

SAFETY DATA SHEET

Creation Date 12-Jul-2010

Revision Date 18-Jan-2018

Revision Number 4

1. Identification

Product Name Ketoconazole

Cat No. : BP2734-1; BP2734-50; BP2734-100; BP2734-500

CAS-No 65277-42-1

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

Recommended Use Laboratory chemicals.

Uses advised against Not for food, drug, pesticide or biocidal product use

Details of the supplier of the safety data sheet**Company**

Fisher Scientific
One Reagent Lane
Fair Lawn, NJ 07410
Tel: (201) 796-7100

Emergency Telephone Number

CHEMTREC®, Inside the USA: 800-424-9300
CHEMTREC®, Outside the USA: 001-703-527-3887

2. Hazard(s) identification**Classification**

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

| | |
|--|-------------|
| Acute oral toxicity | Category 3 |
| Reproductive Toxicity | Category 1B |
| Specific target organ toxicity - (repeated exposure) | Category 1 |
| Target Organs - Liver. | |

Label Elements**Signal Word**

Danger

Hazard Statements

Toxic if swallowed
May damage fertility
Causes damage to organs through prolonged or repeated exposure

**Precautionary Statements****Prevention**

Obtain special instructions before use
Do not handle until all safety precautions have been read and understood
Use personal protective equipment as required
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

Response

IF exposed or concerned: Get medical attention/advice

Ingestion

IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician
Rinse mouth

Storage

Store locked up

Disposal

Dispose of contents/container to an approved waste disposal plant

Hazards not otherwise classified (HNOC)

Very toxic to aquatic life with long lasting effects

3. Composition/Information on Ingredients

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

4. First-aid measures

| | |
|--|--|
| Eye Contact | Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention. |
| Skin Contact | Wash off immediately with plenty of water for at least 15 minutes. Obtain medical attention. |
| Inhalation | Move to fresh air. 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. If not breathing, give artificial respiration. |
| Ingestion | Do not induce vomiting. Call a physician or Poison Control Center immediately. |
| Most important symptoms and effects | No information available. |
| Notes to Physician | Treat symptomatically |

5. Fire-fighting measures

| | |
|---------------------------------------|--|
| Suitable Extinguishing Media | Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide. |
| Unsuitable Extinguishing Media | No information available |

| | |
|--------------------|--------------------------|
| Flash Point | No information available |
| Method - | No information available |

Autoignition Temperature**Explosion Limits**

| | |
|---|--------------------------|
| Upper | No data available |
| Lower | No data available |
| Sensitivity to Mechanical Impact | No information available |
| Sensitivity to Static Discharge | No information available |

Specific Hazards Arising from the Chemical

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

Protective Equipment and Precautions for Firefighters

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.

NFPA

Health
3

Flammability
1

Instability
0

Physical hazards
N/A

6. Accidental release measures

Personal Precautions

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

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 for Containment and Clean Up

Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dust formation.

7. Handling and storage

Handling

Use only under a chemical fume hood. Wear personal protective equipment. Do not get in eyes, on skin, or on clothing. Avoid dust formation. Do not breathe vapors/dust. Do not ingest.

Storage

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

8. Exposure controls / personal protection

Exposure Guidelines

This product does not contain any hazardous materials with occupational exposure limit established by the region specific regulatory bodies.

Engineering Measures

Use only under a chemical fume hood. Ensure that eyewash stations and safety showers are close to the workstation location.

Personal Protective Equipment**Eye/face Protection**

Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166.

Skin and body protection

Wear appropriate protective gloves and clothing to prevent skin exposure.

Respiratory Protection

Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

| | |
|---|---|
| Physical State | Solid |
| Appearance | White |
| Odor | No information available |
| Odor Threshold | No information available |
| pH | No information available |
| Melting Point/Range | 148 - 150 °C / 298.4 - 302 °F |
| Boiling Point/Range | No information available |
| Flash Point | No information available |
| Evaporation Rate | Not applicable |
| Flammability (solid,gas) | No information available |
| Flammability or explosive limits | |
| Upper | No data available |
| Lower | No data available |
| Vapor Pressure | No information available |
| Vapor Density | Not applicable |
| Specific Gravity | No information available |
| Solubility | No information available |
| Partition coefficient; n-octanol/water | No data available |
| Autoignition Temperature | |
| Decomposition Temperature | No information available |
| Viscosity | Not applicable |
| Molecular Formula | C ₂₆ H ₂₈ N ₄ O ₄ Cl ₂ |
| Molecular Weight | 531.1264 |

10. Stability and reactivity

| | |
|---|--|
| Reactive Hazard | None known, based on information available |
| Stability | Stable under normal conditions. |
| Conditions to Avoid | Incompatible products. Excess heat. Avoid dust formation. |
| Incompatible Materials | Strong oxidizing agents |
| Hazardous Decomposition Products | Carbon monoxide (CO), Carbon dioxide (CO ₂), Nitrogen oxides (NO _x), Hydrogen chloride gas |
| Hazardous Polymerization | Hazardous polymerization does not occur. |
| Hazardous Reactions | None under normal processing. |

