

# Scientific Documentation

## Ketoconazole, 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.

Spectrum Chemical Mfg Corp  
769 Jersey Avenue  
New Brunswick, NJ 08901  
Phone 732.214.1300



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## Specification for Ketoconazole, USP (K1149)

Item Number	K1149
Item	Ketoconazole, USP
CAS Number	65277-42-1
Molecular Formula	C <sub>26</sub> H <sub>28</sub> Cl <sub>2</sub> N <sub>4</sub> O <sub>4</sub>
Molecular Weight	531.43
MDL Number	
Synonyms	(+/-)-cis-1-Acetyl-4-{4-[2-(2,4-dichlorophenyl)-2-imidazol-1-ylmethyl-1,3-dioxolan-4-ylmethoxy]phenyl}piperazine

Test	Specification	
	Min	Max
APPEARANCE		
ASSAY (DRIED BASIS)	98.0	102.0 %
SPECIFIC ROTATION [α] <sub>D</sub>	-1° to +1°	
LOSS ON DRYING		0.5 %
RESIDUE ON IGNITION		0.1 %
ELEMENTAL IMPURITIES	AS REPORTED	
ORGANIC IMPURITIES:		
ANY INDIVIDUAL UNSPECIFIED IMPURITY		0.10 %
TOTAL IMPURITIES		2.0 %
IDENTIFICATION (A) FTIR	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B)	RETENTION TIME CORRESPONDS TO STANDARD	
EXPIRATION DATE		
MANUFACTURE DATE		
MONOGRAPH EDITION		
RESIDUAL SOLVENTS	AS REPORTED	

*Spectrum Chemical Mfg Corp*

Corporate Headquarters: West Coast Facility:

769 Jersey Ave.	14422 S. San Pedro St.
New Brunswick, NJ 08901	Gardena, CA 90248
732.214.1300	310.516.8000

## Certificate Of Analysis

Item Number	K1149	Lot Number	1MC0447
Item	Ketoconazole, USP	Manufacturer Lot	KET/M35722
CAS Number	65277-42-1	Manufacturer Code	14246
Molecular Formula	C <sub>26</sub> H <sub>28</sub> Cl <sub>2</sub> N <sub>4</sub> O <sub>4</sub>	Molecular Weight	531.43

TEST	SPECIFICATION		RESULT
	MIN	MAX	
APPEARANCE			WHITE POWDER
ASSAY (DRIED BASIS)	98.0	102.0 %	99.5 %
SPECIFIC ROTATION [α] <sub>D</sub>	-1° to +1°		-1°
LOSS ON DRYING		0.5 %	0.0 %
RESIDUE ON IGNITION		0.1 %	0.0 %
ELEMENTAL IMPURITIES	AS REPORTED		COMPLIES WITH STANDARD
ORGANIC IMPURITIES:			.
ANY INDIVIDUAL UNSPECIFIED IMPURITY		0.10 %	0.00 %
TOTAL IMPURITIES		2.0 %	0.0 %
IDENTIFICATION (A) FTIR	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
IDENTIFICATION (B)	RETENTION TIME CORRESPONDS TO STANDARD		RETENTION TIME CORRESPONDS TO STANDARD
EXPIRATION DATE			30-SEP-2027
MANUFACTURE DATE			01-OCT-2022
MONOGRAPH EDITION			(USP) 2022
RESIDUAL SOLVENTS	AS REPORTED		.
CLASS 2 (SOLVENT) / METHANOL			<3000 ppm (M)
CLASS 2 (solvent) / METHYLENE CHLORIDE			<600 ppm (M)

TEST	SPECIFICATION		RESULT
	MIN	MAX	
NOTE:All results reported with (M) are from manufacturer certificate of analysis			

Certificate of Analysis Results Entered By:

HBERMUDEZ  
Hernan Bermudez  
12-MAY-23 08:27:33

Spectrum Chemical Mfg Corp  
14422 South San Pedro Street  
Gardena 90248 CA



Certificate of Analysis Results Approved By:

JAMAYA  
Javier Amaya  
12-MAY-23 09:03:52

**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 Piramal Pharma Limited at Sy.Nos. 7-70, 70/1 and 70/2, Digwal Village, Kohir Mandal, Sangareddy, Telangana 502321, 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

