



# Naftin 1% Gel Safety Data Sheet (SDS)

SDS Revision Date:

03 JUN 2016

## 1. Identification

### 1.1. Product identifier

**Product Identity** Naftin Gel 1%

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

**Intended use** Naftin Gel, 1% is indicated for the topical treatment of tinea pedis, tinea cruris, and tinea corporis caused by the organisms Trichophyton rubrum, Trichophyton mentagrophytes, Trichophyton tonsurans, Epidermophyton floccosum.

### 1.3. Details of the supplier of the safety data sheet

**Company Name** Merz North America, Inc.  
6501 Six Forks Road  
Raleigh, NC 27615  
844-469-6379

**24 hour Emergency Telephone No.** Hazmat Service Emergency Number: 800-373-7542  
International Shipments: +1-484-951-2432

## 2. Hazard(s) Identification

### 2.1. Classification of the substance or mixture

Flam. Liq. 3;H226 Flammable liquid and vapor  
Eye Irrit. 2;H319 Causes serious eye irritation\*

\*Note: Hazard classification is not required by GHS classification of this mixture.

### 2.2. Label elements

Using the Toxicity Data listed in section 11 and 12 the product is labeled as follows.



### Warning

H226 Flammable liquid and vapor.



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### [Prevention]:

P210 Keep away from heat / sparks / open flames / hot surfaces - No smoking.

P235 Keep cool.

P240 Ground / bond container and receiving equipment.

P241 Use explosion-proof electrical / ventilating / light / equipment.

P242 Use only non-sparking tools.

P243 Take precautionary measures against static discharge.

P280 Wear protective gloves / eye protection / face protection.

### [Response]:

P303+361+353 IF ON SKIN (or hair): Remove / Take off immediately all contaminated clothing. Rinse skin with water / shower.

P370+378 In case of fire: Use extinguishing media listed in section 5 of SDS for extinction.

### [Storage]:

P403+233 Store in a well-ventilated place. Keep container tightly closed.

### [Disposal]:

P501 Dispose of contents / container in accordance with local / national regulations.

## 3. Composition/Information on Ingredients

This product contains the following substances that present a hazard within the meaning of the relevant State and Federal Hazardous Substances regulations.

Ingredient/Chemical Designations	Weight %	GHS Classification	Notes
Ethanol CAS Number: 0000064-17-5	35 - 50	Flam. Liq. 2;H225	[1][2]
Diisopropanolamine CAS Number: 0001335-54-2	1.0 - 10	Eye Irrit. 2;H319	[1]
Naftifine hydrochloride CAS Number: 0065473-14-5	1.0 - 10	Not Classified	[1]

In accordance with paragraph (i) of §1910.1200, the specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret.

[1] Substance classified with a health or environmental hazard.

[2] Substance with a workplace exposure limit.

[3] PBT-substance or vPvB-substance.

\*The full texts of the phrases are:

H225 Highly flammable liquid and vapor.

H319 Causes serious eye irritation.



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### 4. First Aid Measures

#### 4.1. 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.

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

- Overview**
- Eye Contact: Contact with the eyes may result in moderate to severe irritation.
- Skin Contact: If irritation develops, wash skin thoroughly with soap and water and contact a healthcare professional.
- Inhalation: Not likely to occur under normal conditions of use.
- Ingestion: Contact a healthcare professional or poison control center immediately.
- Exposure to solvent vapor concentrations from the component solvents in excess of the stated occupational exposure limits may result in adverse health effects such as mucous membrane and respiratory system irritation and adverse effects on the kidneys, liver and central nervous system. Symptoms include headache, nausea, dizziness, fatigue, muscular weakness, drowsiness and in extreme cases, loss of consciousness.
- Repeated or prolonged contact with the preparation may cause removal of natural fat from the skin resulting in dryness, irritation and possible non-allergic contact dermatitis. Solvents may also be absorbed through the skin. Splashes of liquid in the eyes may cause irritation and soreness with possible reversible damage.



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### 5. Fire-fighting Measures

#### 5.1. Extinguishing media

Carbon Dioxide, Foam, Dry Chemical and Water Fog.

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

Hazardous decomposition: Carbon dioxide and carbon monoxide

Keep away from heat / sparks / open flames / hot surfaces - No smoking.

Keep cool.

Ground / bond container and receiving equipment.

Use explosion-proof electrical / ventilating / light / equipment.

Use only non-sparking tools.

Take precautionary measures against static discharge.

