



KETOCONAZOLE (CARBONYL-13C, 99%)

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830 and according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Date of issue: 31/05/2011

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Supersedes: 31/05/2011

Version: 2.0

CLM-7118

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form	: Substance
Substance name	: KETOCONAZOLE (CARBONYL-13C, 99%)
EC Index No	: 613-283-00-6 (Unlabeled)
EC No	: 265-667-4 (Unlabeled)
CAS No	: 65277-42-1 (Unlabeled)
Product code	: CLM-7118
Formula	: *CC25H28Cl2N4O4
Synonyms	: (±)-cis-1-Acetyl-4-(4-[(2-[2,4-dichlorophenyl]-2-[1H-imidazol-1-ylmethyl]-1,3-dioxolan-4-yl)-methoxy]phenyl)piperazine

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

1.2.1. Relevant identified uses

Main use category	: Professional use
Industrial/Professional use spec	: For professional use only

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Cambridge Isotope Laboratories, Inc.
50 Frontage Road
Andover, MA 01810
USA

USA: 1-800-322-1174 Int: 1-978-749-8000
cilsales@isotope.com www.isotope.com

Emergency telephone number

Emergency numbers:

Chemtrec: 1-800-424-9300 (24 hours)
International: 1-703-741-5970 (24 hours)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Acute Tox. 3 (Oral) H301
Repr. 1B H360
STOT RE 2 H373
Aquatic Chronic 1 H410

Full text of hazard classes and H-statements : see section 16

Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]

T; R25
Repr.Cat.1; R60
Repr.Cat.1; R61
Xn; R48/20/21/22
N; R50/53

Full text of R-phrases: see section 16

GHS-US classification

Acute Tox. 3 (Oral) H301
Repr. 1B H360
STOT RE 2 H373
Aquatic Chronic 1 H410

Full text of H statements : see section 16

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Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)



Signal word (CLP)

: Danger

Hazard statements (CLP)

: H301 - Toxic if swallowed
H360 - May damage fertility. May damage the unborn child (if inhaled, if swallowed, in contact with skin)
H373 - May cause damage to organs (liver, testis, prostate) through prolonged or repeated exposure (if inhaled, if swallowed, in contact with skin)
H410 - Very toxic to aquatic life with long lasting effects

Precautionary statements (CLP)

: P260 - Do not breathe dust, fume, gas, mist, spray, vapours
P264 - Wash hands, forearms and face thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P273 - Avoid release to the environment
P280 - Wear eye protection, face protection, protective clothing, protective gloves
P301+P310 - IF SWALLOWED: Immediately call a doctor, a POISON CENTER
P314 - Get medical advice/attention if you feel unwell
P330 - Rinse mouth

GHS-US labelling

Hazard pictograms (GHS-US)



Signal word (GHS-US)

: Danger

Hazard statements (GHS-US)

: H301 - Toxic if swallowed
H360 - May damage fertility. May damage the unborn child (Dermal, Inhalation, oral)
H373 - May cause damage to organs (liver, prostate, testis) through prolonged or repeated exposure (Dermal, Inhalation, oral)
H410 - Very toxic to aquatic life with long lasting effects

Precautionary statements (GHS-US)

: P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P260 - Do not breathe dust, fume, gas, mist, spray, vapours
P264 - Wash hands, forearms and face thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P273 - Avoid release to the environment
P280 - Wear face protection, eye protection, protective clothing, protective gloves
P301+P310 - If swallowed: Immediately call a doctor, a POISON CENTER
P308+P313 - If exposed or concerned: Get medical advice/attention
P314 - Get medical advice/attention if you feel unwell
P321 - Specific treatment (see Hazardous component(s) for labelling on this label)
P330 - Rinse mouth
P391 - Collect spillage
P405 - Store locked up
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

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Name	Product identifier	%	Classification according to Directive 67/548/EEC
KETOCONAZOLE (CARBONYL-13C, 99%)	(CAS No) 65277-42-1 (Unlabeled) (EC No) 265-667-4 (Unlabeled) (EC Index No) 613-283-00-6 (Unlabeled)	100	T; R25 Repr.Cat.1; R60 Repr.Cat.1; R61 Xn; R48/20/21/22 N; R50/53