11. Toxicological information

Acute Toxicity
Product Information
Component Information

| Component | LD50 Oral | LD50 Dermal | LC50 Inhalation |
|--------------|--------------------------|-------------|-----------------|
| Ketoconazole | LD50 = 166 mg/kg (Rat) | Not listed | Not listed |

Toxicologically Synergistic No information available

Products

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

| | |
|------------------------|--|
| Irritation | No information available |
| Sensitization | No information available |
| Carcinogenicity | The table below indicates whether each agency has listed any ingredient as a carcinogen. |

| Component | CAS-No | IARC | NTP | ACGIH | OSHA | Mexico |
|--------------|------------|------------|------------|------------|------------|------------|
| Ketoconazole | 65277-42-1 | Not listed | Not listed | Not listed | Not listed | Not listed |

Mutagenic Effects No information available

Reproductive Effects May impair fertility.

Developmental Effects No information available.

Teratogenicity No information available.

STOT - single exposure None known

STOT - repeated exposure Liver

Aspiration hazard No information available

Symptoms / effects, both acute and delayed No information available

Endocrine Disruptor Information

| Component | EU - Endocrine Disruptors Candidate List | EU - Endocrine Disruptors - Evaluated Substances | Japan - Endocrine Disruptor Information |
|--------------|--|--|---|
| Ketoconazole | Group III Chemical | Not applicable | Not applicable |

Other Adverse Effects The toxicological properties have not been fully investigated.

12. Ecological information

Ecotoxicity

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 No information available

Bioaccumulation/ Accumulation No information available.

Mobility No information available.

13. Disposal considerations

Waste Disposal Methods Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. Chemical waste generators must also consult local, regional, and national hazardous waste regulations to ensure complete and accurate classification.

14. Transport information

DOT

| | |
|------------------------------|------------------------------|
| UN-No | UN2811 |
| Proper Shipping Name | TOXIC SOLID, ORGANIC, N.O.S. |
| Proper technical name | (KETOCONAZOLE) |
| Hazard Class | 6.1 |
| Packing Group | III |

TDG

| | |
|-----------------------------|------------------------------|
| UN-No | UN2811 |
| Proper Shipping Name | TOXIC SOLID, ORGANIC, N.O.S. |
| Hazard Class | 6.1 |

| | |
|-----------------------------|------------------------------|
| Packing Group | III |
| IATA | |
| UN-No | UN2811 |
| Proper Shipping Name | TOXIC SOLID, ORGANIC, N.O.S. |
| Hazard Class | 6.1 |
| Packing Group | III |
| IMDG/IMO | |
| UN-No | UN2811 |
| Proper Shipping Name | TOXIC SOLID, ORGANIC, N.O.S. |
| Hazard Class | 6.1 |
| Packing Group | III |

15. Regulatory information

International Inventories

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

Legend:

X - Listed

E - Indicates a substance that is the subject of a Section 5(e) Consent order under TSCA.

F - Indicates a substance that is the subject of a Section 5(f) Rule under TSCA.

N - Indicates a polymeric substance containing no free-radical initiator in its inventory name but is considered to cover the designated polymer made with any free-radical initiator regardless of the amount used.

P - Indicates a commenced PMN substance

R - Indicates a substance that is the subject of a Section 6 risk management rule under TSCA.

S - Indicates a substance that is identified in a proposed or final Significant New Use Rule

T - Indicates a substance that is the subject of a Section 4 test rule under TSCA.

XU - Indicates a substance exempt from reporting under the Inventory Update Rule, i.e. Partial Updating of the TSCA Inventory Data Base Production and Site Reports (40 CFR 710(B)).

Y1 - Indicates an exempt polymer that has a number-average molecular weight of 1,000 or greater.

Y2 - Indicates an exempt polymer that is a polyester and is made only from reactants included in a specified list of low concern reactants that comprises one of the eligibility criteria for the exemption rule.

U.S. Federal Regulations

TSCA 12(b) Not applicable

SARA 313 Not applicable

SARA 311/312 Hazard Categories See section 2 for more information

CWA (Clean Water Act) Not applicable

Clean Air Act Not applicable

OSHA Occupational Safety and Health Administration
Not applicable

CERCLA Not applicable

California Proposition 65 This product does not contain any Proposition 65 chemicals

U.S. State Right-to-Know Regulations Not applicable

U.S. Department of Transportation

Reportable Quantity (RQ): N
DOT Marine Pollutant N
DOT Severe Marine Pollutant N

U.S. Department of Homeland Security

This product does not contain any DHS chemicals.

Other International Regulations

Mexico - Grade No information available

16. Other information

| | |
|-------------------------|---|
| Prepared By | Regulatory Affairs Thermo Fisher Scientific Email: EMSDS.RA@thermofisher.com |
| Creation Date | 12-Jul-2010 |
| Revision Date | 18-Jan-2018 |
| Print Date | 18-Jan-2018 |
| Revision Summary | This document has been updated to comply with the US OSHA HazCom 2012 Standard replacing the current legislation under 29 CFR 1910.1200 to align with the Globally Harmonized System of Classification and Labeling of Chemicals (GHS). |

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 SDS