#### 5.3. Advice for fire-fighters

Use self-contained breathing apparatus in enclosed or confined spaces or as otherwise needed.

**ERG Guide No.** 128

### 6. Accidental Release Measures

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

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

#### 6.2. Environmental precautions

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.

Collect in flammable waste container for disposal.

#### 6.3. Methods and material for containment and cleaning up

Sweep up or take up with absorbent material and wash with water. If large quantities are spilled, flush spill area with water.

### 7. Handling and Storage

#### 7.1. Precautions for safe handling

Avoid unintentional contact with skin surfaces. Do not allow contact with eyes. Wash thoroughly after handling. Observe all labeling precautions. No eating, drinking or smoking in area.

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

Handle containers carefully to prevent damage and spillage.

Naked flames and smoking should not be permitted in storage areas. It is recommended that fork lift trucks and electrical equipment are protected to the appropriate standard.

Incompatible materials: Store away from oxidizers and heat. Store below 30°C.

Store in a cool (below 30°C), dry location out of direct sunlight. Keep container closed when not in use.



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### 7.3. Specific end use(s)

No data available.

## 8. Exposure Controls and Personal Protection

### 8.1. Control parameters

CAS No.	Ingredient	Source	Exposure
			Value
0000064-17-5	Ethanol	OSHA	TWA 1000 ppm (1900 mg/m3)
		ACGIH	STEL: 1000 ppm Revised 2009
		NIOSH	TWA 1000 ppm (1900 mg/m3)
		Supplier	No Established Limit
0001335-54-2	Diisopropanolamine	OSHA	No Established Limit
		ACGIH	No Established Limit
		NIOSH	No Established Limit
		Supplier	No Established Limit
0065473-14-5	Naftifine hydrochloride	OSHA	No Established Limit
		ACGIH	No Established Limit
		NIOSH	No Established Limit
		Supplier	No Established Limit

### Carcinogen Data

CAS No.	Ingredient	Source	Value
0000064-17-5	Ethanol	OSHA	Select Carcinogen: No
		NTP	Known: No; Suspected: No
		IARC	Group 1: Yes; Group 2a: No; Group 2b: No; Group 3: No; Group 4: No
0001335-54-2	Diisopropanolamine	OSHA	Select Carcinogen: No
		NTP	Known: No; Suspected: No
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; Group 4: No
0065473-14-5	Naftifine hydrochloride	OSHA	Select Carcinogen: No
		NTP	Known: No; Suspected: No
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; Group 4: No

### 8.2. Exposure controls

#### Respiratory

None necessary for normal product handling.

#### Eyes

None necessary for normal product handling. Avoid eye contact.

#### Skin

None necessary for normal product handling. Persons repeatedly applying the product to others should wear gloves when handling NAFTIN Gel.

#### Engineering Controls

None necessary for normal product handling.

#### 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.



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### 9. Physical and Chemical Properties

<b>Appearance</b>	Liquid
<b>Odor</b>	Not provided
<b>Odor threshold</b>	Not Measured
<b>pH</b>	Not Measured
<b>Melting point / freezing point</b>	Not Measured
<b>Initial boiling point and boiling range</b>	80°C (Ethyl Alcohol)
<b>Flash Point</b>	77°F (Seta Flash Cup)
<b>Evaporation rate (Ether = 1)</b>	Not Measured
<b>Flammability (solid, gas)</b>	Not Applicable
<b>Upper/lower flammability or explosive limits</b>	<b>Lower Explosive Limit:</b> Not Measured <b>Upper Explosive Limit:</b> Not Measured
<b>Vapor pressure (Pa)</b>	30 mm @ 25°C (Ethyl Alcohol)
<b>Vapor Density</b>	Not Measured
<b>Specific Gravity</b>	Not Measured
<b>Solubility in Water</b>	Not Measured
<b>Partition coefficient n-octanol/water (Log Kow)</b>	Not Measured
<b>Auto-ignition temperature</b>	870°F
<b>Decomposition temperature</b>	Not Measured
<b>Viscosity (cSt)</b>	Not Measured

### 10. Stability and Reactivity

#### 10.1. Reactivity

Hazardous Polymerization will not occur.

#### 10.2. Chemical stability

Stable under normal circumstances.

#### 10.3. Possibility of hazardous reactions

No data available.

#### 10.4. Conditions to avoid

High temperatures and fires.

#### 10.5. Incompatible materials

Store away from oxidizers and heat. Store below 30°C.

