can be used to ensure that patient daily exposures by oral administration to the selected elements are not exceeded in the formulation of pharmaceutical products.

Spectrum Chemical Mfg. Corp. repackages Active Pharmaceutical Ingredient chemicals provided by other manufacturers and suppliers. For traceability purposes, Spectrum's Certificate of Analysis contains an identifier code unique to each manufacturer or supplier, as well as the chemical's lot number provided on the original manufacturer Certificate of Analysis. This material is manufactured by RA CHEM PHARMA LIMITED at Rs No 50/1, Mukteswarapuram Jaggalahpet Mandal, Krishna, Andhra Pradesh 521175, India (IND). Copies of the original Certificate of Analysis are available upon request from your Spectrum Sales Representative or by calling Spectrum's Quality Department at 1-800-772-8786.

# SAFETY DATA SHEET

Preparation Date: 3/09/2016

Revision Date: 6/19/2018

Revision Number: G2

## 1. IDENTIFICATION

### Product identifier

**Product code:** I2662  
**Product Name:** ITRACONAZOLE, MICRONIZED, USP

### Other means of identification

**Synonyms:** 3H-1,2,4-Triazol-3-one,  
 4-(4-(4-(4-((2-(2,4-dichlorophenyl)-2-(1H-1,2,4-triazol-1-ylmethyl)-1,3-dioxolan-4-yl)methoxy)phenyl)-1-piperazinyl)phenyl)-2,4-dihydro-2-(1-methylpropyl)-;  
 Oriconazole

**CAS #:** 84625-61-6  
**RTECS #** XZ5481000  
**CI#:** Not available

### Recommended use of the chemical and restrictions on use

**Recommended use:** Medication. Antifungal.  
**Uses advised against** No information available

**Supplier:** Spectrum Chemical Mfg. Corp  
 14422 South San Pedro St.  
 Gardena, CA 90248  
 (310) 516-8000

**Order Online At:** <https://www.spectrumchemical.com>

**Emergency telephone number** Chemtrec 1-800-424-9300

**Contact Person:** Martin LaBenz (West Coast)

**Contact Person:** Ibad Tirmiz (East Coast)

## 2. HAZARDS IDENTIFICATION

### Classification

This chemical is considered hazardous according to the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Considered a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Acute toxicity - Oral	Category 4
Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2A
Specific target organ toxicity (single exposure)	Category 3

### Label elements

#### **Warning**

#### **Hazard statements**

Harmful if swallowed

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MICRONIZED, USP

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Causes skin irritation  
Causes serious eye irritation  
May cause respiratory irritation



**Hazards not otherwise classified (HNOC)**

Not Applicable

**Other hazards**

Not available

**Precautionary Statements - Prevention**

Wash face, hands and any exposed skin thoroughly after handling  
Do not eat, drink or smoke when using this product  
Avoid breathing dust/fume/gas/mist/vapors/spray  
Wear protective gloves  
Wear eye/face protection  
Use only outdoors or in a well-ventilated area

**Precautionary Statements - Response**

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.  
IF ON SKIN: Wash with plenty of water  
If skin irritation occurs: Get medical advice/attention  
Take off contaminated clothing and wash it before reuse  
IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER or doctor/physician if you feel unwell.  
IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell  
Rinse mouth

**Precautionary Statements - Storage**

Store in a well-ventilated place. Keep container tightly closed  
Store locked up

**Precautionary Statements - Disposal**

Dispose of contents/container to an approved waste disposal plant

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Components	CAS-No.	Weight %
Itraconazole	84625-61-6	100

**4. FIRST AID MEASURES**

**First aid measures**

**General Advice:**

National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222.

**Skin Contact:**

Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention. If skin irritation persists, call a physician.

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**Eye Contact:** Flush eyes with water for 15 minutes. Get medical attention.

**Inhalation:** Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

**Ingestion:** Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Obtain medical attention.

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

**Symptoms**

- Irritating to eyes and skin
- Skin rash
- Irritating to respiratory system
- Upset stomach
- May cause stomach cramping
- Nausea
- Vomiting
- May cause diarrhea
- Central nervous system effects
- May affect the liver
- Jaundice
- Dark urine
- May cause loss of appetite
- May affect the cardiovascular system
- Hypertension
- Heart failure
- Hypokalemia
- Dyspnea (Shortness of breath and difficulty breathing)

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

**Notes to Physician:** Treat symptomatically.

**Protection of first-aiders**

First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste.