# spectrum®



Revision date 12-February-2020

Revision Number 2

## 1. Identification

### Product identifier

**Product Name** KETOCONAZOLE, USP

### Other means of identification

**Product Code(s)** K1149

**UN/ID no** UN2811

**Synonyms** None

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

**Recommended use** No information available

**Restrictions on use** No information available

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

#### Supplier Address

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

### Emergency telephone number

**Emergency Telephone** Chemtrec 1-800-424-9300

## 2. Hazard(s) identification

### Classification

Acute toxicity - Oral	Category 3
Reproductive toxicity	Category 1B
Specific target organ toxicity (repeated exposure)	Category 2

### Hazards not otherwise classified (HNOC)

Not applicable

### Label elements

**Danger**

#### Hazard statements

Toxic if swallowed  
May damage fertility or the unborn child  
May cause damage to organs through prolonged or repeated exposure



**Appearance** crystalline

**Physical state** Solid

**Odor** Odorless

**Precautionary Statements - Prevention**

Obtain special instructions before use  
Do not handle until all safety precautions have been read and understood  
Wear protective gloves/protective clothing/eye protection/face protection  
Wash face, hands and any exposed skin thoroughly after handling  
Do not eat, drink or smoke when using this product  
Do not breathe dust/fume/gas/mist/vapors/spray

**Precautionary Statements - Response**

IF exposed or concerned: Get medical advice/attention  
Specific treatment (see .? on this label)  
IF SWALLOWED: Immediately call a POISON CENTER or doctor  
Rinse mouth

**Precautionary Statements - Storage**

Store locked up

**Precautionary Statements - Disposal**

Dispose of contents/container to an approved waste disposal plant

**Other information**

Very toxic to aquatic life with long lasting effects. Very toxic to aquatic life.

### 3. Composition/information on ingredients

**Substance**

Chemical name	CAS No	Weight-%	Trade secret
Ketoconazole	65277-42-1	100	*

\*The exact percentage (concentration) of composition has been withheld as a trade secret.

### 4. First-aid measures

**Description of first aid measures**

<b>General advice</b>	Show this safety data sheet to the doctor in attendance.
<b>Inhalation</b>	Remove to fresh air.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
<b>Skin contact</b>	Wash skin with soap and water.
<b>Ingestion</b>	Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Get medical attention.

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



**Symptoms** No information available.

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

**Note to physicians** Treat symptomatically.

## **5. Fire-fighting measures**

**Suitable Extinguishing Media** Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

**Large Fire** CAUTION: Use of water spray when fighting fire may be inefficient.

**Unsuitable extinguishing media** Do not scatter spilled material with high pressure water streams.

**Specific hazards arising from the chemical** No information available.

**Explosion data**

**Sensitivity to mechanical impact** none.

**Sensitivity to static discharge** none.

**Special protective equipment for fire-fighters** Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

## **6. Accidental release measures**

**Personal precautions, protective equipment and emergency procedures**

**Personal precautions** Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas.

**Other information** Refer to protective measures listed in Sections 7 and 8.

**Methods and material for containment and cleaning up**

**Methods for containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up** Pick up and transfer to properly labeled containers.

## **7. Handling and storage**

**Precautions for safe handling**

**Advice on safe handling** Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes. Ensure adequate ventilation.

**Conditions for safe storage, including any incompatibilities**

**Storage Conditions** Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children. Store locked up.

## **8. Exposure controls/personal protection**

**Control parameters**

**Exposure Limits** The following ingredients are the only ingredients of the product above the cut-off level (or

level that contributes to the hazard classification of the mixture) which have an exposure limit applicable in the region for which this safety data sheet is intended or other recommended limit. At this time, the other relevant constituents have no known exposure limits from the sources listed here.

### **Appropriate engineering controls**

<b>Engineering controls</b>	Showers Eyewash stations Ventilation systems.
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### **Individual protection measures, such as personal protective equipment**

<b>Eye/face protection</b>	No special protective equipment required.
<b>Hand protection</b>	Wear suitable gloves.
<b>Skin and body protection</b>	Wear suitable protective clothing.
<b>Respiratory protection</b>	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.
<b>General hygiene considerations</b>	Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product.

