



Safety Data Sheet

Voriconazole Oral Suspension, 40mg/mL

Revision Date: 03/13/2025

Section 1. Identification

Product identifier**Product Identity**

Voriconazole Oral Suspension, 40mg/mL

Other means of identification

Not Applicable

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

Antifungal

Details of the supplier of the safety data sheet**Company Name**

Lupin Somerset
400 Campus Drive
Somerset, NJ 08873

Emergency**24 hour Emergency Telephone No.****Customer Service:**

800-642-5263

Section 2. Hazard(s) identification

Emergency Overview

WARNING! MAY FORM COMBUSTIBLE DUST CONCENTRATIONS IN AIR (DURING PROCESSING)

Classification of the substance or mixture under OSHA's Hazard Communication Standard (1910.1200) revised 2024 (GHS revision 7).

Acute toxicity(oral), category 4;H302

Harmful if swallowed.

Carcinogen, category 2;H351

Suspected of causing cancer.

Reproductive toxicity, category 2;H361

Suspected of damaging fertility or the unborn child.

Specific target organ toxicity, repeated exposure category 2;H373

May cause damage to organs through prolonged or repeated exposure.

Combustible Dust

May form combustible dust concentrations in air.

Label elements

Warning

H302 Harmful if swallowed.

H351 Suspected of causing cancer.

H361 Suspected of damaging fertility or the unborn child.

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

May form combustible dust concentrations in air.



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[Prevention]

- 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, mist, vapors or spray.
- P264 Wash thoroughly after handling.
- P270 Do not eat, drink or smoke when using this product.
- P280 Wear protective gloves, eye protection, and face protection.

[Response]

- P301+312 IF SWALLOWED: Call a POISON CENTER, doctor or physician if you feel unwell.
- P308+313 IF exposed or concerned: Get medical advice or attention.
- P312 Call a POISON CENTER, doctor or physician if you feel unwell.
- P314 Get Medical advice or attention if you feel unwell.
- P330 Rinse mouth.

[Storage]

- P405 Store locked up.

[Disposal]

- P501 Dispose of contents or container in accordance with local and national regulations.

Other hazards

- This product contains no PBT/vPvB/vPvM chemicals.
- This product contains no endocrine disrupting chemicals.
- May form combustible dust concentrations in air.
- Does not contain component(s) that meet a 'definition' of per & poly fluoroalkyl substance (PFAS) per US or Canadian regulations.

Section 3. Composition/information on ingredients

This product contains the following substances that present a hazard within the meaning of the OSHA's Hazard Communication Standard (1910.1200) revised 2024 (GHS revision 7).

| Ingredient/Chemical Designations | Weight % | GHS Classification | Notes |
|---|----------|--|-------|
| Sucrose CAS Number: 57-50-1 Synonyms: (2R,3R,4S,5S,6R)-2-[(2S,3S,4S,5R)-3,4-dihydroxy-2,5-bis(hydroxymethyl)oxolan-2-yl]oxy-6-(hydroxymethyl)oxane-3,4,5-triol, alpha-D-Glucopyranoside, beta-D-fructofuranosyl, beta-D-fructofuranosyl alpha-D-glucopyranoside | 80 - 100 | Combustible Dust | ----- |
| Voriconazole CAS Number: 137234-62-9 Synonyms: (2R, 3S)-2-(2, 4-difluorophenyl)-3-(5-fluoropyrimidin-4-yl)-1-(1H-1, 2, 4-triazol-1-yl)butan-2-ol | 3 - 7 | Acute toxicity(oral), category 3;H301 Carcinogen, category 2;H351 Reproductive toxicity, category 2;H361 Specific target organ toxicity, repeated exposure category 2;H373 Aquatic toxicity (chronic), category 3;H412 | ----- |
| trisodium citrate CAS Number: 6132-04-3 Synonyms: No available information | 1 - 5 | Not Classified | ----- |



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| | | | |
|--|---------|--|-------|
| Citric acid CAS Number: 77-92-9 Synonyms: 2-HYDROXY 1, 2, 3 PROPANE TRICARBOXYLIC ACID | 1 - 5 | Eye Dam. 2;H319 Specific target organ toxicity, Single exposure category 3;H335 | ----- |
| Silicon dioxide, chemically prepared CAS Number: 112945-52-5 Synonyms: Amorphous fumed silica | 0.1 - 1 | Not Classified | ----- |

The actual concentration or concentration range is withheld as a trade secret.

*PBT/vPvB - PBT, vPvM or vPvB-substance.

The full texts of the phrases are shown in Section 16.

