

SAFETY DATA SHEET



LOTRIMIN Liquid Aerosol Powder 0.13% Spray

Version 2.1 Revision Date: 10/18/2021 SDS Number: 122000016711 Date of last issue: 03/19/2021
Date of first issue: 11/10/2017

SECTION 1. IDENTIFICATION

Product identifier

Product name : LOTRIMIN Liquid Aerosol Powder 0.13% Spray

UI Number : 1612506

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

Use of the Sub-stance/Mixture : Medicinal products

Details of the supplier of the safety data sheet

Company

Bayer HealthCare, LLC
100 Bayer Boulevard PO Box 915
WHIPPANY 07981-0915
UNITED STATES OF AMERICA
(800) 743-5423

Emergency telephone number

In case of emergency: (800) 331-4536
Chemtrec: (800) 424-9300

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Eye irritation : Category 2A

Flammable aerosols : Category 1

Gases under pressure : Compressed gas

GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H222 Extremely flammable aerosol.
H319 Causes serious eye irritation.
H280 Contains gases under pressure, may explode if heated.

Precautionary Statements : **Prevention:**
P210 Keep away from heat/ sparks/ open flames/ hot surfaces.
No smoking.
P211 Do not spray on an open flame or other ignition source.

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P251 Pressurized container: Do not pierce or burn, even after use.
P264 Wash skin thoroughly after handling.
P280 Wear protective gloves/protective clothing/eye protection/face protection.

Response:

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Dimethyl ether	115-10-6	75
Ethanol	64-17-5	18.62
Macrogol-15-Hydroxystearat P.I	70142-34-6	6.25
Miconazole Nitrate (+ -)	22832-87-7	0.13

SECTION 4. FIRST AID MEASURES

General advice : No hazards which require special first aid measures.

If inhaled : Consult a physician after significant exposure.
In case of skin contact : If skin reactions occur, contact a physician.
In case of eye contact : Flush eyes with water as a precaution.
If swallowed : In case of accidental ingestion, contact your regional poison center or physician immediately.

Most important symptoms and effects, both acute and delayed : Causes serious eye irritation.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Any
Unsuitable extinguishing media : High volume water jet

Specific hazards during fire fighting : Fire may cause evolution of:
Carbon monoxide (CO)
Carbon dioxide (CO₂)

Further information : Prevent fire extinguishing water from contaminating surface water or the ground water system.

Special protective equipment for fire-fighters : In the event of fire, wear self-contained breathing apparatus.

SECTION 6. ACCIDENTAL RELEASE MEASURES

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- Personal precautions, protective equipment and emergency procedures : Ensure adequate ventilation.
Keep away from heat and sources of ignition.
- Environmental precautions : No special environmental precautions required.
- Methods and materials for containment and cleaning up : Suppress (knock down) gases/vapours/mists with a water spray jet.
Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).
Place in closed containers. Label for proper disposal.

SECTION 7. HANDLING AND STORAGE

- Advice on protection against fire and explosion : Keep away from open flames, hot surfaces and sources of ignition.
- Advice on safe handling : Pressurized container: protect from sunlight and do not expose to temperatures exceeding 50 °C. Do not pierce or burn, even after use.
- Conditions for safe storage : Store at temperatures and conditions as indicated on the product label.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Dimethyl ether	115-10-6	TWA	1,000 ppm	US WEEL
Ethanol	64-17-5	STEL	1,000 ppm	ACGIH
		TWA	1,000 ppm 1,900 mg/m ³	NIOSH REL
		TWA	1,000 ppm 1,900 mg/m ³	OSHA Z-1
		TWA	1,000 ppm 1,900 mg/m ³	OSHA P0

Personal protective equipment

- Respiratory protection : Recommended Filter type:
HEPA
None required for consumer use of this product.
- Hand protection
Material : Chemically resistant gloves.
- Remarks : None required for consumer use of this product.
- Eye protection : Safety glasses
None required for consumer use of this product.
- Protective measures : Wear suitable protective equipment.
Please consult label for end-user requirements.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

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Appearance : aerosol
Color : No data available
Odor : No data available
pH : No data available

Melting point/range : No data available

Boiling point/boiling range : -12.6 °F / -24.8 °C

Flash point : -44 °F / -42 °C
(1,013 hPa)

Burning rate : No data available

Self-ignition : No data available

Burning number : No data available

Upper explosion limit / Upper flammability limit : 24.4 %(V)
(for a component of this mixture)

Lower explosion limit / Lower flammability limit : 2.8 %(V)
(for a component of this mixture)