## **9. Physical and chemical properties**

### **Information on basic physical and chemical properties**

<b>Physical state</b>	Solid
<b>Appearance</b>	crystalline
<b>Color</b>	white
<b>Odor</b>	Odorless
<b>Odor threshold</b>	No information available

<b><u>Property</u></b>	<b><u>Values</u></b>	<b><u>Remarks • Method</u></b>
<b>pH</b>	no data available	None known
<b>Melting point / freezing point</b>	146 - 147 °C / 294.8 - 296.6 °F	None known
<b>Boiling point / boiling range</b>	no data available	None known
<b>Flash point</b>	no data available	None known
<b>Evaporation rate</b>	no data available	None known
<b>Flammability (solid, gas)</b>	no data available	None known
<b>Flammability Limit in Air</b>		None known
<b>Upper flammability or explosive limits</b>	No data available	
<b>Lower flammability or explosive limits</b>	No data available	
<b>Vapor pressure</b>	No data available	None known
<b>Vapor density</b>	no data available	None known
<b>Relative density</b>	no data available	None known
<b>Water solubility</b>	No data available	None known
<b>Solubility(ies)</b>	no data available	None known
<b>Partition coefficient</b>	3.507	None known
<b>Autoignition temperature</b>	no data available	None known
<b>Decomposition temperature</b>		None known
<b>Kinematic viscosity</b>	no data available	None known
<b>Dynamic viscosity</b>	No data available	None known

### **Other information**

<b>Explosive properties</b>	No information available
<b>Oxidizing properties</b>	No information available
<b>Softening point</b>	No information available

<b>Molecular weight</b>	No information available
<b>VOC Content (%)</b>	No information available
<b>Liquid Density</b>	No information available
<b>Bulk density</b>	No information available

## 10. Stability and reactivity

<b>Reactivity</b>	No information available.
<b>Chemical stability</b>	Stable under normal conditions.
<b>Possibility of hazardous reactions</b>	None under normal processing.
<b>Conditions to avoid</b>	None known based on information supplied.
<b>Incompatible materials</b>	None known based on information supplied.
<b>Hazardous decomposition products</b>	Spontaneous polymerisation.

## 11. Toxicological information

### Information on likely routes of exposure

#### Product Information

<b>Inhalation</b>	Specific test data for the substance or mixture is not available.
<b>Eye contact</b>	Specific test data for the substance or mixture is not available.
<b>Skin contact</b>	Specific test data for the substance or mixture is not available.
<b>Ingestion</b>	Specific test data for the substance or mixture is not available. Toxic if swallowed. (based on components).

### Symptoms related to the physical, chemical and toxicological characteristics

<b>Symptoms</b>	No information available.
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### Acute toxicity

#### Numerical measures of toxicity

	166 mg/kg		
Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Ketoconazole 65277-42-1	= 166 mg/kg ( Rat )	-	-

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

<b>Skin corrosion/irritation</b>	No information available.
<b>Serious eye damage/eye irritation</b>	No information available.
<b>Respiratory or skin sensitization</b>	No information available.
<b>Germ cell mutagenicity</b>	No information available.
<b>Reproductive toxicity</b>	Contains a known or suspected reproductive toxin. Classification based on data available for ingredients. May damage fertility or the unborn child.
<b>STOT - single exposure</b>	No information available.
<b>STOT - repeated exposure</b>	May cause damage to organs through prolonged or repeated exposure.
<b>Aspiration hazard</b>	No information available.

<b>Other adverse effects</b>	No information available.
<b>Interactive effects</b>	No information available.

## 12. Ecological information

<b>Ecotoxicity</b>	Very toxic to aquatic life with long lasting effects.
<b>Persistence and degradability</b>	No information available.
<b>Bioaccumulation</b>	Inherently biodegradable.
<b>Other adverse effects</b>	No information available.

## 13. Disposal considerations

### Waste treatment methods

<b>Waste from residues/unused products</b>	Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.
<b>Contaminated packaging</b>	Do not reuse empty containers.