Section 4. First aid measures

Description of first aid measures

| | |
|--|--|
| General | In all cases of doubt, or when symptoms persist, seek medical attention. Never give anything by mouth to an unconscious person. |
| Inhalation | Remove to fresh air, keep patient warm and at rest. If breathing is irregular or stopped, give artificial respiration. If unconscious, place in the recovery position and obtain immediate medical attention. Give nothing by mouth. |
| Eyes | Irrigate copiously with clean water for at least 15 minutes, holding the eyelids apart and seek medical attention. |
| Skin | Remove contaminated clothing. Wash skin thoroughly with soap and water or use a recognized skin cleanser. |
| Ingestion | If swallowed obtain immediate medical attention. Keep at rest. Do NOT induce vomiting. |
| Most important symptoms and effects, both acute and delayed | |
| Overview | No specific symptom data available. Possible cancer hazard. Contains an ingredient which may cause cancer based on animal data (See Section 3 and Section 15 for each ingredient). Risk of cancer depends on duration and level of exposure. Treat symptomatically. See section 2 for further details. |
| Ingestion | Harmful if swallowed. |

Section 5. Fire-fighting measures

Extinguishing media

Recommended extinguishing media; alcohol resistant foam, CO², powder, water spray.

Unsuitable extinguishing media: Do not use; water jet.

Special hazards arising from the substance or mixture

Hazardous decomposition: No hazardous decomposition data available.

Explosion: Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

Do not breathe dust, fume, mist, vapors or spray.



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Advice for fire-fighters

As with all fires, wear positive pressure, self-contained breathing apparatus, (SCBA) with a full face piece and protective clothing. Persons without respiratory protection should leave area. Wear SCBA during clean-up immediately after fire. No smoking.

Dust explosions are possible.

ERG Guide No. ---

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Put on appropriate personal protective equipment (see section 8).

Dust Deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.

Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).

Nonsparking tools should be used.

Environmental precautions

Explosion: Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

Do not allow spills to enter drains or waterways.

Use good personal hygiene practices. Wash hands before eating, drinking, smoking, or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

Methods and material for containment and cleaning up

Sweep or vacuum to clean up spills. Do not use any procedure which causes dispersion of dust into the air if any possibility of ignition exists. Dispose of in accordance with local, state and federal regulations.

Section 7. Handling and storage

Precautions for safe handling

Handle containers carefully to prevent damage and spillage.

Avoid dust generation when handling product to minimize dust explosion potential.

See section 2 for further details. - [Prevention]

Conditions for safe storage, including any incompatibilities

Keep container tightly closed.

Minimize dust generation and accumulation. Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces. Dry powders can build static electricity charges when subjected to the friction of transfer and mixing operations. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Incompatible materials: No data available.

See section 2 for further details. - [Storage]



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Specific end use(s)

No data available.

Section 8. Exposure controls / personal protection

Control parameters

Exposure Limits

| CAS No. | Ingredient | Source | Value |
|-------------|--------------------------------------|--------|--|
| 57-50-1 | Sucrose | OSHA | 5 mg/m ³ (Respirable fraction), 15 mg/m ³ (total dust) |
| | | ACGIH | 10 mg/m ³ |
| | | NIOSH | TWA 10 mg/m ³ (total) TWA 5 mg/m ³ (resp) |
| 77-92-9 | Citric acid | OSHA | No Established Limit |
| | | ACGIH | No Established Limit |
| | | NIOSH | No Established Limit |
| 6132-04-3 | trisodium citrate | OSHA | No Established Limit |
| | | ACGIH | No Established Limit |
| | | NIOSH | No Established Limit |
| 112945-52-5 | Silicon dioxide, chemically prepared | OSHA | No Established Limit |
| | | ACGIH | No Established Limit |
| | | NIOSH | No Established Limit |
| 137234-62-9 | Voriconazole | OSHA | No Established Limit |
| | | ACGIH | No Established Limit |
| | | NIOSH | No Established Limit |

The exposure limits for nuisance dust are: OSHA PEL: 15 mg/m³ (50 mppcf*) TWA, ACGIH 10 mg/m³.

Exposure controls

Respiratory

If workers are exposed to concentrations above the exposure limit, they must use the appropriate, certified respirators.

Eyes

Protective safety glasses recommended

Skin

Protective gloves recommended.

Engineering Controls

It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in handling of this product contain explosion relief vents or an explosion suppression system or an oxygen- deficient environment. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment). Use only appropriately classified electrical equipment and powered industrial trucks.

Other Work Practices

Use good personal hygiene practices. Wash hands before eating, drinking, smoking, or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

See section 2 for further details.