Vapor pressure : 5,100 hPa (68 °F / 20 °C)

Relative vapor density : No data available

Density : No data available

Bulk density : No data available

Solubility(ies)
Water solubility : No data available
Solubility in other solvents : No data available

Partition coefficient: n-octanol/water : No data available

Autoignition temperature : No data available

Decomposition temperature : No data available

Temperature of polymerization (SAPT) : No data available

Viscosity
Viscosity, dynamic : No data available
Viscosity, kinematic : No data available

Explosive properties : No data available
Oxidizing properties : No data available

Impact sensitivity : No data available

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Minimum explosible dust concentration : No data available
Minimum ignition energy : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : No data available
Chemical stability : No data available
Possibility of hazardous reactions : No data available
Conditions to avoid : No data available
Incompatible materials : Oxidizing agents
Hazardous decomposition products : Carbon monoxide (CO)
Carbon dioxide (CO₂)

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Not classified based on available information.

Components:

Dimethyl ether:

Acute inhalation toxicity : LC50 (Rat): 164000 ppm
Exposure time: 4 h
Test atmosphere: gas
Remarks: Unconsciousness

Ethanol:

Acute oral toxicity : LD50 (Rat): 10,470 mg/kg
Method: OECD 401
Acute dermal toxicity : LD50 (Rabbit): 15,800 mg/kg

Macrogol-15-Hydroxystearat P.I.:

Acute oral toxicity : LD50 (Rat): > 20,600 mg/kg

Miconazole Nitrate (+ -):

Acute oral toxicity : LD50 (Rat): 920 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

Ethanol:

Species : Rabbit
Method : OECD 404
Result : No skin irritation

Macrogol-15-Hydroxystearat P.I.:

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Result : No skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

Ethanol:

Species : Rabbit
Result : Eye irritation
Method : OECD 405

Macrogol-15-Hydroxystearat P.I.:

Result : No eye irritation

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Product:

Test Type : Skin sensitisation
Result : Not a skin sensitizer.
Remarks : Expert judgement

Components:

Ethanol:

Test Type : Local lymph node assay (LLNA)
Species : Mouse
Method : OECD 429
Result : negative

Macrogol-15-Hydroxystearat P.I.:

Test Type : Skin sensitisation
Species : Guinea pig
Assessment : May cause an allergic skin reaction.
Method : OECD 406
Result : May cause sensitisation by skin contact.

Miconazole Nitrate (+ -):

Result : May cause sensitisation by skin contact.

Germ cell mutagenicity

Not classified based on available information.

Components:

Dimethyl ether:

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Genotoxicity in vitro : Test Type: Ames test
Test system: Salmonella typhimurium
Result: negative

Test Type: Chromosome aberration test in vitro
Test system: Human lymphocytes
Result: negative

Ethanol:

Genotoxicity in vitro : Test Type: Ames test
Test system: Salmonella typhimurium
Method: OECD 471
Result: negative

Test Type: Mouse lymphoma assay
Method: OECD 476
Result: negative

Genotoxicity in vivo : Test Type: Chromosome aberration test in vivo
Species: Mouse
Method: OECD 478
Result: Ambiguous

Test Type: Micronucleus test
Species: Mouse
Method: OECD 474
Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Ethanol:

Result : Animal testing did not show any carcinogenic effects.

IARC Group 1: Carcinogenic to humans
Ethanol 64-17-5

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Not classified based on available information.

Components:

Ethanol:

Effects on fertility : Species: Mouse
Application Route: Oral
General Toxicity Parent: NOAEL: 15 %

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General Toxicity F1: NOAEL: 10 %
General Toxicity F2: NOAEL: < 15 %
Method: OECD 416
Result: Animal testing did not show any effects on fertility.

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

Further information

Components:

Ethanol:

Remarks : Breathing of the fumes may lead to narcotic symptoms.

