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Version: Discofinechem8
Revision date 27/09/2023

MATERIAL SAFETY DATA SHEET

Itraconazole

SECTION 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

1.1 Product identifiers :
Product name : Itraconazole
Product number : 0084625616
Brand : Discovery
Reach No.: A registration number is not available for this substance as the substance or its uses are exempted from registration, the annual tonnage does not require registration or the registration is envisaged for a later Registration deadline.
Cas No. : 84625-61-6

1.2 Relevant identified uses of the substance or mixture and uses advised against
Identified uses : laboratory chemicals, manufacture of substances

1.3 Details of the supplier of the safety data sheet

Company:	Discovery Fine Chemicals Ltd Unit 4A, Old Forge Road, Ferndown Ind. Estate, Wimborne, Dorset, BH21 7RR. United Kingdom
Telephone:	+44 (0)1202 874517
Fax:	+44 (0)845 0944 385
E-mail:	discovery@discofinechem.com

1.4 Emergency telephone : +44 (0)7912 646956

SECTION 2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture
Classification according to Regulation (EC) No 1272/2008
Acute toxicity, oral (Category 4), H302
Skin irritation (Category 2), H315
Skin sensitization (Category 1), H317
Eye irritation (category 2A) H319
STOT SE (category 3) H335 – single exposure (Category 3), respiratory system, H335
For the full text of the H-Statements mentioned in this section see section 16
Classification according to EU Directives 67/548/EEC or 1999/45/EC
2.2 Label elements
Labelling according Regulation (EC) No 1272/2008
Pictogram

Signal word: Warning
Hazard statement(s)
H302 harmful if swallowed
H315 Causes skin irritation.
H319 Causes serious eye irritation
H335 May cause respiratory irritation

Precautionary statement(s)
P261 Avoid breathing dust
P264 Wash skin thoroughly after handling
P270 do not eat, drink or smoke when using this product
P302+P352+ If on skin rinse cautiously with water.
P305+P351+P338 If in eyes rinse cautiously with water for several minutes. Remove contact lenses. Continue rinsing.

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.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances
Formula: $C_{35}H_{38}N_8O_4$
Molecular Weight: 705.63 g/mol
Cas No: 84625-61-6
E.C.No: 617-596-9

Component	Classification	Concentration
Itraconazole CAS-No.84625-61-6 E.C.No. 617-596-6	acute tox 4. Skin irr.2 Eye irr.2; STOT SE 3 H302, H315, H319, H335	<=100%

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

4. FIRST AID MEASURES

4.1 Description of first aid measures
General advice
Show this safety data sheet to the doctor in attendance.
If inhaled - If breathed in, move person into fresh air. Consult a doctor if feeling unwell.
In case of skin contact – Remove all contaminated clothing. Rinse skin with water. Consult a physician.
In case of eye contact – Flush eyes with water. Remove contact lenses. Call an ophthalmologist.
If swallowed – Make victim drink water (two glasses at most) and consult a doctor
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

5. FIREFIGHTING MEASURES
5.1 Extinguishing media
Suitable extinguishing media – use water foam carbon dioxide (CO2)
Unsuitable extinguishing media – for this substance no limitations of extinguishing agents are given.
5.2 Special hazards arising from the substance or mixture
Carbon oxides Nitrogen oxides (NOx) Hydrogen Chloride gas
Combustible
Development of hazardous combustion gases 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.
5.4 Further information – suppress gases and vapours with a water spray jet. Prevent fire extinguishing water from contaminating surface water or the ground of water system.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures
Avoid inhalation of dusts. Avoid substance contact. Ensure adequate ventilation. Evacuate the danger area. 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 – pick up and arrange disposal without creating dust. Sweep and shovel up. Keep in suitable closed containers for disposal.
6.4 Reference to other sections - For disposal see section 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling
Work under hood. Do not inhale substance/mixture.
Hygiene measures
Immediately change contaminated clothing, apply preventative 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
Store in cool place. Keep container tightly closed in a dry and well-ventilated place.
Recommended storage temperature: 2-8˚C.
Storage class (TRGS 510): 11: combustible solids.
7.3 Specific end use(s)
Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Personal protective equipment
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 EN374 please contact the supplier of CE-approved gloves (e.g. KCL GmbH, D-36124 Eichenzell, Internet: www.kcl.de).
Full contact
Material: Nitrile rubber Minimum layer thickness: 0.11 mm
Break through time: 480 min
Material tested:KCL 741 Dermatril® 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 EN374 please contact the supplier of CE-approved gloves (e.g. KCL GmbH, D-36124 Eichenzell, Internet: www.kcl.de).
Splash contact
Material: Nitrile rubber
Minimum layer thickness: 0.11 mm
Break through time: 480 min
Material tested:KCL 741 Dermatril® 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties
a) Appearance - Form: powder, off-white
b) Odour - no data available
c) Odour Threshold - no data available
d) Melting point/range: - 166.2°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 – not applicable
i) Autoignition temperature - no data available
j) Decomposition temperature - no data avaialble
k) pH - no data available
l) Viscosity – viscosity,kinematic: no data available
- viscosity dynamic: no data available
m) Water solubility – insoluble
n) Partition coefficient: no data available .
o) Vapour pressure - no data available
p) Density - no data available
Relative density – no data available
q) Relative vapour density - no data available
r) Particle characteristics - no data available
s) Explosive properties – no data available
t) Oxidizing properties - no data available
9.2 Other safety information - no data available

