

This safety data sheet was created pursuant to the requirements of: OSHA HCS2012

Revision date 20-Jul-2023 Revision Number 1

1. Identification

Product identifier

Product Name Itraconazole Mono N-Oxide

Other means of identification

Product Code(s) TRC-l937528-10MG

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended use Laboratory use

Restrictions on use Not to be used for human or animal consumption

Details of the supplier of the safety data sheet

Supplier Address

VHG LGC Standards 276 Abby Road Manchester, NH 03103 UNITED STATES OF AMERICA

Tel:+1 (603) 622-7660 Fax:+1 (603) 622-5180 Email: lgcusa@lgcgroup.com

Web: Igcstandards.com

E-mail sds-request@lgcgroup.com

Emergency telephone number

Emergency Telephone

For Hazardous Materials or Dangerous Goods Incident Spill, Leak, Fire Exposure, or Accident Call CHEMTREC: USA & Canada 1-800-424-9300 Rest of the world +1 703-741-5970

2. Hazard(s) identification

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Classification

Classified according to OSHA.

Acute toxicity - Oral	Category 4
Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2
Reproductive toxicity	Category 1B
Effects on or via lactation	Yes
Specific target organ toxicity (single exposure)	Category 3
Chronic aquatic toxicity	Category 3

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Danger

Hazard statements

Classified according to OSHA.

Harmful if swallowed

Causes skin irritation

Causes serious eye irritation

May damage fertility or the unborn child

May cause harm to breast-fed children

May cause respiratory irritation

Harmful to aquatic life with long lasting effects



Precautionary Statements - Prevention

Obtain special instructions before use

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

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

Do not breathe dusts or mists

Avoid contact during pregnancy/while nursing

Wash face, hands and any exposed skin thoroughly after handling

Do not eat, drink or smoke when using this product

Use only outdoors or in a well-ventilated area

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Precautionary Statements - Response

IF exposed or concerned: Get medical advice/attention

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

If eye irritation persists: Get medical advice/attention IF ON SKIN: Wash with plenty of water and soap If skin irritation occurs: Get medical advice/attention Take off contaminated clothing and wash it before reuse

IF INHALED: Remove person to fresh air and keep comfortable for breathing

IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell

Rinse mouth

Precautionary Statements - Storage

Store locked up

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

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Other information

Harmful to aquatic life.

3. Composition/information on ingredients

Substance

Formula $C_{35}H_{38}Cl_2N_8O_5$

Chemical name	CAS No	Weight-%	Trade secret
Itraconazole Mono N-Oxide	-	100	*

4. First-aid measures

Description of first aid measures

General advice Show this safety data sheet to the doctor in attendance.

Inhalation Remove to fresh air. IF exposed or concerned: Get medical advice/attention. Get medical

attention immediately if symptoms occur.

Eye contact Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.

Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area. Get medical attention if irritation develops and

persists.

Skin contact Wash off immediately with soap and plenty of water for at least 15 minutes. Get medical

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attention if irritation develops and persists.

Ingestion Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious

person. Call a physician.

Self-protection of the first aider Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8).

Most important symptoms and effects, both acute and delayed

Symptoms May cause redness and tearing of the eyes. Burning sensation.

Indication of any immediate medical attention and special treatment needed

Note to physiciansTreat symptomatically.

5. Fire-fighting measures

surrounding environment.

Large Fire CAUTION: Use of water spray when fighting fire may be inefficient.

Unsuitable extinguishing media Do not scatter spilled material with high pressure water streams.

Specific hazards arising from the

chemical

No information available.

Explosion data

Sensitivity to mechanical impact None.

Sensitivity to static discharge None.

Special protective equipment and precautions for fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.

Use personal protection equipment.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions Ensure adequate ventilation. Use personal protective equipment as required. Evacuate

personnel to safe areas. Avoid contact with skin, eyes or clothing.

Other information Refer to protective measures listed in Sections 7 and 8.

Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

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Methods for cleaning up Pick up and transfer to properly labeled containers.

7. Handling and storage

Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with

skin, eyes or clothing. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes. Take off contaminated clothing and wash before reuse. Ensure adequate ventilation. Avoid breathing vapors or mists. In case of insufficient

ventilation, wear suitable respiratory equipment.

Conditions for safe storage, including any incompatibilities

Storage Conditions Please refer to the manufacturer's certificate for specific storage and transport temperature

conditions. Store only in the original receptacle unless other advice is given on the CoA. Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach

of children.

8. Exposure controls/personal protection

Control parameters

Exposure LimitsThis product, as supplied, does not contain any hazardous materials with occupational

exposure limits established by the region specific regulatory bodies.

Biological occupational exposure limits

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies.

Appropriate engineering controls

Engineering controls Showers

Eyewash stations Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection Avoid contact with eyes. Wear safety glasses with side shields (or goggles). If splashes are

likely to occur, wear safety glasses with side-shields.

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The protective gloves to be used must comply with the specifications of EC Directive Hand protection

89/686/EEC and the related standard EN374. Wear suitable gloves. Impervious gloves.

Wear suitable protective clothing. Long sleeved clothing. Skin and body protection

Respiratory protection No protective equipment is needed under normal use conditions. If exposure limits are

exceeded or irritation is experienced, ventilation and evacuation may be required.

Environmental exposure controls Do not allow into any sewer, on the ground or into any body of water.

General hygiene considerations Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this

> product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection. Wash hands before breaks and immediately after handling the product.

> > None known

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state Solid **Appearance** Solid

Color white; to; off-white No information available Odor **Odor threshold** No information available

Property Values Remarks • Method

No data available None known Melting point / freezing point No data available None known Initial boiling point and boiling rangeNo data available None known Flash point No data available None known **Evaporation rate** No data available None known **Flammability** No data available None known Flammability Limit in Air None known

Upper flammability or explosive No data available

limits No data available

Lower flammability or explosive

limits

Vapor pressure No data available None known No data available Relative vapor density None known No data available Relative density None known No data available Water solubility None known No data available None known Solubility(ies) None known No data available Partition coefficient

Autoignition temperature No data available

Decomposition temperature None known No data available Kinematic viscosity None known No data available **Dynamic viscosity** None known

Other information

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Explosive propertiesNo information availableOxidizing propertiesNo information availableSoftening pointNo information available

Molecular weight 721.63

VOC content

Liquid Density

Bulk density

No information available
No information available
No information available

10. Stability and reactivity

Reactivity No information available.

Chemical stability Stable under normal conditions.

Possibility of hazardous reactions None under normal processing.

Conditions to avoid None known based on information supplied.

Incompatible materials Strong acids. Strong bases. Strong oxidizing agents.

Hazardous decomposition products None known based on information supplied.

11. Toxicological information

Information on likely routes of exposure

Product Information

Inhalation Specific test data for the substance or mixture is not available. May cause irritation of

respiratory tract.

Eye contact Specific test data for the substance or mixture is not available. Causes serious eye irritation.

(based on components). May cause redness, itching, and pain.

Skin contact Specific test data for the substance or mixture is not available. Causes skin irritation. (based

on components).

Ingestion Specific test data for the substance or mixture is not available. Ingestion may cause

gastrointestinal irritation, nausea, vomiting and diarrhea. Harmful if swallowed. (based on

components).

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Redness. May cause redness and tearing of the eyes.

Acute toxicity

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Numerical measures of toxicity

No information available

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

Skin corrosion/irritationClassification based on data available for ingredients. Causes skin irritation. May cause skin

irritation.

Serious eye damage/eye irritation Classification based on data available for ingredients. Causes serious eye irritation.

Respiratory or skin sensitization No information available.

Germ cell mutagenicity No information available.

Carcinogenicity No information available.

