

Occupational Safety and Health (Classification, Labelling and Safety Data Sheet of Hazardous Chemicals) Regulations 2013

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING
Product Identifier

Nama Produk **Ketoconazole**
Product Description: **Ketoconazole**
Cat No. : BP2734-1; BP2734-100; BP2734-50; BP2734-500
Synonyms 1-[4-[4-[[[(2SR,4RS)-2-(2,4-dichlorophenyl)-2-(imidazol-1-ylmethyl)-1,3-dioxolan-4-yl]methoxy]phenyl]piperazin-1-yl]ethanone
CAS-No 65277-42-1
Molecular Formula C₂₆H₂₈N₄O₄Cl₂

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

Recommended Use Laboratory chemicals.
Uses advised against No Information available

Details of the supplier of the safety data sheet

Company Fisher Scientific (M) Sdn Bhd No. 3, Jalan Sepadu 25/123,
 Taman Perindustrian Axis, Seksyen 25,
 40400 Shah Alam, Selangor Darul Ehsan, Malaysia.

Supplier
E-mail address Enquiry.my@thermofisher.com

Emergency Telephone Number
 (603) 5122 8888

SECTION 2: HAZARDS IDENTIFICATION
Classification of the substance or mixture

Acute oral toxicity	Category 3 (H301)
Reproductive Toxicity	Category 1B (H360F)
Specific target organ toxicity - (repeated exposure)	Category 2 (H373)
Acute aquatic toxicity	Category 1 (H400)
Chronic aquatic toxicity	Category 1 (H410)

Label Elements

Signal Word
Danger
Hazard Statements

H301 - Toxic if swallowed
 H360F - May damage fertility
 H373 - May cause damage to organs through prolonged or repeated exposure

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H410 - Very toxic to aquatic life with long lasting effects

Precautionary Statements

P264 - Wash face, hands and any exposed skin thoroughly after handling
P301 + P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician
P201 - Obtain special instructions before use
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P308 + P313 - IF exposed or concerned: Get medical advice/attention

Other Hazards

No information available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS-No	Weight %
Ketoconazole	65277-42-1	>95

SECTION 4: FIRST AID MEASURES

Description of first aid measures

General Advice

Show this safety data sheet to the doctor in attendance. Immediate medical attention is required.

Eye Contact

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

Skin Contact

Wash off immediately with plenty of water for at least 15 minutes. Immediate medical attention is required.

Ingestion

Do NOT induce vomiting. Call a physician or poison control center immediately.

Inhalation

Remove to fresh air. If not breathing, give artificial respiration. Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Immediate medical attention is required.

Self-Protection of the First Aider

Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination.

Most important symptoms and effects, both acute and delayed

None reasonably foreseeable.

Indication of any immediate medical attention and special treatment needed

Notes to Physician

Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

Extinguishing media

Suitable Extinguishing Media

Water spray, carbon dioxide (CO₂), dry chemical, alcohol-resistant foam.

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Extinguishing media which must not be used for safety reasons

No information available.

Special hazards arising from the substance or mixture

Keep product and empty container away from heat and sources of ignition. Do not allow run-off from fire-fighting to enter drains or water courses.

Hazardous Combustion Products

Carbon monoxide (CO), Carbon dioxide (CO₂), Nitrogen oxides (NO_x), Hydrogen chloride gas.

Advice for fire-fighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear. Thermal decomposition can lead to release of irritating gases and vapors.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Ensure adequate ventilation. Use personal protective equipment as required. Avoid dust formation. Keep people away from and upwind of spill/leak. Evacuate personnel to safe areas.

Environmental precautions

Do not flush into surface water or sanitary sewer system. Do not allow material to contaminate ground water system. Prevent product from entering drains. Local authorities should be advised if significant spillages cannot be contained.

Methods and Material for Containment and Cleaning Up

Sweep up and shovel into suitable containers for disposal. Avoid dust formation.