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
KETOCONAZOLE (CARBONYL-13C, 99%)	(CAS No) 65277-42-1 (Unlabeled) (EC No) 265-667-4 (Unlabeled) (EC Index No) 613-283-00-6 (Unlabeled)	100	Acute Tox. 3 (Oral), H301 Repr. 1B, H360 STOT RE 2, H373 Aquatic Chronic 1, H410

Full text of R- and H-statements: see section 16

Name	Product identifier	%	GHS-US classification
KETOCONAZOLE (CARBONYL-13C, 99%) (Main constituent)	(CAS No) 65277-42-1 (Unlabeled)	100	Acute Tox. 3 (Oral), H301 Repr. 1B, H360 STOT RE 2, H373 Aquatic Chronic 1, H410

Full text of H-statements: see section 16

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: If you feel unwell, seek medical advice (show the label where possible). Evacuate danger area.
First-aid measures after inhalation	: When symptoms occur: go into open air and ventilate suspected area. If not breathing, give artificial respiration. Get immediate medical advice/attention.
First-aid measures after skin contact	: Wash with plenty of soap and water. Get immediate medical advice/attention.
First-aid measures after eye contact	: Rinse immediately with plenty of water. Get immediate medical advice/attention.
First-aid measures after ingestion	: Never give anything by mouth to an unconscious person. Rinse mouth out with water. Get immediate medical advice/attention.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries after inhalation	: May be harmful if inhaled. May cause respiratory irritation.
Symptoms/injuries after skin contact	: May be harmful in contact with skin. May cause skin irritation.
Symptoms/injuries after eye contact	: May cause eye irritation.
Symptoms/injuries after ingestion	: Toxic if swallowed.

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Fire-fighting measures

5.1. Extinguishing media

Suitable extinguishing media : Water spray, dry chemical powder, alcohol-resistant foam, carbon dioxide (CO2).

5.2. Special hazards arising from the substance or mixture

No additional information available

5.3. Advice for firefighters

Firefighting instructions	: Fight fire with normal precautions from a reasonable distance. Wear a self contained breathing apparatus. Do not enter fire area without proper protective equipment, including respiratory protection.
Protection during firefighting	: Do not enter fire area without proper protective equipment, including respiratory protection. Wear recommended personal protective equipment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Protective equipment	: Wear recommended personal protective equipment.
Emergency procedures	: Avoid breathing dust, mist, vapours, gas. Avoid dust formation. Ensure adequate air ventilation. Evacuate area.

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6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Prevent entry to sewers and public waters. Do not allow to enter drains or water courses. Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

For containment : Take up mechanically (sweeping, shovelling) and collect in suitable container for disposal.
Methods for cleaning up : This material and its container must be disposed of in a safe way, and as per local legislation.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Provide adequate ventilation to minimize dust and/or vapour concentrations.
Hygiene measures : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Store in a well-ventilated place. Keep container tightly closed.
Storage conditions : Store refrigerated (-5°C to 5°C). Protect from light.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.
Personal protective equipment : Gloves. Protective clothing. Protective goggles. Self-contained breathing apparatus.



Materials for protective clothing : Wear suitable protective clothing and gloves.
Hand protection : Wear suitable protective clothing and gloves.
Eye protection : Wear eye protection. Chemical goggles or face shield with safety glasses.
Skin and body protection : Wear suitable protective clothing, gloves and eye/face protection.
Respiratory protection : In case of inadequate ventilation wear respiratory protection. Approved supplied air respirator.
Environmental exposure controls : Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

The properties listed below are for the solvent, the main component of this mixture.

Physical state : Solid
Appearance : Solid
Molecular mass : 532.42 g/mol (Labeled)
Colour : White, light brown
Odour : No data available
Odour threshold : No data available
pH : No data available
Relative evaporation rate (butylacetate=1) : No data available
Melting point : 147 °C (297 °F)
Freezing point : No data available
Boiling point : No data available
Flash point : No data available
Auto-ignition temperature : No data available

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Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: No data available
Log Pow	: 3.507
Log Kow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

Stable if stored under recommended conditions.