## 5. FIRE-FIGHTING MEASURES

**Extinguishing Media**

**Suitable Extinguishing Media:** Dry chemical. Carbon dioxide (CO<sub>2</sub>). Water spray mist or foam.

**Unsuitable Extinguishing Media:** No information available.

**Specific hazards arising from the chemical**

**Hazardous Combustion Products:** Carbon Monoxide, Carbon Dioxide. Nitrogen Oxides. Hydrogen Chloride Gas.

**Specific hazards:** May be combustible at high temperatures.

**Special Protective Actions for Firefighters**

**Specific Methods:** No information available.

**Special Protective Equipment for Firefighters:** As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear



## 6. ACCIDENTAL RELEASE MEASURES

### Personal precautions, protective equipment and emergency procedures

**Personal Precautions:** Ensure adequate ventilation. Keep people away from and upwind of spill/leak. Avoid contact with skin, eyes and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Use personal protective equipment. Avoid dust formation. Remove all sources of ignition.

**Environmental precautions** Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. Prevent entry into waterways, sewers, basements or confined areas.

### Methods and material for containment and cleaning up

**Methods for containment** Stop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.

**Methods for cleaning up** Sweep up and shovel into suitable containers for disposal. Clean contaminated surface thoroughly.

## 7. HANDLING AND STORAGE

### Precautions for safe handling

#### **Technical Measures/Precautions:**

Provide sufficient air exchange and/or exhaust in work rooms. Avoid dust formation. Keep away from incompatible materials.

#### **Safe Handling Advice**

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid dust formation. Do not ingest. Do not breathe vapors/dust. Keep away from heat and sources of ignition. Handle in accordance with good industrial hygiene and safety practice.

### Conditions for safe storage, including any incompatibilities

#### **Technical Measures/Storage Conditions:**

Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Protect from light. Sensitive to light. Store in light-resistant containers. Store away from incompatible materials.

#### **Incompatible Materials:**

Oxidizing agents

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Control parameters

#### **National occupational exposure limits**

##### **United States**

Components	CAS-No.	OSHA	NIOSH	ACGIH	AIHA WEEL
Itraconazole	84625-61-6	None	None	None	None

##### **Canada**

Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Itraconazole	84625-61-6	None	None	None	None

## Australia and Mexico

Components	CAS-No.	Australia	Mexico
Itraconazole	84625-61-6	None	None

### Appropriate engineering controls

#### Engineering measures to reduce exposure:

Ensure adequate ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

### Individual protection measures, such as personal protective equipment

#### Personal Protective Equipment

**Eye protection:** Goggles

**Skin and body protection:** Long sleeved clothing  
Chemical resistant apron  
Gloves

**Respiratory protection:** Wear respirator with dust filter. Be sure to use an approved/certified respirator or equivalent.

**Hygiene measures:** Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product. When using, do not eat, drink or smoke.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical state:</b> Solid	<b>Appearance:</b> Powder.	<b>Color:</b> White. Off-white. Slightly yellow.
<b>Odor:</b> None.	<b>Taste</b> No information available.	<b>Formula:</b> C35-H38-Cl2-N8-O4
<b>Molecular/Formula weight:</b> 705.63	<b>Flammability:</b> No information available	<b>Flashpoint (°C/°F):</b> No information available.
<b>Flash Point Tested according to:</b> Not applicable	<b>Autoignition Temperature (°C/°F):</b> No information available	<b>Lower Explosion Limit (%):</b> No information available
<b>Upper Explosion Limit (%):</b> No information available	<b>Melting point/range(°C/°F):</b> 163-170 °C/325.4-338 °F	<b>Decomposition temperature(°C/°F):</b> No information available
<b>Boiling point/range(°C/°F):</b> No information available	<b>Bulk density:</b> No information available	<b>Density (g/cm3):</b> No information available
<b>Specific gravity:</b> No information available	<b>pH:</b> No information available	<b>Vapor pressure @ 20°C (kPa):</b> No information available
<b>Evaporation rate:</b> No information available	<b>Vapor density:</b> No information available	<b>VOC content (g/L):</b> No information available
<b>Odor threshold (ppm):</b> No information available	<b>Partition coefficient (n-octanol/water):</b>	

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No information available

**Viscosity:**

No information available

**Miscibility:**

No information available

**Solubility:**

Practically insoluble in water

## 10. STABILITY AND REACTIVITY

**Reactivity**

Reactive with oxidizing agents

**Chemical stability**

**Stability:**

Stable under recommended storage conditions.