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 recommended storage conditions
10.3 Possibility of hazardous reactions
Violent reactions possible with: strong oxidising agents
10.4 Conditions to avoid
no data available
10.5 Incompatible materials
oxidizing agents
10.6 Hazardous decomposition products
In the event of fire see section 5

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects
Acute toxicity
LD50 oral-mouse 500.1mg/kg
Inhalation – irritating to respiratory system
Dermal – no data available
Skin corrosion/irritation – causes skin irritation
Serious eye damage/eye irritation
Causes serious eye irritation.
Respiratory or skin sensitization
May cause allergic skin reaction.
Germ cell mutagenicity
Test Type: unscheduled DNA synthesis assay
Test system: rat hepatocytes Result: negative
Test Type: Ames test
Test system: Salmonella typhimurium Result: negative
Test Type: Ames test
Test system: Escherichia coli Result: negative
Carcinogenicity
No data available
Reproductive toxicity
Laboratory experiments have shown teratogenic effects.
Specific target organ toxicity - single exposure
Inhalation - May cause respiratory irritation.
Specific target organ toxicity - repeated exposure
No data available
Aspiration hazard
No data available

11.2 Additional Information
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 Commision Regulation (EU) 2018/605 at levels of 0.1% or higher.
RTECS: XZ5481000
To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

12. ECOLOGICAL INFORMATION

12.1 Toxicity - no data available
12.2 Persistence and degradability - no data available
12.3 Bio-accumulative 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, bio accumulative and toxic (PBT),or very persistent and very bio accumulative (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 Regulation (EU) 2018/605 at levels of 0.1% or higher.
12.7 Other adverse effects
No data available

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods
Product
Waste material must be disposed of in accordance with the national and local regulations. Leave chemicals in original containers. No mixing with other waste. Handle uncleaned containers like the product itself according to notice directive on waste 2008/98/EC.

14. TRANSPORT INFORMATION

14.1 UN number NONE
14.2 UN proper shipping name
ADR/RID: none
IMDG: none
IATA: none
14.3 Transport hazard class(es)
ADR/RID: - none
14.4 Packaging group
ADR/RID: - none
14.5 Environmental hazards
ADR/RID: no IMDG Marine Pollutant: no IATA: no
14.6 Special precautions for user
Further Information
Not classified as dangerous in the meaning of transport regulations

15. REGULATORY INFORMATION

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

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

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.

16. OTHER INFORMATION

Text of H-code(s) and R-phrase(s) mentioned in Section 2 and 3

Hazard statement(s)

H302 harmful if swallowed
H315 Causes skin irritation.
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H335 May cause respiratory irritation

Precautionary statement(s)

P261 Avoid breathing dust
P264 Wash skin thoroughly after handling
P270 do not eat, drink or smoke when using this product
P302+P352+ If on skin rinse cautiously with water.
P305+P351+P338 If in eyes rinse cautiously with water for several minutes. Remove contact lenses. Continue rinsing.

Further information

WARRANTY

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product.

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APPENDIX

ABBREVIATIONS FULL TEXT

ADN European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR European Agreement concerning the International Carriage of Dangerous Goods by Road
ALARP As low as is reasonably practicable
CAS Chemical Abstracts Service
CLP Classification, Labelling and Packaging Regulations
COSHH Control of Substances Hazardous to Health EC Number European Community Number
EC50 Effective Concentration 50%
ECHA European Chemicals Agency
ELINCS European List of Notified Chemical Substances
EINECS European Inventory of Existing Commercial Chemical Substances GHS Globally Harmonised System HSE Health & Safety Executive UK
IATA International Air Transport Association

IM Intramuscular
IMDG The International Maritime Dangerous Goods Code
IP Intraperitoneal
IV Intravascular
LD50 Lethal Dose 50%
LOEC Lowest Observable Effective Concentration
LTEL Long Term Exposure Limit
NOEC No Observable Effective Concentration
OECD Organisation for Economic Cooperations and Development
OSHA European Agency for Safety and Health at work
PBT Persistent Bioaccumulative and Toxic substance
PPE Personal Protective Equipment
REACH Registration, Evaluation, Authorisation and Restriction of Chemicals
RID Regulations Concerning the International Carriage of Dangerous Goods by Rail
SC Subcutaneous
SDS Safety Data Sheet
SIEF Substance Information Exchange Forum
STEL Short Term Exposure Limit
STOT (RE) Specific Target Organ Toxicity – repeated exposure
STOT (SE) Specific Target Organ Toxicity – single exposure
SVHC Substance of Very High Concern
VOC Volatile Organic Compounds
vPvB Very Persistent and Very Bioaccumulative
WEL Workplace Exposure Limits