## 14. Transport information

### DOT

<b>UN/ID no</b>	UN2811
<b>Proper Shipping Name:</b>	Toxic solids, organic, n.o.s.
<b>Hazard class</b>	6.1
<b>Packing group:</b>	III
<b>Special Provisions</b>	IB8, IP3, T1, TP33
<b>Marine Pollutant</b>	Severe Marine Pollutant
<b>Description:</b>	UN2811, Toxic solids, organic, n.o.s. (Ketoconazole), 6.1, III
<b>Emergency Response Guide Number</b>	154

### TDG

<b>UN-No:</b>	UN2811
<b>Proper Shipping Name:</b>	Toxic solid, organic, n.o.s.
<b>Hazard class</b>	6.1
<b>Packing Group:</b>	III
<b>Description:</b>	UN2811, Toxic solid, organic, n.o.s. (Ketoconazole), 6.1, III

### MEX

<b>UN-No</b>	UN2811
<b>Proper Shipping Name</b>	Toxic solid, organic, n.o.s.
<b>Hazard class</b>	6.1
<b>Special Provisions</b>	223, 274
<b>Packing Group</b>	III
<b>Description</b>	UN2811, Toxic solid, organic, n.o.s. (Ketoconazole), 6.1, III

### ICAO (air)

<b>UN-No:</b>	UN2811
<b>Proper Shipping Name:</b>	Toxic solid, organic, n.o.s.
<b>Hazard class</b>	6.1
<b>Packing Group:</b>	III
<b>Special Provisions</b>	A3, A5
<b>Description:</b>	UN2811, Toxic solid, organic, n.o.s. (Ketoconazole), 6.1, III

### IATA

<b>UN number</b>	UN2811
<b>Proper Shipping Name:</b>	Toxic solid, organic, n.o.s.
<b>Transport hazard class(es)</b>	6.1
<b>Packing group</b>	III
<b>Description:</b>	UN2811, Toxic solid, organic, n.o.s. (Ketoconazole), 6.1, III

#### **IMDG**

<b>UN number</b>	UN2811
<b>Proper shipping name</b>	Toxic solid, organic, n.o.s.
<b>Transport hazard class(es)</b>	6.1
<b>Packing group</b>	III
<b>EmS-No</b>	F-A, S-A
<b>Special Provisions</b>	223, 274
<b>Marine pollutant</b>	P
<b>Description</b>	UN2811, Toxic solid, organic, n.o.s. (Ketoconazole), 6.1, III, Marine pollutant

#### **RID**

<b>UN number</b>	UN2811
<b>Proper Shipping Name:</b>	Toxic solid, organic, n.o.s.
<b>Transport hazard class(es)</b>	6.1
<b>Packing group</b>	III
<b>Classification code</b>	T2
<b>Special Provisions</b>	274, 614
<b>Description:</b>	UN2811, Toxic solid, organic, n.o.s. (Ketoconazole), 6.1, III, ENVIRONMENTALLY HAZARDOUS
<b>Labels</b>	6.1

#### **ADR**

<b>UN number</b>	2811
<b>Proper Shipping Name:</b>	Toxic solid, organic, n.o.s.
<b>Transport hazard class(es)</b>	6.1
<b>Packing group</b>	III
<b>Classification code</b>	T2
<b>Tunnel restriction code</b>	(E)
<b>Special Provisions</b>	274, 614
<b>Description:</b>	2811, Toxic solid, organic, n.o.s. (Ketoconazole), 6.1, III, (E), ENVIRONMENTALLY HAZARDOUS
<b>Labels</b>	6.1

#### **ADN**

<b>UN/ID No</b>	UN2811
<b>Proper shipping name</b>	Toxic solid, organic, n.o.s.
<b>Transport hazard class(es)</b>	6.1
<b>Packing Group</b>	III
<b>Classification code</b>	T2
<b>Special Provisions</b>	274, 614, 802
<b>Description</b>	UN2811, Toxic solid, organic, n.o.s. (Ketoconazole), 6.1, III, ENVIRONMENTALLY HAZARDOUS
<b>Hazard label(s)</b>	6.1
<b>Limited quantity (LQ)</b>	5 kg
<b>Equipment Requirements</b>	PP, EP

