

# OTTO CHEMIE PVT LTD

An ISO 9001 : 2015 & GMP Certified Company  
101, Aarkay Ruby Industrial Estate (1B), Opp Shree Narayan Industrial Estate,  
Chinchpada, Vasai East, Waliv, Maharashtra 401208. Tel : + 91 98200 41841  
Email : [info@ottokemi.com](mailto:info@ottokemi.com) Web : [www.ottokemi.com](http://www.ottokemi.com)

## MATERIAL SAFETY DATA SHEET (MSDS)

### SECTION 1. Product identifiers

Product name: Ketoconazole, 98%  
Product Code: K 2436  
CAS No : 65277-42-1

1.2. Relevant identified uses of the substance or mixture and uses advised against  
Use : Industrial. For professional use only.

1.3. Details of the supplier of the safety data sheet

Company identification  
OTTO CHEMIE PVT LTD  
101, Aarkay Ruby Industrial Estate(1B), Opp Shree Narayan Industrial Estate,  
Chinchpada, Vasai East, Waliv, Maharashtra 401208.  
Email [info@ottokemi.com](mailto:info@ottokemi.com)

1.4. Emergency telephone number

Phone no. : + 91 22 2207 0099 (9:00am - 6:00 pm).

### SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Acute toxicity, (Category 3)

Reproductive toxicity, (Category 1B)

Specific target organ toxicity - repeated exposure, (Category 2)

Short-term (acute) aquatic hazard, (Category 1)

Long-term (chronic) aquatic hazard, (Category 1)

2.2 Label elements

Labelling according Regulation (EC) No 1272/2008

Pictogram

Signal Word

Hazard Statements

H301

H360F

H373

H410

Precautionary Statements

P202

P260

P264

P273

P280

P301 + P310

Supplemental Hazard

Statements

Restricted to professional users.

Reduced Labeling (<= 125 ml)

Pictogram

Signal Word

Hazard Statements

H301

H360F

Precautionary Statements

H301: Toxic if swallowed.

H360F: May damage fertility.

H373: May cause damage to organs through prolonged or repeated exposure.

H400: Very toxic to aquatic life.

H410: Very toxic to aquatic life with long lasting effects.

Danger

Toxic if swallowed.

May damage fertility.

May cause damage to organs through prolonged or repeated exposure.

Very toxic to aquatic life with long lasting effects.

Do not handle until all safety precautions have been read and understood.

Do not breathe dust.

Wash skin thoroughly after handling.

Avoid release to the environment.

Wear protective gloves/ protective clothing/ eye protection/ face protection.

IF SWALLOWED: Immediately call a POISON CENTER/ doctor. none

Danger

Toxic if swallowed.

May damage fertility.

### DISCLAIMER

Otto Chemie Pvt Ltd - products are only for laboratory use only. Not for drug, medicinal, household or any other use. No liability accepted for mishandling in use - please test before use

Otto Chemie Pvt Ltd - shall not be responsible for any damage resulting from handling or from contact with the above product.

Otto Chemie Pvt Ltd - provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy.

This document is intended only as a guide to the appropriate precautionary handling of the material by a properly trained person using this product

# OTTO CHEMIE PVT LTD

An ISO 9001 : 2015 & GMP Certified Company  
101, Aarkay Ruby Industrial Estate (1B), Opp Shree Narayan Industrial Estate,  
Chinchpada, Vasai East, Waliv, Maharashtra 401208. Tel : + 91 98200 41841  
Email : [info@ottokemi.com](mailto:info@ottokemi.com) Web : [www.ottokemi.com](http://www.ottokemi.com)

P202

Do not handle until all safety precautions have been read and understood.

P264

Wash skin thoroughly after handling.

P280

Wear protective gloves/ protective clothing/ eye protection/ face protection.

P301 + P310

IF SWALLOWED: Immediately call a POISON CENTER/ doctor. none

Supplemental Hazard Statements

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information:

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information:

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

## SECTION 3: Composition/information on ingredients

3.1 Substances

Synonyms : (±)-cis-1-Acetyl-4-(4-[(2-[2,4-dichlorophenyl]-2-[1H-imidazol-1-ylmethyl]-1,3-dioxolan-4-yl)-methoxy]phenyl)piperazine  
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 g/mol  
CAS-No. : 65277-42-1  
EC-No. : 265-667-4

Component	Classification	Concentration
Ketoconazole		
CAS-No. 65277-42-1 EC-No. 265-667-4	Acute Tox. 3; Repr. 1B; STOT RE 2; Aquatic Acute 1; Aquatic Chronic 1; H301, H360F, H373, H400, H410 M- Factor - Aquatic Acute: 10	<= 100 %

For the full text of the H-Statements mentioned in this Section, see Section 16.