Reference to Other Sections

Refer to protective measures listed in Sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

Precautions for Safe Handling

Wear personal protective equipment/face protection. Do not get in eyes, on skin, or on clothing. Avoid dust formation. Use only under a chemical fume hood. Do not breathe (dust, vapor, mist, gas). Do not ingest.

Conditions for Safe Storage, Including any Incompatibilities

Keep containers tightly closed in a dry, cool and well-ventilated place. Keep refrigerated.

Specific End Uses

Use in laboratories.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Control Parameters

Exposure Controls

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Engineering Measures

Use only under a chemical fume hood. Ensure that eyewash stations and safety showers are close to the workstation location. Wherever possible, engineering control measures such as the isolation or enclosure of the process, the introduction of process or equipment changes to minimise release or contact, and the use of properly designed ventilation systems, should be adopted to control hazardous materials at source

Personal protective equipment

Eye Protection	Wear safety glasses with side shields (or goggles)
Hand Protection	Protective gloves
Skin and body protection	Long sleeved clothing

Inspect gloves before use.

Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. (Refer to manufacturer/supplier for information)

Ensure gloves are suitable for the task: Chemical compatability, Dexterity, Operational conditions, User susceptibility, e.g. sensitisation effects, also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion.

Remove gloves with care avoiding skin contamination.

Respiratory Protection	When workers are facing concentrations above the exposure limit they must use appropriate certified respirators
Recommended Filter type:	Particulates filter conforming to EN 143 To protect the wearer, respiratory protective equipment must be the correct fit and be used and maintained properly When RPE is used a face piece Fit Test should be conducted

Hygiene Measures Handle in accordance with good industrial hygiene and safety practice

Environmental exposure controls Prevent product from entering drains Do not allow material to contaminate ground water system Local authorities should be advised if significant spillages cannot be contained

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance	White	
Physical State	Solid	
Odor	No information available	
Odor Threshold	No data available	
pH	No information available	
Melting Point/Range	148 - 150 °C / 298.4 - 302 °F	
Softening Point	No data available	
Boiling Point/Range	No information available	
Flash Point	Not applicable	Method - No information available
Evaporation Rate	Not applicable	Solid
Flammability (solid,gas)	No information available	
Explosion Limits	No data available	
Vapor Pressure	No data available	
Vapor Density	Not applicable	Solid
Specific Gravity / Density	No data available	

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Bulk Density	No data available
Water Solubility	No information available
Solubility in other solvents	No information available

Partition Coefficient (n-octanol/water)

Component	log Pow
Ketoconazole	4.34

Autoignition Temperature	No data available	
Decomposition Temperature	Not applicable	Solid
Viscosity	No information available	
Explosive Properties	No information available	
Oxidizing Properties	No information available	

Molecular Formula	C ₂₆ H ₂₈ N ₄ O ₄ Cl ₂
Molecular Weight	531.1264

SECTION 10: STABILITY AND REACTIVITY

Reactivity

None known, based on information available.

Chemical Stability

Stable under normal conditions.

Possibility of Hazardous Reactions

Hazardous Polymerization	Hazardous polymerization does not occur.
Hazardous Reactions	None under normal processing.

Conditions to Avoid

Incompatible products. Excess heat. Avoid dust formation.

Incompatible Materials

Strong oxidizing agents.

Hazardous Decomposition Products

Carbon monoxide (CO). Carbon dioxide (CO₂). Nitrogen oxides (NO_x). Hydrogen chloride gas.

SECTION 11: TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

Acute Toxicity

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Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
Ketoconazole	LD50 = 166 mg/kg (Rat)		

Chronic Toxicity

Carcinogenicity

There are no known carcinogenic chemicals in this product

Sensitization

No information available

Mutagenic Effects

No information available

Reproductive Effects

May impair fertility

Developmental Effects

No information available

Target Organs

Liver, Endocrine System.