#### 10.6. Hazardous decomposition products

Carbon dioxide and carbon monoxide



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## 11. Toxicological Information

### Acute toxicity

Exposure to solvent vapor concentrations from the component solvents in excess of the stated occupational exposure limits may result in adverse health effects such as mucous membrane and respiratory system irritation and adverse effects on the kidneys, liver and central nervous system. Symptoms include headache, nausea, dizziness, fatigue, muscular weakness, drowsiness and in extreme cases, loss of consciousness.

Repeated or prolonged contact with the preparation may cause removal of natural fat from the skin resulting in dryness, irritation and possible non-allergic contact dermatitis. Solvents may also be absorbed through the skin. Splashes of liquid in the eyes may cause irritation and soreness with possible reversible damage.

Ingredient	Oral LD50, mg/kg	Skin LD50, mg/kg	Inhalation Vapor LD50, mg/L/4hr	Inhalation Dust/Mist LD50, mg/L/4hr	Inhalation Gas LD50, ppm
Ethanol - (64-17-5)	7,060.00, Rat - Category: NA	20,000.00, Rabbit - Category: NA	124.70, Rat - Category: NA	No data available	No data available
Diisopropanolamine - (1335-54-2)	No data available	No data available	No data available	No data available	No data available
Naftifine hydrochloride - (65473-14-5)	No data available	No data available	No data available	No data available	No data available

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).

Classification	Category	Hazard Description
Acute toxicity (oral)	---	Not Applicable
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	---	Not Applicable
Reproductive toxicity	---	Not Applicable
STOT-single exposure	---	Not Applicable
STOT-repeated exposure	---	Not Applicable
Aspiration hazard	---	Not Applicable



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### 12. Ecological Information

#### 12.1. Toxicity

Toxic to aquatic life

#### Aquatic Ecotoxicity

Ingredient	96 hr LC50 fish, mg/l	48 hr EC50 crustacea, mg/l	ErC50 algae, mg/l
Ethanol - (64-17-5)	42.00, Oncorhynchus mykiss	2.00, Daphnia magna	17.921 (96 hr), Ulva pertusa
Diisopropanolamine - (1335-54-2)	Not Available	Not Available	Not Available
Naftifine hydrochloride - (65473-14-5)	Not Available	Not Available	Not Available

#### 12.2. Persistence and degradability

There is no data available on the preparation itself.

#### 12.3. Bioaccumulative potential

Not Measured

#### 12.4. Mobility in soil

No data available.

#### 12.5. Results of PBT and vPvB assessment

This product contains no PBT/vPvB chemicals.

#### 12.6. Other adverse effects

No data available.

### 13. Disposal Considerations

#### 13.1. Waste treatment methods

Observe all federal, state and local regulations when disposing of this substance.





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### 14. Transport Information

	DOT (Domestic Surface Transportation)	IMO / IMDG (Ocean Transportation)	ICAO/IATA
14.1. UN number	UN1993	UN1993	UN1993
14.2. UN proper shipping name	UN1993, Flammable liquids, n.o.s., (Ethyl Alcohol Solution), 3, III	Flammable liquids, n.o.s., (Ethyl Alcohol Solution)	Flammable liquids, n.o.s., (Ethyl Alcohol Solution)
14.3. Transport hazard class(es)	DOT Hazard Class: 3	IMDG: 3 Sub Class: Not Applicable	Air Class: 3
14.4. Packing group	III	III	III
14.5. Environmental hazards	IMDG Marine Pollutant: No		
14.6. Special precautions for user	No further information		

Note: See 49 CFR 173.150 for information regarding the limited quantity exemption as it pertains to transport of Class 3 Flammable Liquids

### 15. Regulatory Information

Regulatory Overview	The regulatory data in Section 15 is not intended to be all-inclusive, only selected regulations are represented.
Toxic Substance Control Act (TSCA)	Not Applicable-Substances that are regulated under other federal regulations (ie, food additives, drug, cosmetics etc) are not subject to TSCA.
WHMIS Classification	B2

US EPA Tier II Hazards

Fire: Yes  
Sudden Release of Pressure: No  
Reactive: No  
Immediate (Acute): No  
Delayed (Chronic): No

**EPCRA 311/312 Chemicals and RQs:** To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

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



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**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.

**New Jersey RTK Substances (>1%):**

Ethanol

**Pennsylvania RTK Substances (>1%):**

Ethanol

### 16. Other Information

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.

**This is the first version in the GHS SDS format. Listings of changes from previous versions in other formats are not applicable.**

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