## **15. Regulatory information**

### **International Inventories**

<b>TSCA</b>	Not listed
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\*Contact supplier for details. One or more substances in this product are either not listed on the US TSCA inventory, listed on the confidential US TSCA inventory or are otherwise exempted from inventory listing requirements

<b>DSL/NDL</b>	Complies
<b>EINECS/ELINCS</b>	Complies
<b>ENCS</b>	This product complies with encs:

**IECSC**  
**KECL**  
**PICCS**  
**AICS**

This product does not comply with china:  
Complies  
Does not Comply  
All the constituents of this material are listed on the Australian Inventory of Chemical Substances (AICS).

**Legend:**

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory  
**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List  
**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances  
**ENCS** - Japan Existing and New Chemical Substances  
**IECSC** - China Inventory of Existing Chemical Substances  
**KECL** - Korean Existing and Evaluated Chemical Substances  
**PICCS** - Philippines Inventory of Chemicals and Chemical Substances

**US Federal Regulations**

**SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

**SARA 311/312 Hazard Categories**

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

**CWA (Clean Water Act)**

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

**CERCLA**

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

**US State Regulations**

**California Proposition 65**

This product does not contain any Proposition 65 chemicals.

**U.S. State Right-to-Know Regulations**

This product does not contain any substances regulated under applicable state right-to-know regulations

**U.S. EPA Label Information**

**EPA Pesticide Registration Number** Not applicable

**16. Other information**

**NFPA**

**Health hazards** 0

**Flammability** 0

**Instability** 0

**Physical and chemical properties** -

**HMIS**

**Health hazards** 1\*

**Flammability** 0

**Physical hazards** 0  
**Personal protection** X  
*Chronic Hazard Star Legend*

\* = Chronic Health Hazard

**Key or legend to abbreviations and acronyms used in the safety data sheet**

**Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	Skin designation

**Key literature references and sources for data used to compile the SDS**

Agency for Toxic Substances and Disease Registry (ATSDR)  
U.S. Environmental Protection Agency ChemView Database  
European Food Safety Authority (EFSA)  
EPA (Environmental Protection Agency)  
Acute Exposure Guideline Level(s) (AEGLS)  
U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act  
U.S. Environmental Protection Agency High Production Volume Chemicals  
Food Research Journal  
Hazardous Substance Database  
International Uniform Chemical Information Database (IUCLID)  
Japan GHS Classification  
Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)  
NIOSH (National Institute for Occupational Safety and Health)  
National Library of Medicine's ChemID Plus (NLM CIP)  
National Library of Medicine's PubMed database (NLM PUBMED)  
National Toxicology Program (NTP)  
New Zealand's Chemical Classification and Information Database (CCID)  
Organization for Economic Co-operation and Development Environment, Health, and Safety Publications  
Organization for Economic Co-operation and Development High Production Volume Chemicals Program  
Organization for Economic Co-operation and Development Screening Information Data Set  
World Health Organization

**Revision date** 12-February-2020  
**Revision Note** No information available.

**Disclaimer**

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

**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
K1149	Ketoconazole, 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", written in a cursive style.