**Possibility of Hazardous Reactions:** Hazardous polymerization does not occur

**Conditions to avoid:**

Heat. Avoid dust formation. Incompatible materials. Exposure to light.

**Incompatible Materials:**

Oxidizing agents

**Hazardous decomposition products:**

Carbon monoxide. Carbon dioxide. Hydrogen chloride gas. Nitrogen oxides (NOx).

**Other Information**

**Corrosivity:**

No information available

**Special Remarks on Corrosivity:** No information available

## 11. TOXICOLOGICAL INFORMATION

**Information on likely routes of exposure**

**Principal Routes of Exposure:**

Ingestion. Inhalation.

**Acute Toxicity**

**Component Information**

Itraconazole

CAS-No. 84625-61-6

**LD50/oral/rat** = > 320 mg/kg Oral LD50 Rat

**LD50/oral/mouse** = No information available

**LD50/dermal/rabbit** = No information available

**LD50/dermal/rat** = No information available

**LC50/inhalation/rat** = No information available

**LC50/inhalation/mouse** = No information available

**Other LD50 or LC50 information** = No information available

**Product Information**

**LD50/oral/rat** =

**VALUE- Acute Tox Oral** = > 320 mg/kg

**LD50/oral/mouse** =

**Value - Acute Tox Oral** = No information available

**Product code:** I2662

**Product name:** ITRACONAZOLE,  
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**LD50/dermal/rabbit**

VALUE-Acute Tox Dermal = No information available

**LD50/dermal/rat**

VALUE -Acute Tox Dermal = No information available

**LC50/inhalation/rat**

VALUE-Vapor = No information available

VALUE-Gas = No information available

VALUE-Dust/Mist = No information available

**LC50/Inhalation/mouse**

VALUE-Vapor = No information available

VALUE - Gas = No information available

VALUE - Dust/Mist = No information available

**Symptoms**

**Skin Contact:** Causes skin irritation. Moderately irritating to the skin.

**Eye Contact:** Causes eye irritation. Moderately irritating to the eyes.

**Inhalation** Irritating to respiratory system.

**Ingestion** Harmful if swallowed. May cause digestive (gastrointestinal) tract irritation. May cause upset stomach. May cause loss of appetite. May cause nausea. May cause vomiting. May cause diarrhea. May cause abdominal discomfort. May cause stomach cramping. May affect the liver and cause jaundice, a yellowing of the skin and/or eyes. May cause skin rash, redness or itching. It may affect cardiovascular system (hypertension). May affect the cardiovascular system (palpitations). May affect the cardiovascular system (tachycardia). May cause hypokalemia. May cause swelling of the ankles, feet, legs. May affect behavior/central nervous system (dizziness, headache). May affect behavior/central nervous system (fatigue, weakness). May affect behavior/central nervous system (tiredness). May affect behavior/central nervous system (confusion). May cause coughing. May affect respiration (shortness of breath).

**Aspiration hazard** No information available.

**Delayed and immediate effects as well as chronic effects from short and long-term exposure**

**Chronic Toxicity** Prolonged or repeated ingestion may affect the liver (jaundice, liver function tests impaired). Prolonged or repeated ingestion may affect the liver (Hepatitis, jaundice). Prolonged or repeated ingestion may affect the blood (changes in serum composition). Prolonged or repeated ingestion may affect the adrenal gland. Prolonged or repeated ingestion may affect the heart (cardiomyopathy including infarction). Chronic exposure may affect the peripheral nervous system (peripheral neuropathy with muscle weakness, paresthesia - a sensation of tingling, pricking, or numbness of the skin (known as the feeling of "pins and needles) generally of the hands and feet (extremities). Prolonged or repeated ingestion may cause decreased libido, enlarged breasts in men. Prolonged or repeated ingestion may affect behavior/central nervous system.

**Sensitization:** May cause sensitization by skin contact.

**Mutagenic Effects:** No information available

**Carcinogenic effects:** Not considered carcinogenic.

Components	CAS-No.	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Itraconazole	84625-61-6	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

*ACGIH (American Conference of Governmental Industrial Hygienists)*

*IARC (International Agency for Research on Cancer)*

*NTP (National Toxicology Program)*

*OSHA (Occupational Safety and Health Administration of the US Department of Labor)*

**Reproductive toxicity** No data is available

**Reproductive Effects:** No information available

**Developmental Effects:** Itraconazole interfered with embryo development in experimental animals at maternally toxic dose levels by a mechanism that appeared not to be relevant to humans

**Teratogenic Effects:** There are no adequate and well-controlled studies in humans

No information available

**Specific Target Organ Toxicity**

**STOT - single exposure** No information available.

**STOT - repeated exposure** No information available.

**Target Organs:** No information available.

## 12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Ecotoxicity effects:** No data available.

**Persistence and degradability:** No information available

**Bioaccumulative potential:** No information available.

**Mobility:** No information available.

## 13. DISPOSAL CONSIDERATIONS

**Disposal Methods**

**Waste from residues / unused products:**

Waste must be disposed of in accordance with Federal, State and Local regulation.