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Section 9. Physical and chemical properties

Information on basic physical and chemical properties

| | |
|---|--|
| Physical State | Solid |
| Color | White Powder |
| Odor | Not Provided |
| Melting point / freezing point | Not Available |
| Initial boiling point and boiling range | Not Available |
| Flammability (solid, gas) | Not Applicable |
| Upper/lower flammability or explosive limits | Lower Explosive Limit: Not Available Upper Explosive Limit: Not Available |
| Flash Point | Not Available |
| Auto-ignition temperature | Not Available |
| Decomposition temperature | Not Available |
| pH | Not Available |
| Viscosity (cSt) | Not Available |
| Solubility in Water | Not Available |
| Partition coefficient n-octanol/water (Log Kow) | Not Available |
| Vapor pressure (Pa) | Not Available |
| Relative Density | Not Available |
| Vapor Density | Not Available |
| Evaporation rate (Ether = 1) | Not Available |
| VOC Content | Not Available |
| Other information | |
| No other relevant information. | |

Section 10. Stability and reactivity

Reactivity

Hazardous Polymerization will not occur.

Chemical stability

Stable under normal circumstances.

Possibility of hazardous reactions

No data available.

Conditions to avoid

No data available.

Incompatible materials

No data available.



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Hazardous decomposition products

No hazardous decomposition data available.

Section 11. Toxicological information

Acute toxicity

Note: When no route specific LD50 data is available for an acute toxin, the converted acute toxicity point estimate was used in the calculation of the product's ATE (Acute Toxicity Estimate).

| Ingredient | Oral LD50, mg/kg | Skin LD50, mg/kg | Inhalation Vapor LC50, mg/L/4hr | Inhalation Dust/Mist LC50, mg/L/4hr | Inhalation Gas LC50, ppm |
|--|-----------------------------|--------------------------------|---------------------------------|-------------------------------------|--------------------------|
| Sucrose - (57-50-1) | 29,700.00 - Category: NA | No data available. | No data available. | No data available. | No data available. |
| Voriconazole - (137234-62-9) | No data available. | No data available. | No data available. | No data available. | No data available. |
| trisodium citrate - (6132-04-3) | No data available. | No data available. | No data available. | No data available. | No data available. |
| Citric acid - (77-92-9) | No data available. | > 2,000.00, Rat - Category: NA | No data available. | No data available. | No data available. |
| Silicon dioxide, chemically prepared - (112945-52-5) | 3,160.00, Rat - Category: 5 | No data available. | No data available. | No data available. | No data available. |

Carcinogen Data

| CAS No. | Ingredient | Source | Value |
|-------------|--------------------------------------|--------|--|
| 57-50-1 | Sucrose | OSHA | Regulated Carcinogen: No; |
| | | NTP | Known: No; Suspected: No; |
| | | IARC | Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; |
| | | ACGIH | A4 |
| 77-92-9 | Citric acid | OSHA | Regulated Carcinogen: No; |
| | | NTP | Known: No; Suspected: No; |
| | | IARC | Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; |
| | | ACGIH | No Established Limit |
| 6132-04-3 | trisodium citrate | OSHA | Regulated Carcinogen: No; |
| | | NTP | Known: No; Suspected: No; |
| | | IARC | Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; |
| | | ACGIH | No Established Limit |
| 112945-52-5 | Silicon dioxide, chemically prepared | OSHA | Regulated Carcinogen: No; |
| | | NTP | Known: No; Suspected: No; |
| | | IARC | Group 1: No; Group 2a: No; Group 2b: No; Group 3: Yes; |
| | | ACGIH | No Established Limit |
| 137234-62-9 | Voriconazole | OSHA | Regulated Carcinogen: No; |
| | | NTP | Known: No; Suspected: No; |
| | | IARC | Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; |
| | | ACGIH | No Established Limit |

| Classification | Category | Hazard Description |
|----------------|----------|--------------------|
|----------------|----------|--------------------|



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| Acute toxicity (oral) | 4 | Harmful if swallowed. |
| Acute toxicity (dermal) | --- | Not Applicable |
| Acute toxicity (inhalation) | --- | Not Applicable |
| Skin corrosion/irritation | --- | Not Applicable |
| Serious eye damage/irritation | --- | Not Applicable |
| Respiratory sensitization | --- | Not Applicable |
| Skin sensitization | --- | Not Applicable |
| Germ cell mutagenicity | --- | Not Applicable |
| Carcinogenicity | 2 | Suspected of causing cancer. |
| Reproductive toxicity | 2 | Suspected of damaging fertility or the unborn child. |
| STOT-single exposure | --- | Not Applicable |
| STOT-repeated exposure | 2 | May cause damage to organs through prolonged or repeated exposure. |
| Aspiration hazard | --- | Not Applicable |

Possible routes of entry: No available information

Symptoms and effects, both acute and delayed:

No specific symptom data available.