Reproductive toxicityContains a known or suspected reproductive toxin. Classification based on data available

for ingredients. May damage fertility or the unborn child. May cause harm to breast-fed

children.

STOT - single exposure May cause respiratory irritation.

STOT - repeated exposureNo information available.

Aspiration hazard No information available.

Other adverse effects No information available.

Interactive effects No information available.

12. Ecological information

Ecotoxicity Harmful to aquatic life with long lasting effects.

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Persistence and degradability No information available.

Bioaccumulation There is no data for this product.

Other adverse effects No information available.

13. Disposal considerations

Disposal methods

Waste from residues/unused

products

Dispose of in accordance with local regulations. Dispose of waste in accordance with

environmental legislation.

Contaminated packaging Do not reuse empty containers.

14. Transport information

DOTNot regulatedTDGNot regulatedMEXNot regulatedIATANot regulatedIMDGNot regulated

15. Regulatory information

International Inventories

TSCA Complies under research and development exemption or is regulated by a different

government agency.

Chemical name	CAS No	US TSCA Inventory listing	US TSCA inactive/active designation
Itraconazole Mono N-Oxide	-	-	Unknown *

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*Contact supplier for details. One or more substances in this product are either not listed on the US TSCA inventory, listed on the confidential US TSCA inventory or are otherwise exempted from inventory listing requirements

DSL/NDSL

EINECS/ELINCS

Contact supplier for inventory compliance status.

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations

California Proposition 65

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This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

This product does not contain any substances regulated under applicable state right-to-know regulations

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

NFPAHealth hazards2Flammability0Instability0Special hazards-HMISHealth hazards2 *Flammability0Physical hazards0Personal protectionX

Chronic Hazard Star Legend *= Chronic Health Hazard

Key or legend to abbreviations and acronyms used in the safety data sheet

Legend Section 8: Exposure controls/personal protection

TWA TWA (time-weighted average) STEL STEL (Short Term Exposure Limit)

Ceiling Maximum limit value * Skin designation

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR) U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA) EPA (Environmental Protection Agency) Acute Exposure Guideline Level(s) (AEGL(s))

U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act

U.S. Environmental Protection Agency High Production Volume Chemicals

Food Research Journal

Hazardous Substance Database

International Uniform Chemical Information Database (IUCLID)

Japan GHS Classification

Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

NIOSH (National Institute for Occupational Safety and Health)

National Library of Medicine's ChemID Plus (NLM CIP)

National Library of Medicine's PubMed database (NLM PUBMED)

National Toxicology Program (NTP)

New Zealand's Chemical Classification and Information Database (CCID)

Organization for Economic Co-operation and Development Environment, Health, and Safety Publications

Organization for Economic Co-operation and Development High Production Volume Chemicals Program

Organization for Economic Co-operation and Development Screening Information Data Set

World Health Organization

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Revision Note No information available.

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Disclaimer

The information in this Safety Data Sheet meets the requirements of the United States OCCUPATIONAL SAFETY AND HEALTH ACT and regulations promulgated thereunder (29 CFR 1910.1200 et. seq.) This document is intended only as a guide to the appropriate precautionary handling of the material by a person trained in, or supervised by a person trained in, chemical handling. The user is responsible for determining the application. Depending on usage, protective clothing including eye and face guards and respirators must be used to avoid contact with material or breathing chemical vapors/fumes. Exposure to this product may have serious adverse health effects. This chemical may interact with other substances. Since the potential uses are so varied, we cannot warn of all of the potential dangers of use or interaction with other chemicals or materials. We warrant that the chemical meets the specifications set forth on the label. We (LGC/VHG/ARMI) disclaim any other warranties, expressed or implied with regard to the product supplied hereunder, its merchantability or its fitness for a particular purpose. The user should recognize that this product can cause severe injury and even death, especially if improperly handled or the known dangers of use are not heeded. Read all precautionary information.

End of Safety Data Sheet

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