**Contaminated packaging:**

Empty containers should be taken for local recycling, recovery or waste disposal

Components	CAS-No.	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Itraconazole	84625-61-6	None	None	None	None

## 14. TRANSPORT INFORMATION

**Product code:** I2662

**Product name:** ITRACONAZOLE,  
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**DOT**

<b>UN-No:</b>	Not Regulated
<b>Proper Shipping Name:</b>	No information available
<b>Hazard Class:</b>	No information available
<b>Subsidiary Class</b>	No information available
<b>Packing group:</b>	No information available
<b>Emergency Response Guide Number</b>	No information available
<b>Marine Pollutant</b>	No data available
<b>DOT RQ (lbs):</b>	No information available
<b>Special Provisions</b>	No Information available
<b>Symbol(s):</b>	No information available
<b>Description:</b>	No information available

**TDG (Canada)**

<b>UN-No:</b>	Not Regulated
<b>Proper Shipping Name:</b>	No information available
<b>Hazard Class:</b>	No information available
<b>Subsidiary Risk:</b>	No information available
<b>Packing Group:</b>	No information available
<b>Marine Pollutant</b>	No Information available
<b>Description:</b>	No information available

**ADR**

<b>UN-No:</b>	Not Regulated
<b>Proper Shipping Name:</b>	No information available
<b>Hazard Class:</b>	No information available
<b>Packing Group:</b>	No information available
<b>Subsidiary Risk:</b>	No information available

**IMO / IMDG**

<b>UN-No:</b>	Not Regulated
<b>Proper Shipping Name:</b>	No information available
<b>Hazard Class:</b>	No information available
<b>Subsidiary Risk:</b>	No information available
<b>Packing Group:</b>	No information available
<b>Marine Pollutant</b>	No information available

**RID**

<b>UN-No:</b>	Not Regulated
<b>Proper Shipping Name:</b>	No information available
<b>Hazard Class:</b>	No information available
<b>Subsidiary Risk:</b>	No information available
<b>Packing Group:</b>	No information available

**ICAO**

<b>UN-No:</b>	Not Regulated
<b>Proper Shipping Name:</b>	No information available
<b>Hazard Class:</b>	No information available
<b>Subsidiary Risk:</b>	No information available
<b>Packing Group:</b>	No information available

**IATA**

<b>UN-No:</b>	Not Regulated
<b>Proper Shipping Name:</b>	No information available
<b>Hazard Class:</b>	No information available
<b>Subsidiary Risk:</b>	No information available
<b>Packing Group:</b>	No information available

**ERG Code:**  
**Special Provisions**

No information available  
No information available

## 15. REGULATORY INFORMATION

### International Inventories

Components	CAS-No.	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
Itraconazole	84625-61-6	Not Listed	Not present	Not present	Not present	Not present	Present	Not present

### U.S. Regulations

#### California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.

##### Chemicals Known to the State of California to Cause Cancer:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

##### Chemicals Known to the State of California to Cause Reproductive Toxicity:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Components	CAS-No.	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Itraconazole	84625-61-6	Not Listed	Not Listed	Not Listed	Not Listed

### CERCLA/SARA

Components	CAS-No.	CERCLA - Hazardous Substances and their Reportable Quantities	Section 302 Extremely Hazardous Substances and TPQs	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category	Section 313 - Reporting de minimis
Itraconazole	84625-61-6	None	None	None	None	None

### U.S. TSCA

Components	CAS-No.	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Itraconazole	84625-61-6	Not Applicable	Not Applicable

### Canada

#### WHMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification Information:

The WHMIS 2015 classification of this product has not been validated or reviewed yet.