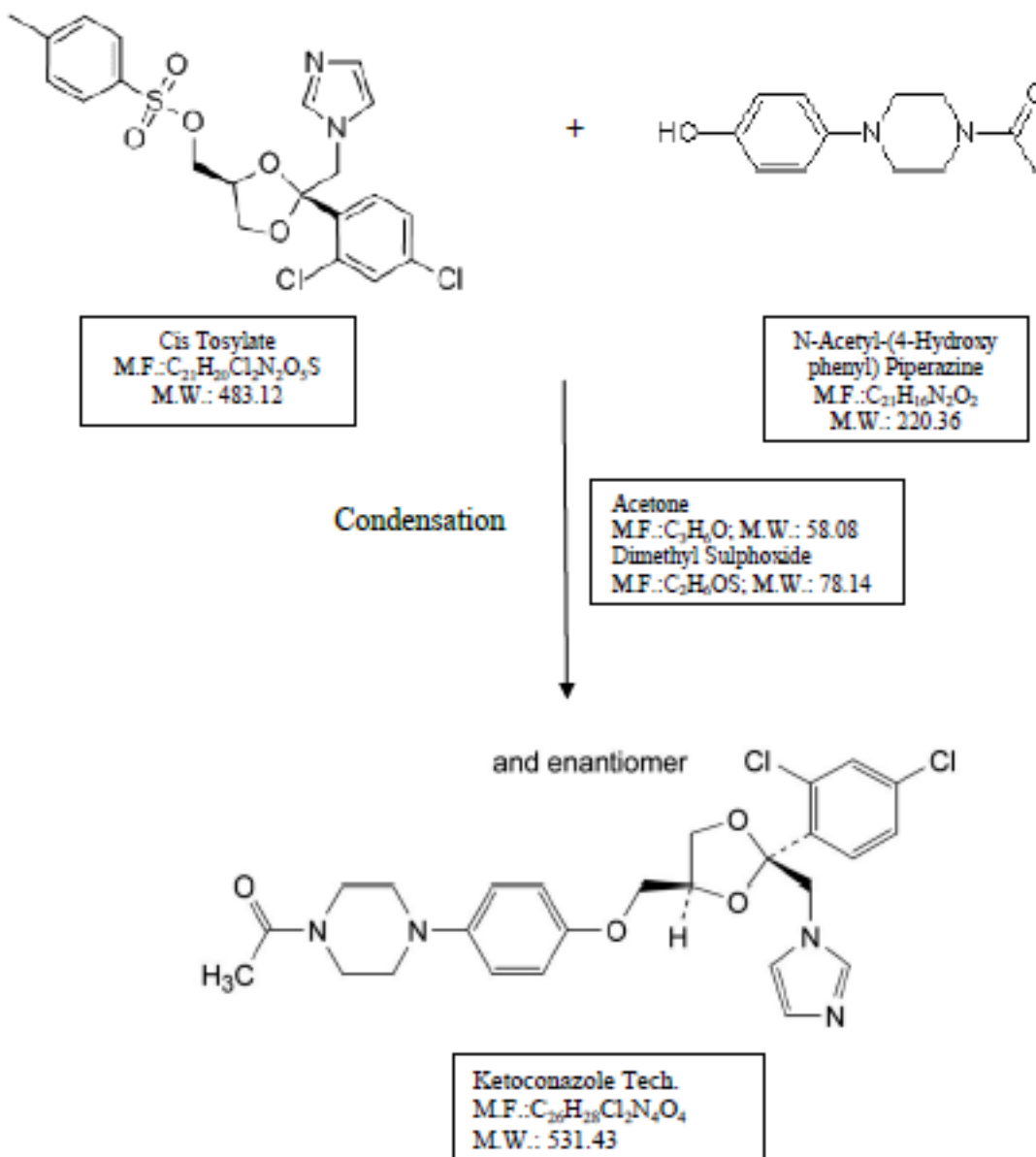
Oralia Chavez  
Quality Assurance Specialist



## Manufacturing Process Flowchart Ketoconazole, USP (Cat# K1149)

### A. Reaction Scheme:

#### i) Stage-I : Ketoconazole Tech



#### CORPORATE HEADQUARTERS

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14422 South San Pedro Street

