

**1 Identification of the substances/ mixture and of the company/ undertaking****1.1 Product Identifiers**

Product Number CMS4322  
Product Name Ketoconazole  
CAS No. : 65277-42-1  
EC No. : 265-667-4

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

**1.2.1** Relevant identified uses Laboratory chemicals, Manufacture of substances

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

Produced by HiMedia Laboratories Private Limited  
Address 23, Vadhani Industrial Estate, LBS Marg, Ghatkopar (W), Mumbai - 400 086 India  
Tel. No. +91-22-2500 0970, +91-22-2500 1607 Fax No. : +91-22-25002468  
Mail Id [info@himedialabs.com](mailto:info@himedialabs.com) Website : [www.himedialabs.com](http://www.himedialabs.com)

**1.4 Emergency Tel. No.**

Emergency Tel. No. Please contact the regional HiMedia representation in your country

**2 Hazards Identification****2.1 Classification of the substance or mixture**

**CLP Classification-Regulation (EC) No. 1272/2008[EU-GHS/CLP]**

Acute toxicity, Oral, (Category 3), H301  
Reproductive toxicity, (Category 1B), H360F  
Specific target organ toxicity, repeated exposure, (Category 2), H373  
Hazardous to the aquatic environment, long term hazard, (Category 1), H410

**2.2 Label elements**

**Labeling according to Regulation (EC) No.1272/2008**



Pictogram

Signal word Danger

Hazard Statement(s)

H301 Toxic if swallowed

H360F May damage fertility

H373 May cause damage to organs through prolonged or repeated exposure

H410 Very toxic to aquatic life with long lasting effects

Precautionary Statement(s)

P201 Obtain special instructions before use.

P273 Avoid release to the environment.

P301+P310+P330 IF SWALLOWED : Immediately call a POISON CENTER/doctor. Rinse mouth.

### 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.

## 3 Composition/Information On Ingredients

### 3.1 Substances

Molecular Formula :  $C_{26}H_{28}Cl_2N_4O_4$

Molecular Weight : 531.43

CAS No. : 65277-42-1

EC No. : 265-667-4

Component	Classification	Concentration
Ketoconazole		
CAS No. : 65277-42-1 EC No. : 265-667-4	<b>As Per EC Regulation 1272/2008</b> Acute Tox.oral. 3; Repr. 1B; STOT RE 2; Aquatic Chronic 1 H301; H360F; H373; H410	100%

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

## 4 First Aid Measures

### 4.1 Description of first aid measures

#### **General advice**

Consult a physician. Show this safety data sheet to the doctor in attendance.

#### **If inhaled**

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

#### **In case of skin contact**

Wash with plenty of soap and water. Consult a physician.

#### **In case of eye contact**

Rinse immediately with plenty of water for at least 15 minutes. Consult a physician.

#### **If swallowed**

Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

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

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

### 4.3 Indication of immediate medical attention and special treatment needed

No data available

## **5 Fire Fighting Measures**

### **5.1 Extinguishing media**

#### ***Suitable extinguishing media***

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

#### ***Unsuitable extinguishing media***

No data available.

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

Carbon oxides, nitrogen oxides (NOx), Hydrogen chloride gas

### **5.3 Precautions for fire-fighters**

Wear self contained breathing apparatus for fire fighting if necessary

### **5.4 Further information**

No data available

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## **6 Accidental Release Measures**

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

Wear respiratory protection. Avoid breathing vapours, mist or gas. Ensure adequate ventilation.

Evacuate personnel to safe areas.

### **6.2 Environmental precautions**

Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into environment must be avoided.

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

Sweep up and shovel. Contain spillage, and then collect with an electrically protected vacuum cleaner or by wet-brushing and place in container for disposal according to local regulations (see section 13). Keep in suitable, closed containers for disposal.

### **6.4 Reference to other sections**

For disposal see Section 13.

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## **7 Handling and Storage**

### **7.1 Precautions for safe handling**

Avoid contact with skin and eyes. Avoid inhalation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed. For precautions see section 2.2

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

Store in cool place. Keep container tightly closed in a dry and well-ventilated place.

***Recommended Storage Temperature*** : Below 30°C

### **7.3 Specific end uses**

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

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## **8 Exposure Controls/Personal Protection**

### **8.1 Control parameters**

Components with workplace control parameters

### **8.2 Exposure controls**

***Appropriate engineering controls***

Handle in accordance to general industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

**Personal protective equipment**

**Hygiene measure**

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

**Eye/face protection**

Faceshield and safety goggles.

**Skin protection**

Handle with gloves.

**Body protection**

Complete suit protecting against chemicals.