**Canada Hazardous Products Regulation** This product has been classified according to the hazard criteria of the HPR (Hazardous Products Regulation) and the SDS contains all of the information required by the HPR

#### WHMIS 1988 Hazard Class

D2B Toxic materials

D1B Toxic materials

#### Canada Controlled Products Regulation:

This product has been classified according to the hazard criteria of the CPR (Controlled Products Regulation) and the MSDS

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contains all of the information required by the CPR.

## Inventory

Components	CAS-No.	Canada (DSL)	Canada (NDSL)
Itraconazole	84625-61-6	Not Listed	Not Listed

Components	CAS-No.	CEPA Schedule I - Toxic Substances
Itraconazole	84625-61-6	Not listed
Components	CAS-No.	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Itraconazole	84625-61-6	Not listed

## EU Classification

### EU GHS - SV - CLP 1272/2008

Components	CAS-No.	EU GHS - SV - CLP (1272/2008)
Itraconazole	84625-61-6	

### EU - CLP (1272/2008)

### R-phrases(s)

R22 - Harmful if swallowed.

R36/37/38 - Irritating to eyes, respiratory system and skin.

### S -phrase(s)

S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S46 - If swallowed, seek medical advice immediately and show this container or label.

S37/39 - Wear suitable gloves and eye/face protection.

Components	CAS-No.	Classification	Concentration Limits:	Safety Phrases
Itraconazole	84625-61-6		No information	

The product is classified in accordance with Annex VI to Directive 67/548/EEC

### Indication of danger:

Xi - Irritant.

Xn - Harmful.

Xi



Xn



## 16. OTHER INFORMATION

Preparation Date: 3/09/2016  
Revision Date: 6/19/2018  
Prepared by: Sonia Owen

### Disclaimer:

All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or



implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

**End of Safety Data Sheet**



**Certification of Compliance with current Good Manufacturing Practices**

Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies that the following product(s) is produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

Catalog Number	Product Name
I2662	Itraconazole, Micronized, USP

Spectrum is an FDA registered and inspected Drug Establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

Spectrum-Gardena, CA: 2020632  
Spectrum-New Brunswick, NJ: 2246824

Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at [qualityassurance@spectrumchemical.com](mailto:qualityassurance@spectrumchemical.com)

Sincerely,

A handwritten signature in black ink, appearing to read "Oralia Chavez".

Oralia Chavez  
Quality Assurance Specialist

## I2662, Itraconazole, Micronized, USP

### Source Statement

The above mentioned catalog item is manufactured by chemical synthesis. No animal or plant derived products are used in the manufacturing process.

### BSE/TSE Statement

The above mentioned catalog item does not contain nor is manufactured using any animal derived products and is therefore, BSE/TSE free.

### Allergen Statement

The above mentioned catalog item does not contain any of the following:

- Milk
- Egg
- Fish
- Shellfish
- Tree Nuts
- Wheat
- Peanuts
- Soy
- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Corn
- Latex
- Sulfites > 10 ppm

### EU Fragrance Allergen Statement

The above mentioned catalog item does not contain any of the 26 EU fragrance allergens listed in Annex III lines 67-92. These substances are not intentionally added to the following chemical and therefore are not expected to be present.

### GMO Statement

The above mentioned catalog item is manufactured without the use of genetically modified organisms and is therefore GMO free.

### Melamine Statement

The above mentioned catalog does not use or add melamine to the manufacturing process and is considered melamine-free.

## **Nitrosamine Statement**

Based on knowledge of the manufacturing process, nitrosamine impurities are not known or suspected to be present in this material.

## **Animal Testing Statement**

The above mentioned catalog item has not been tested on animals.

## **Organic Compliance Statement**

The above mentioned catalog item has not been produced using GMOs, irradiation, ethylene oxide (EtO) or sewage sludge.

## **Shelf Life Statement**

The above mentioned catalog item is typically assigned a shelf life of 60 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

## **Other Chemicals Statement**

Spectrum does not have any reason to suspect the above mentioned catalog item contains any of the following chemicals. This product does not come into contact with these chemicals during packaging or storage:

- |                     |                 |
|---------------------|-----------------|
| • Aflatoxins        | • Parabens      |
| • Antibiotics       | • Pesticides    |
| • Bisphenol A (BPA) | • Phthalates    |
| • CMR Substances    | • Preservatives |



**RE: Elemental Impurities - Itraconazole, Micronized, USP (Cat# I2662)**

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. The following elemental impurities are likely to be present:

Elemental Impurity		Class	Expected Concentration
Palladium	Pd	2B	< 10 ppm

Other elemental impurities considered by USP <232>, <233> and ICH Q3D which are not addressed in the above mentioned table are not likely to be present. These substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

This information is subject to change and is intended for risk assessment only. It is responsibility of the end user to evaluate suitability of any chemical for the intended use as well as to assess compound-specific limits of daily intake of metal impurities. For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at [TechServices@spectrumchemical.com](mailto:TechServices@spectrumchemical.com).