## SECTION 4: First aid measures

4.1 Description of first-aid measures

General advice

Show this material safety data sheet to the doctor in attendance.

If inhaled

After inhalation: fresh air. Call in physician.

In case of skin contact

In case of skin contact: Take off immediately all contaminated clothing. Rinse skin with water/ shower. Consult a physician.

In case of eye contact

After eye contact: rinse out with plenty of water. Call in ophthalmologist. Remove contact lenses.

If swallowed

If swallowed: give water to drink (two glasses at most). Seek medical advice immediately.

In exceptional cases only, if medical care is not available within one hour, induce vomiting (only in persons who are wide awake and fully conscious), administer activated charcoal (20 - 40 g in a 10% slurry) and consult a doctor as quickly as possible.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed

No data available

## DISCLAIMER

Otto Chemie Pvt Ltd - products are only for laboratory use only. Not for drug, medicinal, household or any other use. No liability accepted for mishandling in use - please test before use

Otto Chemie Pvt Ltd - shall not be responsible for any damage resulting from handling or from contact with the above product.

Otto Chemie Pvt Ltd - provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy.

This document is intended only as a guide to the appropriate precautionary handling of the material by a properly trained person using this product

# OTTO CHEMIE PVT LTD

An ISO 9001 : 2015 & GMP Certified Company  
101, Aarkay Ruby Industrial Estate (1B), Opp Shree Narayan Industrial Estate,  
Chinchpada, Vasai East, Waliv, Maharashtra 401208. Tel : + 91 98200 41841  
Email : [info@ottokemi.com](mailto:info@ottokemi.com) Web : [www.ottokemi.com](http://www.ottokemi.com)

---

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide. Water Foam

Carbon dioxide (CO<sub>2</sub>) Dry powder

Unsuitable extinguishing media

For this substance/mixture no limitations of extinguishing agents are given. For this substance/mixture no limitations of extinguishing agents are given.

### 5.2 Special hazards arising from the substance or mixture

Carbon oxides

Nitrogen oxides (NO<sub>x</sub>)

Hydrogen chloride gas

Combustible.

Development of hazardous combustion gases or vapours possible in the event of fire.

### 5.3 Advice for firefighters

Stay in danger area only with self-contained breathing apparatus. Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.

### 5.4 Further information

Suppress (knock down) gases/vapors/mists with a water spray jet. Prevent fire extinguishing water from contaminating surface water or the ground water system.

## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel: Avoid inhalation of dusts. Avoid substance contact.

Ensure adequate ventilation. Evacuate the danger area, observe emergency procedures, consult an expert.

For personal protection see section 8.

### 6.2 Environmental precautions

Do not let product enter drains.

### 6.3 Methods and materials for containment and cleaning up

Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up carefully. Dispose of properly. Clean up affected area.

Avoid generation of dusts.

### 6.4 Reference to other sections

For disposal see section 13.

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

Advice on safe handling

Work under hood. Do not inhale substance/mixture.

Hygiene measures

Immediately change contaminated clothing. Apply preventive skin protection. Wash hands and face after working with substance.

For precautions see section 2.2.

### 7.2 Conditions for safe storage, including any incompatibilities

Storage conditions

Tightly closed. Dry. Keep in a well-ventilated place. Keep locked up or in an area accessible only to qualified or authorized persons.

Storage stability Recommended storage temperature

2 - 8 °C

Storage class

Storage class (TRGS 510): 6.1C: Combustible, acute toxic Cat.3 / toxic compounds or compounds which causing chronic effects

### 7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

Ingredients with workplace control parameters

### 8.2 Exposure controls

Personal protective equipment

---

## DISCLAIMER

Otto Chemie Pvt Ltd - products are only for laboratory use only. Not for drug, medicinal, household or any other use. No liability accepted for mishandling in use - please test before use

Otto Chemie Pvt Ltd - shall not be responsible for any damage resulting from handling or from contact with the above product.

Otto Chemie Pvt Ltd - provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy.