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PHONE 310.516.8000

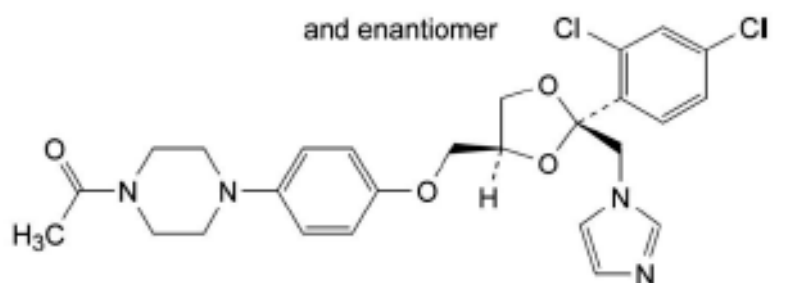
FAX 310.516.9843

**3.2. S DRUG SUBSTANCE**

**3.2. S.2 MANUFACTURE**

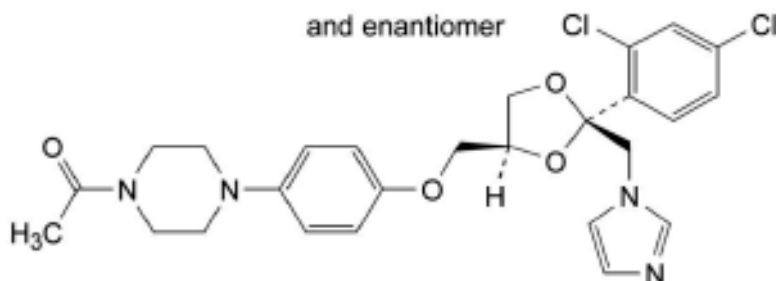
**3.2. S.2.2 Description of Manufacturing Process and Process Controls**