Remarks : If inhaled:
Headache
Vomiting
Nausea

Remarks : After absorption of large quantities
hypotension
Coma
Unconsciousness
respiratory paralysis

Miconazole Nitrate (+ -):

Pharmaceutic effects
Remarks : Antimycotic

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Dimethyl ether:

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 4,400 mg/l
Exposure time: 48 h
Test Type: static test

Ecotoxicology Assessment

Acute aquatic toxicity : slightly hazardous to water

Ethanol:

Toxicity to fish : EC50 (Pimephales promelas (fathead minnow)): 15,300 mg/l

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Exposure time: 96 h
Test Type: flow-through test
Method: US-EPA

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 9,268 - 14,221 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants : EC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l
Exposure time: 72 h

NOEC (Chlorella vulgaris (Fresh water algae)): 11.5 mg/l
Exposure time: 72 h

Toxicity to microorganisms : Toxic limit concentration (Pseudomonas putida): 6,500 mg/l

Macrogol-15-Hydroxystearat P.I:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 100 mg/l
Exposure time: 96 h
Test Type: Acute Fish toxicity
Method: OECD 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia (water flea)): 100 mg/l
Exposure time: 48 h
Method: OECD 202

Toxicity to algae/aquatic plants : EC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l
Exposure time: 72 h
Method: OECD 201

Toxicity to microorganisms : EC20 (activated sludge, adapted): > 1,000 mg/l
Method: ISO 8192

Ecotoxicology Assessment

Acute aquatic toxicity : Harmful to aquatic life.

Chronic aquatic toxicity : Harmful to aquatic life with long lasting effects.

Persistence and degradability

Components:

Ethanol:

Biodegradability : Result: rapidly biodegradable
Biodegradation: 94 %
Method: OECD 301E

Biochemical Oxygen Demand (BOD) : 930 - 1,670 mg/g
Incubation time: 5 d

ThOD : 2,100 mg/g

Macrogol-15-Hydroxystearat P.I:

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Biodegradability : aerobic
Inoculum: activated sludge
Biodegradation: 90 - 100 %
Exposure time: 21 d
Method: OECD 301 A
Remarks: Biodegradable

Bioaccumulative potential

Components:

Ethanol:

Bioaccumulation : Remarks: Bioaccumulation is unlikely.

Partition coefficient: n-octanol/water : log Pow: -0.320

Mobility in soil

No data available

Other adverse effects

Product:

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Waste disposal should be in accordance with existing federal, state and local environmental control laws.
However, under RCRA, it is the responsibility of the product user to determine at the time of disposal, whether a material containing the product or derived from the product should be classified as a hazardous waste. (40 CFR 261.20-24)

SECTION 14. TRANSPORT INFORMATION

International Regulations

IATA-DGR

UN/ID No. : UN 1950
Proper shipping name : AEROSOLS, FLAMMABLE
Class : 2.1
Packing group : Not assigned by regulation
Labels : 2.1

IMDG-Code

UN number : UN 1950
Proper shipping name : AEROSOLS
Class : 2.1
Packing group : Not assigned by regulation
Labels : 2.1
Marine pollutant : no

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

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Domestic regulation

49 CFR

UN/ID/NA number : UN 1950
Proper shipping name : AEROSOLS
Class : 2.1
Packing group : Not assigned by regulation
Labels : Flammable Gas
Marine pollutant : no

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Flammable (gases, aerosols, liquids, or solids)
Serious eye damage or eye irritation

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

The following chemical(s) are listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F):

Dimethyl ether	115-10-6	75 %
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The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCM I Intermediate or Final VOC's (40 CFR 60.489):

Dimethyl ether	115-10-6	75 %
Ethanol	64-17-5	18.62 %

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

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This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

This product does not contain any priority pollutants related to the U.S. Clean Water Act

US State Regulations

Massachusetts Right To Know

Dimethyl ether 115-10-6
Ethanol 64-17-5

Pennsylvania Right To Know

Dimethyl ether 115-10-6
Ethanol 64-17-5

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

California Permissible Exposure Limits for Chemical Contaminants

Ethanol 64-17-5

International Regulations

Montreal Protocol : Not applicable
Rotterdam Convention (Prior Informed Consent) : Not applicable
Stockholm Convention (Persistent Organic Pollutants) : Not applicable

The ingredients of this product are reported in the following inventories:

TSCA : Product contains substance(s) not listed on TSCA inventory.

TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

SECTION 16. OTHER INFORMATION

Further information

NFPA 704:

Health - 2 Flammability - 4 Instability - 0 Others -

HMIS® IV:

Health - 2 Flammability - 4 Instability - 0 Others -

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

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NIOSH REL	:	USA. NIOSH Recommended Exposure Limits
OSHA P0	:	USA. OSHA - TABLE Z-1 Limits for Air Contaminants - 1910.1000
OSHA Z-1	:	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
US WEEL	:	USA. Workplace Environmental Exposure Levels (WEEL)
ACGIH / STEL	:	Short-term exposure limit
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA P0 / TWA	:	8-hour time weighted average
OSHA Z-1 / TWA	:	8-hour time weighted average
US WEEL / TWA	:	8-hr TWA

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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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