Possible cancer hazard. Contains an ingredient which may cause cancer based on animal data (See Section 3 and Section 15 for each ingredient). Risk of cancer depends on duration and level of exposure.

Treat symptomatically.

Ingestion Harmful if swallowed.

Section 12. Ecological information

Toxicity

No additional information provided for this product. See Section 3 for chemical specific data.

Aquatic Ecotoxicity

| Ingredient | 96 hr LC50 fish, mg/L | 48 hr EC50 crustacea, mg/L | ErC50 algae, mg/L |
|--|------------------------|----------------------------|--------------------|
| Sucrose - (57-50-1) | No data available. | No data available. | No data available. |
| Voriconazole - (137234-62-9) | No data available. | No data available. | No data available. |
| trisodium citrate - (6132-04-3) | No data available. | No data available. | No data available. |
| Citric acid - (77-92-9) | 600.00, Leuciscus idus | 2,083.00, Daphnia magna | No data available. |
| Silicon dioxide, chemically prepared - (112945-52-5) | No data available. | No data available. | No data available. |

Persistence and degradability

There is no data available on the preparation itself.



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Bioaccumulative potential

Not Available

Mobility in soil

No data available.

Results of PBT and vPvB assessment

This product contains no PBT/vPvB/vPvM chemicals.

Other adverse effects

No data available.

Section 13. Disposal considerations

Waste treatment methods

Waste should not be released to sewers. Observe all federal, state, and local regulations when disposing of this substance.

Section 14. Transport information

| | DOT (Domestic Surface Transportation) | IMO / IMDG (Ocean Transportation) | ICAO/IATA |
|------------------------------|--|--|--|
| UN number | Not Regulated | Not Regulated | Not Regulated |
| UN proper shipping name | Not Regulated | Not Regulated | Not Regulated |
| Transport hazard class(es) | Class: Not Applicable Sub Class: Not Applicable | Class: Not Applicable Sub Class: Not Applicable | Class: Not Applicable Sub Class: Not Applicable |
| Packing group | Not Applicable | Not Applicable | Not Applicable |
| Environmental hazards | Marine Pollutant: No; | | |
| Special precautions for user | Not Applicable | | |

Section 15. Regulatory information

Regulatory Overview The regulatory data in Section 15 is not intended to be all-inclusive, only selected regulations are represented.

Classification of the substance or mixture under OSHA's Hazard Communication Standard (1910.1200) revised 2024 (GHS revision 7).



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Toxic Substance Control Act (TSCA)

| CAS Number | Ingredient | Toxic Substance Control Act (TSCA) | Comments | Status |
|--------------|--------------------------------------|------------------------------------|----------|--------|
| 0000077-92-9 | Citric acid | Yes | | ACTIVE |
| 0112945-52-5 | Silicon dioxide, chemically prepared | No | | |
| 0000057-50-1 | Sucrose | Yes | | ACTIVE |
| 0006132-04-3 | trisodium citrate | No | | |
| 0137234-62-9 | Voriconazole | No | | |

EPCRA 302 Extremely Hazardous:

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

EPCRA 313 Toxic Chemicals:

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Proposition 65 - Carcinogens (>0.0%):

Acetaldehyde

Proposition 65 - Developmental Toxins (>0.0%):

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Proposition 65 - Female Repro Toxins (>0.0%):

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Proposition 65 - Male Repro Toxins (>0.0%):

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Proposition 65 Label Warning:



WARNING: This product can expose you to chemicals including [Acetaldehyde], which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

Note: Ethanol (Ethyl alcohol) has been placed on the California Proposition 65 Cancer and Developmental Lists when in alcoholic beverages.

Section 16. Other information

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The information and recommendations contained herein are based upon data believed to be correct. However, no guarantee or warranty of any kind, expressed or implied, is made with respect to the information contained herein. We accept no responsibility and disclaim all liability for any harmful effects which may be caused by exposure to our products. Customers/users of this product must comply with all applicable health and safety laws, regulations, and orders.

Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.



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The full text of the phrases appearing in section 3 is:

H301 Toxic if swallowed.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H351 Suspected of causing cancer.

H361 Suspected of damaging fertility or the unborn child.

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

H412 Harmful to aquatic life with long lasting effects.

Disclaimer: The information presented herein is supplied as a guide to those who handles or use this product. Safe work practices must be employed when working with any materials. It is important that the end user makes a determination regarding the adequacy of the safety procedures employed during the use of this product.

Reviewed & Approved by: IES Engineers

Authored by: Quantum SDS

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