Sincerely,

Technical Services  
Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.

CORPORATE HEADQUARTERS

769 Jersey Avenue  
New Brunswick, NJ 08901  
PHONE 732.214.1300  
FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street  
Gardena, California 90248  
PHONE 310.516.8000  
FAX 310.516.9843



**RE: Residual Solvents - Itraconazole, Micronized, USP (Cat# I2662)**

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned catalog item complies with the requirements of USP <467> Residual Solvents and ICH Q3C Residual Solvents Guideline. The following solvents are likely to be present:

Residual Solvent	Class	Expected Concentration
<i>N,N</i> -Dimethylformamide	2	< 880 ppm
Methanol	2	< 3000 ppm
Toluene	2	< 890 ppm

No Class 1, Class 3 or other solvents are used or produced in the manufacturing process of this material.

For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at [TechServices@spectrumchemical.com](mailto:TechServices@spectrumchemical.com).

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Gardena, California 90248

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## Label Information

The Spectrum label presents technical and safety information in an easily understood format. Our technical specialists stay abreast of the latest requirements of the Globally Harmonized System for Classification and Labelling of Chemicals (GHS), as well as the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA) and other government regulatory agencies in order to ensure compliance, accuracy and concise hazard communication. Below you will find a typical label example for this catalog item.

**WARNING**

• Harmful if swallowed • Causes serious eye irritation • Causes skin irritation • May cause respiratory irritation.

• Do not eat, drink or smoke when using this product • Wear protective gloves, eye protection, face protection • Avoid breathing dust • Use only outdoors or in a well-ventilated area • Wash face, hands and any exposed skin thoroughly after handling.

**FIRST AID:** Call a POISON CENTER or physician if you feel unwell. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical attention. IF ON SKIN: Wash with plenty of water. Take off contaminated clothing and wash it before reuse. If skin irritation occurs: Get medical attention. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF SWALLOWED: Rinse mouth.

**KEEP FROM CHILDREN**



**I2662**

**SIZ SY**

**Itraconazole**

Micronized

USP

CAS 84625-61-6

**CAUTION:** For manufacturing, processing, repacking, or for prescription compounding. Rx only.

**Read and understand the label and Safety Data Sheet (SDS) prior to use.**

**Chemical Emergency: (800)424-9300**

[www.SpectrumChemical.com](http://www.SpectrumChemical.com)

$C_{35}H_{38}Cl_2N_8O_4$  F.W. 705.64

Manufacturer/Supplier Code.....?

Manufacturer Lot Number.....?

Assay (Dried Basis).....98.0-102.0%

Optical Rotation,  $[\alpha]_D^{20}$ .....-0.10° to +0.10°

MAXIMUM LIMITS

Residue on Ignition.....0.1%

Loss on Drying.....0.5%

Organic Impurities:

4-Methoxy Derivative.....0.5%

4-Triazolyl Isomer.....0.5%

Propyl Analog.....0.5%

Isopropyl Analog.....0.5%

Epimer.....0.5%

n-Butyl Isomer.....0.5%

Didioxolanyl Analog.....0.5%

Any Unspecified Impurity.....0.10%

Total Impurities.....1.25%

Elemental Impurities.....As reported

Residual Solvents.....To pass test

LIGHT SENSITIVE: Keep tightly closed in light-resistant containers.

Repackaged by Spectrum as:

Lot No. XQ####

Exp. Date: 00-00-0000



**I2662**

**SIZ SY**

**Itraconazole**

Micronized

USP

CAS 84625-61-6

**CAUTION:** For manufacturing, processing, repacking, or for prescription compounding. Rx only.

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Total Impurities.....1.25%

Elemental Impurities.....As reported

Residual Solvents.....To pass test

LIGHT SENSITIVE: Keep tightly closed in light-resistant containers.

Repackaged by Spectrum as:

Lot No. XQ####

### Spectrum Chemical Mfg Corp

#### Corporate Headquarters:

769 Jersey Ave.  
New Brunswick, NJ 08901  
732.214.1300

#### West Coast Facility:

14422 S. San Pedro St.  
Gardena, CA 90248  
310.516.8000