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

Strong oxidizing agents.

10.6. Hazardous decomposition products

Carbon oxides (CO, CO₂). Nitrogen oxides.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Oral: Toxic if swallowed.

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LD50 oral rat	166 mg/kg
ATE CLP (oral)	166.000 mg/kg bodyweight

Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: human. lymphocytes. DNA inhibition
Carcinogenicity	: Not classified
Reproductive toxicity	: Reproductive toxicity
STOT-single exposure	: Not classified
STOT-repeated exposure	: May cause damage to organs (liver, testis, prostate) through prolonged or repeated exposure (if inhaled, if swallowed, in contact with skin).
Aspiration hazard	: Not classified
Potential adverse human health effects and symptoms	: This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.
Symptoms/injuries after inhalation	: May be harmful if inhaled. May cause respiratory irritation.
Symptoms/injuries after skin contact	: May be harmful in contact with skin. May cause skin irritation.
Symptoms/injuries after eye contact	: May cause eye irritation.
Symptoms/injuries after ingestion	: Toxic if swallowed.

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SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Very toxic to aquatic life with long lasting effects.

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

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Log Pow	3.507
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12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

Other adverse effects : Very toxic to aquatic life with long lasting effects. Avoid release to the environment. Disposal must be done according to official regulations.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional legislation (waste) : Waste materials should be disposed of under conditions which meet Federal, State, and Local environmental control regulations.

Product/Packaging disposal recommendations: : Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material.

Ecology - waste materials : Dispose of as unused product.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

14.1. UN number

UN-No.(DOT) : 2811

DOT NA no. UN2811

14.2. UN proper shipping name

Proper Shipping Name (DOT) : Toxic solids, organic, n.o.s.

Class (DOT) : 6.1 - Class 6.1 - Poisonous materials 49 CFR 173.132

Hazard labels (DOT) : 6.1 - Poison



DOT Symbols : G - Identifies PSN requiring a technical name

Packing group (DOT) : III - Minor Danger

DOT Special Provisions (49 CFR 172.102) : IB8 - Authorized IBCs: Metal (11A, 11B, 11N, 21A, 21B, 21N, 31A, 31B and 31N); Rigid plastics (11H1, 11H2, 21H1, 21H2, 31H1 and 31H2); Composite (11HZ1, 11HZ2, 21HZ1, 21HZ2, 31HZ1 and 31HZ2); Fiberboard (11G); Wooden (11C, 11D and 11F); Flexible (13H1, 13H2, 13H3, 13H4, 13H5, 13L1, 13L2, 13L3, 13L4, 13M1 or 13M2).
IP3 - Flexible IBCs must be sift-proof and water-resistant or must be fitted with a sift-proof and water-resistant liner.

T1 - 1.5 178.274(d)(2) Normal..... 178.275(d)(2)

TP33 - The portable tank instruction assigned for this substance applies for granular and powdered solids and for solids which are filled and discharged at temperatures above their melting point which are cooled and transported as a solid mass. Solid substances transported or offered for transport above their melting point are authorized for transportation in portable tanks conforming to the provisions of portable tank instruction T4 for solid substances of packing group III or T7 for solid substances of packing group II, unless a tank with more stringent requirements for minimum shell thickness, maximum allowable working pressure, pressure-relief devices or bottom outlets are assigned in which case the more stringent tank instruction and special provisions shall apply. Filling limits must be in accordance with portable tank special provision TP3. Solids meeting the definition of an elevated temperature material must be transported in accordance with the applicable requirements of this subchapter.

DOT Packaging Exceptions (49 CFR 173.xxx) : 153

DOT Packaging Non Bulk (49 CFR 173.xxx) : 213

DOT Packaging Bulk (49 CFR 173.xxx) : 240

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14.3. Additional information

Emergency Response Guide (ERG) Number : 154

Other information : No supplementary information available.