**ii) Stage-II : Ketoconazole (Pharma)**



Ketoconazole Tech.  
M.F.:  $C_{26}H_{28}Cl_2N_4O_4$   
M.W.: 531.43

Methanol  
M.F.:  $CH_4O$ ; M.W.: 32.04



Ketoconazole Pharma  
M.F.:  $C_{26}H_{28}Cl_2N_4O_4$   
M.W.: 531.43

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**WEST COAST FACILITY**

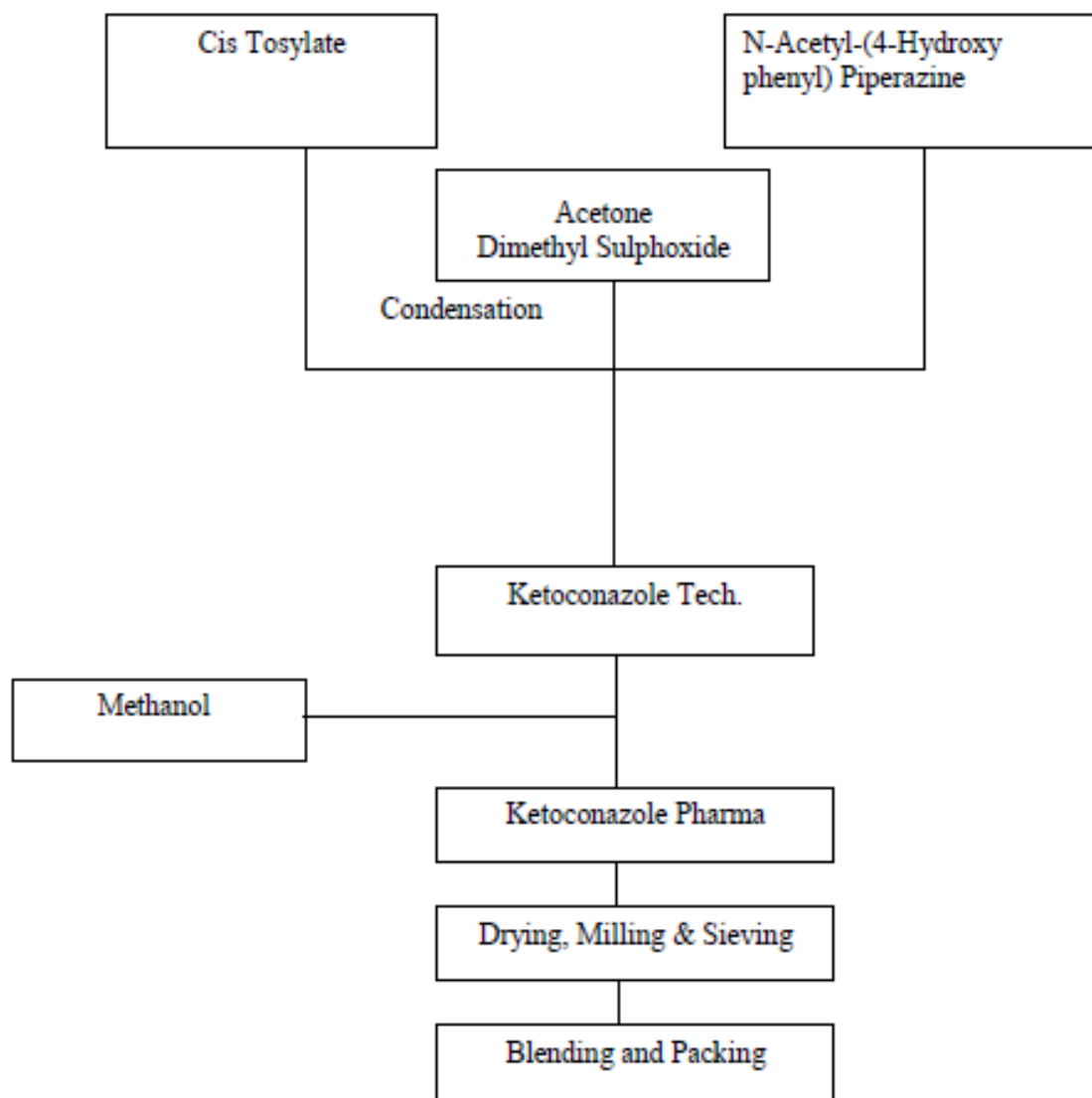
14422 South San Pedro Street

Gardena, California 90248

PHONE 310.516.8000

FAX 310.516.9843

**3.2. S DRUG SUBSTANCE**  
**3.2. S.2 MANUFACTURE**  
**3.2. S.2.2 Description of Manufacturing Process and Process Controls**  
**B. Manufacturing process flow Chart:**



**CORPORATE HEADQUARTERS**

769 Jersey Avenue  
New Brunswick, NJ 08901  
PHONE 732.214.1300  
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## K1149, Ketoconazole, 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 - Ketoconazole, USP (Cat# K1149)**

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
Nickel	Ni	2A	< 5.0 ppm
Molybdenum	Mo	3	< 75 ppm
Chromium	Cr	3	< 275 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.

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New Brunswick, NJ 08901  
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**RE: Residual Solvents - Ketoconazole, USP (Cat# K1149)**

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
Methanol	2	< 3000 ppm
Methylene Chloride	2	< 600 ppm
Acetic Acid	3	< 5000 ppm
Dimethyl Sulfoxide	3	< 5000 ppm

No Class 1 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).

Sincerely,

Technical Services  
Spectrum Chemical Mfg. Corp.

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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.



Exp. Date: 00-00-0000



**DANGER**

• Toxic if swallowed • May damage fertility or the unborn child • May cause damage to organs through prolonged or repeated exposure.

• Obtain special instructions before use • Do not handle until all safety precautions have been read and understood • Do not eat, drink or smoke when using this product • Wear protective gloves, protective clothing, eye protection, face protection • Do not breathe dust • Wash face, hands and any exposed skin thoroughly after handling.

**FIRST AID:** Immediately call a POISON CENTER or physician. IF SWALLOWED: Rinse mouth.

**KEEP FROM CHILDREN**

**K1149                      SIZ SY**

**Ketoconazole**

**USP**

CAS 65277-42-1

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

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

DOT: UN2811, Toxic solid, organic, n.o.s. (ketoconazole), 6.1, PG III

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

www.SpectrumChemical.com

$C_{26}H_{28}Cl_2N_4O_4$                       F.W. 531.43

Manufacturer/Supplier Code .....?

Manufacturer Lot Number .....?

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

Specific Rotation,  $[\alpha]_D^{20}$  ..... -1° to +1°

MAXIMUM LIMITS

Loss on Drying ..... 0.5%

Residue on Ignition ..... 0.1%

Elemental Impurities ..... As reported

Organic Impurities:

Any Individual Unspecified Impurity ..... 0.10%

Total Impurities ..... 2.0%

Residual Solvents ..... To pass test

**WARNING:** Cancer and Reproductive Harm-  
www.P65Warnings.ca.gov

Repackaged by Spectrum as:

B 8/J2GHS-A                      ?                      Lot No. XQ####

### Spectrum Chemical Mfg Corp

#### Corporate Headquarters:

769 Jersey Ave.  
New Brunswick, NJ 08901  
732.214.1300

#### West Coast Facility:

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