**Respiratory protection**

Air-purifying respirators.

**Environment exposure controls**

Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

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**9 Physical and chemical properties**

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

Appearance	White to light brown powder
Odour	No data available
Odour Threshold	No data available
pH	No data available
Melting/freezing point	No data available
Initial boiling point and boiling range	No data available
Flash point	No data available
Upper/lower flammability or explosive limits	No data available
Evaporation rate	No data available
Flammability (Solid, gas)	No data available
Vapour pressure	No data available
Relative density	No data available
Water Solubility	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available
Explosive properties	No data available
Oxidizing properties	No data available
Vapour density	No data available
Thermal decomposition	No data available

**9.2 Other safety information**

No data available

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**10 Stability and Reactivity**

**10.1 Reactivity**

No data available

**10.2 Chemical stability**

Stable under recommended storage conditions.

**10.3 Possibility of hazardous reactions**

No data available

**10.4 Conditions to avoid**

Incompatible material

**10.5 Incompatible materials**

No data available

**10.6 Hazardous decomposition products**

Other decomposition products - refer section 5.2.

In the event of fire - refer section 5.

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**11 Toxicological Information**

**11.1 Information on toxicological effects**

***Acute toxicity***

No data available

***Skin corrosion/irritation***

No data available

***Serious eye damage/eye irritation***

No data available

***Respiratory or skin sensitisation***

No data available

***Germ cell mutagenicity***

No data available

***Carcinogenicity***

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

***Reproductive toxicity***

No data available

***Specific target organ toxicity- single exposure***

No data available

***Specific target organ toxicity - repeated exposure***

No data available

***Aspiration hazard***

No data available

***Additional Information***

RTECS : TK7912300

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**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 PBT and vPvB assessment**

PBT and vPVB assessment not available Chemical safety assessment is not required

**12.6 Other adverse effects**

Discharge into the environment must be avoided.

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**13 Disposal Considerations****13.1 Waste treatments methods****Product**

Offer surplus and non-recyclable solutions to a licensed disposal company. Dissolve or mix the material with a combustive solvent and burn in chemical incinerator equipped with an afterburner and scrubber.

**13.2 Contaminated packaging**

Dispose of as unused product.

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**14 Transport Information****14.1 UN-No**

ADNR : 2811 ADR : 2811 IATA\_C : 2811 IATA\_P : 2811 IMDG : 2811 RID : 2811

**14.2 UN proper shipping name**

ADNR : Toxic solids, organic, n.o.s.  
ADR : Toxic solids, organic, n.o.s.  
IATA\_C : Toxic solids, organic, n.o.s.  
IATA\_P : Toxic solids, organic, n.o.s.  
IMDG : Toxic solids, organic, n.o.s.  
RID : Toxic solids, organic, n.o.s.

**14.3 Transport hazard class(es)**

ADNR : 6.1 ADR : 6.1 IATA\_C : 6.1 IATA\_P : 6.1 IMDG : 6.1 RID : 6.1

**14.4 Packaging group**

ADNR : III ADR : III IATA\_C : III IATA\_P : III IMDG : III RID : III

**14.5 Environmental hazards**

ADNR : No ADR : No IMDG : Marine Pollutant : No IATA\_C : No IATA\_P : No RID : No

**14.6 Special precautions for use**

No data available

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**15 Regulatory Information**

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

**15.1 Safety health and environment regulations/legislation specific for the substance or**

**mixture**

No data available

**15.2 Chemical Safety Assessment**

No data available

**16 Other information**

Text of H-Statements and EUH-Phrases mentioned in section 3

H301	Toxic if swallowed
H360F	May damage fertility
H373	May cause damage to organs through prolonged or repeated exposure
H410	Very toxic to aquatic life with long lasting effects
Acute Tox.oral. 3	Acute toxicity, oral, Category 3
Repr. 1B	Reproductive toxicity, Category 1B
STOT RE 2	Specific target organ toxicity, repeated exposure, Category 2
Aquatic Chronic 1	Hazardous to the aquatic environment, long term hazard, Category 1

**Further Information**

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The information given in this safety data sheet is believed to be correct yet does not claim to be all inclusive. This document is intended only as a guide for appropriate precautionary handling of the material by properly trained individuals, information here being commensurate with the present state of our knowledge regarding the manner and conditions of use, handling, storage or disposal. The information provided herein shall not be considered as guarantee of the properties of the product. HiMedia Laboratories, shall not be held liable for any damage resulting from improper handling or contact with the above product. Unless explicitly stated on the product or in any of the documentation accompanying the product, it is intended for research or testing purpose only and is not to be used for any other purpose.