This document is intended only as a guide to the appropriate precautionary handling of the material by a properly trained person using this product

# OTTO CHEMIE PVT LTD

An ISO 9001 : 2015 & GMP Certified Company  
101, Aarkay Ruby Industrial Estate (1B), Opp Shree Narayan Industrial Estate,  
Chinchpada, Vasai East, Waliv, Maharashtra 401208. Tel : + 91 98200 41841  
Email : [info@ottokemi.com](mailto:info@ottokemi.com) Web : [www.ottokemi.com](http://www.ottokemi.com)

---

## Eye/face protection

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU). Safety glasses

## Skin protection

This recommendation applies only to the product stated in the safety data sheet, supplied by us and for the designated use. When dissolving in or mixing with other substances and under conditions deviating from those stated in EN 16523-1 please contact the supplier of CE-approved gloves (e.g. KCL GmbH, D-36124 Eichenzell, Internet: [www.kcl.de](http://www.kcl.de)).

### Full contact

Material: Nitrile rubber

Minimum layer thickness: 0,11 mm

Break through time: 480 min

Material tested: KCL 741 Dermatrill® L

This recommendation applies only to the product stated in the safety data sheet, supplied by us and for the designated use. When dissolving in or mixing with other substances and under conditions deviating from those stated in EN 16523-1 please contact the supplier of CE-approved gloves (e.g. KCL GmbH, D-36124 Eichenzell, Internet: [www.kcl.de](http://www.kcl.de)).

### Splash contact

Material: Nitrile rubber

Minimum layer thickness: 0,11 mm

Break through time: 480 min

Material tested: KCL 741 Dermatrill® L

## Body Protection protective clothing

## Respiratory protection

required when dusts are generated.

Our recommendations on filtering respiratory protection are based on the following standards: DIN EN 143, DIN 14387 and other accompanying standards relating to the used respiratory protection system.

Recommended Filter type: Filter type P3

The entrepreneur has to ensure that maintenance, cleaning and testing of respiratory protective devices are carried out according to the instructions of the producer.

These measures have to be properly documented.

Control of environmental exposure

Do not let product enter drains.

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

a) Physical state	powder
b) Color	white, off-white
c) Odor	No data available
d) Melting point/freezing point	Melting point: 146 °C
e) Initial boiling point and boiling range	No data available
f) Flammability (solid, gas)	No data available
g) Upper/lower flammability or explosive limits	No data available
h) Flash point	No data available
i) Autoignition temperature	No data available
j) Decomposition temperature	No data available
k) pH	No data available
l) Viscosity	Viscosity, kinematic: No data available Viscosity, dynamic: No data available
m) Water solubility	No data available

---

## DISCLAIMER

Otto Chemie Pvt Ltd - products are only for laboratory use only. Not for drug, medicinal, household or any other use. No liability accepted for mishandling in use - please test before use

Otto Chemie Pvt Ltd - shall not be responsible for any damage resulting from handling or from contact with the above product.

Otto Chemie Pvt Ltd - provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy.

This document is intended only as a guide to the appropriate precautionary handling of the material by a properly trained person using this product

# OTTO CHEMIE PVT LTD

An ISO 9001 : 2015 & GMP Certified Company  
101, Aarkay Ruby Industrial Estate (1B), Opp Shree Narayan Industrial Estate,  
Chinchpada, Vasai East, Waliv, Maharashtra 401208. Tel : + 91 98200 41841  
Email : [info@ottokemi.com](mailto:info@ottokemi.com) Web : [www.ottokemi.com](http://www.ottokemi.com)

n) Partition coefficient: n-octanol/water	ca.log Pow: 4,043 at 25 °C - Potential bioaccumulation, (Lit.)
o) Vapor pressure	No data available
p) Density	ca. 1,38 g/cm <sup>3</sup> at 20 °C - (calculated)
Relative density	No data available
q) Relative vapor density	No data available
r) Particle characteristics	No data available
s) Explosive properties	No data available
t) Oxidizing properties	none
9.2 Other safety information	
No data available	

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

The following applies in general to flammable organic substances and mixtures: in correspondingly fine distribution, when whirled up a dust explosion potential may generally be assumed.

### 10.2 Chemical stability

The product is chemically stable under standard ambient conditions (room temperature) .