Overland transport

Packing group (ADR) : III
Class (ADR) : 6.1 - Toxic substances
Hazard identification number (Kemler No.) : 60
Classification code (ADR) : T2
Danger labels (ADR) : 6.1 - Toxic substances



Orange plates :



Tunnel restriction code (ADR) : E
Limited quantities (ADR) : 5kg
EAC code : 2X
Excepted quantities (ADR) : E1

Transport by sea

DOT Vessel Stowage Location : A - The material may be stowed "on deck" or "under deck" on a cargo vessel and on a passenger vessel.
MFAG-No : 154

Air transport

DOT Quantity Limitations Passenger aircraft/rail (49 CFR 173.27) : 100 kg
DOT Quantity Limitations Cargo aircraft only (49 CFR 175.75) : 200 kg
Civil Aeronautics Law : Toxic and infectious substances/Toxic substances(Hazardous materials notice Appended Table 1 Article 194 of the Enforcement Regulations)

14.4. Environmental hazards

Dangerous for the environment :



Other information : No supplementary information available.

14.5. Special precautions for user

14.6. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

SECTION 15: Regulatory information

15.1. US Federal regulations

KETOCONAZOLE (CARBONYL-13C, 99%) (65277-42-1 (Unlabeled))

SARA Section 302 Threshold Planning Quantity (TPQ)	Not subject to reporting requirements of the United States SARA Section 302
SARA Section 311/312 Hazard Classes	Immediate (acute) health hazard Delayed (chronic) health hazard
SARA Section 313 - Emission Reporting	Not subject to reporting requirements of the United States SARA Section 313

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15.2. International regulations

CANADA

KETOCONAZOLE (CARBONYL-13C, 99%) (65277-42-1 (Unlabeled))

Listed on the Canadian DSL (Domestic Substances List)

15.2.1. National regulations

No additional information available

15.3. US State regulations

KETOCONAZOLE (CARBONYL-13C, 99%)(65277-42-1 (Unlabeled))

U.S. - California - Proposition 65 - Carcinogens List	No
U.S. - California - Proposition 65 - Developmental Toxicity	No
U.S. - California - Proposition 65 - Reproductive Toxicity - Female	No
U.S. - California - Proposition 65 - Reproductive Toxicity - Male	No
State or local regulations	U.S. - New Jersey - Right to Know Hazardous Substance List U.S. - Pennsylvania - RTK (Right to Know) List

SECTION 16: Other information

Other information : This product is not radioactive. The data given for this product are those of the corresponding unlabeled compound, unless specifically indicated otherwise. Health and safety data for labeled compounds are generally not available, but are assumed to be similar or identical to the corresponding unlabeled compound.

Full text of R-, H- and EUH-statements:

Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1
Repr. 1B	Reproductive toxicity, Category 1B
STOT RE 2	Specific target organ toxicity — Repeated exposure, Category 2
H301	Toxic if swallowed
H360	May damage fertility or the unborn child
H373	May cause damage to organs through prolonged or repeated exposure
H410	Very toxic to aquatic life with long lasting effects
R25	Toxic if swallowed
R48/20/21/22	Harmful: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed
R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
R60	May impair fertility
R61	May cause harm to the unborn child
N	Dangerous for the environment
T	Toxic
Xn	Harmful

NFPA health hazard

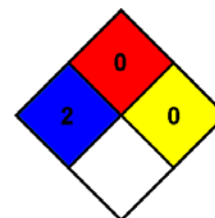
: 2 - Materials that, under emergency conditions, can cause temporary incapacitation or residual injury.

NFPA fire hazard

: 0 - Materials that will not burn under typical dire conditions, including intrinsically noncombustible materials such as concrete, stone, and sand.

NFPA reactivity

: 0 - Material that in themselves are normally stable, even under fire conditions.



HMIS III Rating

Health

: 2 Moderate Hazard - Temporary or minor injury may occur

Flammability

: 0 Minimal Hazard

Physical

: 0 Minimal Hazard

CIL Mixture SDS

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product