Endocrine Disruptor Information

Component	EU - Endocrine Disruptors Candidate List	EU - Endocrine Disruptors - Evaluated Substances	Japan - Endocrine Disruptor Information
Ketoconazole	Group III Chemical		

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity effects

Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. The product contains following substances which are hazardous for the environment.

Persistence and degradability

Degradation in sewage treatment plant

No information available

Contains substances known to be hazardous to the environment or not degradable in waste water treatment plants.

Bioaccumulative potential

No information available

Component	log Pow	Bioconcentration factor (BCF)
Ketoconazole	4.34	No data available

Mobility in soil

No information available.

Other adverse effects

No information available

SECTION 13: DISPOSAL CONSIDERATIONS

Waste treatment methods

Waste from Residues/Unused Products

Should not be released into the environment Waste is classified as hazardous Dispose of in accordance with the European Directives on waste and hazardous waste Dispose of in accordance with local regulations

Contaminated Packaging

Dispose of this container to hazardous or special waste collection point.

Other Information

Do not dispose of waste into sewer Waste codes should be assigned by the user based on the application for which the product was used Do not empty into drains Do not let this

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chemical enter the environment

SECTION 14: TRANSPORT INFORMATION

IMDG/IMO

UN-No UN2811
Hazard Class 6.1
Packing Group III
Proper Shipping Name Toxic solid, organic, n.o.s.
Ketoconazole

Road and Rail Transport

UN-No UN2811
Hazard Class 6.1
Packing Group III
Proper Shipping Name Toxic solid, organic, n.o.s.
Ketoconazole

IATA

UN-No UN2811
Hazard Class 6.1
Packing Group III
Proper Shipping Name Toxic solid, organic, n.o.s.
Ketoconazole

Special Precautions for User No special precautions required

SECTION 15: REGULATORY INFORMATION

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

International Inventories X = listed

Component	EINECS	ELINCS	NLP	TSCA	DSL	NDSL	PICCS	ENCS	IECSC	AICS	KECL
Ketoconazole	265-667-4	-		-	X	-	-	-	-	X	KE-0011 6

National Regulations

Persistent Organic Pollutant This product does not contain any known or suspected substance
Ozone Depletion Potential This product does not contain any known or suspected substance

SECTION 16: OTHER INFORMATION

Legend

CAS - Chemical Abstracts Service

TSCA - United States Toxic Substances Control Act Section 8(b)
Inventory

EINECS/ELINCS - European Inventory of Existing Commercial Chemical

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Substances/EU List of Notified Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances
IECSC - Chinese Inventory of Existing Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

ENCS - Japanese Existing and New Chemical Substances
AICS - Australian Inventory of Chemical Substances
NZIoC - New Zealand Inventory of Chemicals

WEL - Workplace Exposure Limit

ACGIH - American Conference of Governmental Industrial Hygienists

RPE - Respiratory Protective Equipment

LC50 - Lethal Concentration 50%

POW - Partition coefficient Octanol:Water

TWA - Time Weighted Average

IARC - International Agency for Research on Cancer

LD50 - Lethal Dose 50%

EC50 - Effective Concentration 50%

ADR - European Agreement Concerning the International Carriage of Dangerous Goods by Road

IMO/IMDG - International Maritime Organization/International Maritime Dangerous Goods Code

OECD - Organisation for Economic Co-operation and Development

BCF - Bioconcentration factor

ICAO/IATA - International Civil Aviation Organization/International Air Transport Association

MARPOL - International Convention for the Prevention of Pollution from Ships

ATE - Acute Toxicity Estimate

VOC (volatile organic compound)

Key literature references and sources for data

Suppliers safety data sheet, Chemadvisor - LOLI, Merck index, RTECS

Revision Date 07-Feb-2020

Revision Summary SDS sections updated.

In accordance with local and national regulations: Occupational Safety and Health (Classification, Labelling and Safety Data Sheet of Hazardous Chemicals) Regulations 2013

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