### 10.3 Possibility of hazardous reactions

No data available

### 10.4 Conditions to avoid

no information available

### 10.5 Incompatible materials

Strong oxidizing agents

### 10.6 Hazardous decomposition products

In the event of fire: see section 5

## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

Routes of Entry: Absorbed through skin. Dermal contact. Eye contact. Toxicity to Animals:

Oral LD50 Rat: 1500 mg/kg; Dermal LD50 Rabbit: 2000mg/kg

Inhalation LC50 Rat: > 50mg/L.

Chronic Effects on Humans: CARCINOGENIC EFFECTS: Classified None. by NTP, None. by OSHA, None. by NIOSH.

Other Toxic Effects on Humans: Hazardous in case of skin contact (irritant), of inhalation (lung irritant).

Special Remarks on Toxicity

to Animals: Not available.

Special Remarks on Chronic Effects on Humans: Not available.

Special Remarks on other Toxic Effects on Humans: Not available.

## SECTION 12: Ecological information

### 12.1 Toxicity

No data available

### 12.2 Persistence and degradability

No data available

### 12.3 Bioaccumulative potential

No data available

### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### 12.6 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission

## DISCLAIMER

Otto Chemie Pvt Ltd - products are only for laboratory use only. Not for drug, medicinal, household or any other use. No liability accepted for mishandling in use - please test before use

Otto Chemie Pvt Ltd - shall not be responsible for any damage resulting from handling or from contact with the above product.

Otto Chemie Pvt Ltd - provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy.

This document is intended only as a guide to the appropriate precautionary handling of the material by a properly trained person using this product



# OTTO CHEMIE PVT LTD

An ISO 9001 : 2015 & GMP Certified Company  
101, Aarkay Ruby Industrial Estate (1B), Opp Shree Narayan Industrial Estate,  
Chinchpada, Vasai East, Waliv, Maharashtra 401208. Tel : + 91 98200 41841  
Email : [info@ottokemi.com](mailto:info@ottokemi.com) Web : [www.ottokemi.com](http://www.ottokemi.com)

---

Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects  
No data available

## SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

See [www.retrologistik.com](http://www.retrologistik.com) for processes regarding the return of chemicals and containers, or contact us there if you have further questions.

## SECTION 14: Transport information

14.1 UN number

ADR/RID: 2811

IMDG: 2811

IATA: 2811

14.2 UN proper shipping name

ADR/RID : TOXIC SOLID, ORGANIC, N.O.S. (Ketoconazole)

IMDG : TOXIC SOLID, ORGANIC, N.O.S. (Ketoconazole)

IATA : Toxic solid, organic, n.o.s. (Ketoconazole)

14.3 Transport hazard class(es)

ADR/RID: 6.1

IMDG: 6.1

IATA: 6.1

14.4 Packaging group

ADR/RID: III

IMDG: III

IATA: III

14.5 Environmental hazards

ADR/RID: yes

IMDG Marine pollutant: yes

IATA: no

14.6 Special precautions for user

Tunnel restriction code : (E)

Further information : No data available

## SECTION 15: Regulatory information

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

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

Authorisations and/or restrictions on use  
REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)

: Ketoconazole

National legislation

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

H2 ACUTE TOXIC

E1 ENVIRONMENTAL HAZARDS

Other regulations

Observe work restrictions regarding maternity protection in accordance to Dir 92/85/EEC or stricter national regulations where applicable.

Take note of Dir 94/33/EC on the protection of young people at work.

15.2 Chemical Safety Assessment

For this product a chemical safety assessment was not carried out

## SECTION 16: Other Information

This safety data sheet should be used in conjunction with technical sheets. It does not replace them. The information given is based on our knowledge of this product, at the time of publication. It is given in good faith. The attention of the user is drawn to the possible risks incurred by using the product for any other purpose other than that for which it was intended. This does not in any way excuse the user from knowing and applying all the regulations governing his activity. It is the sole responsibility of the user to take all precautions required in handling the product. The aim of the mandatory regulations mentioned is to help the user to fulfill his obligations regarding the use of hazardous products.

---

### DISCLAIMER

Otto Chemie Pvt Ltd - products are only for laboratory use only. Not for drug, medicinal, household or any other use. No liability accepted for mishandling in use - please test before use

Otto Chemie Pvt Ltd - shall not be responsible for any damage resulting from handling or from contact with the above product.

Otto Chemie Pvt Ltd - provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy.

This document is intended only as a guide to the appropriate precautionary handling of the material by a properly trained person using this product