



Naftin 1% Cream Safety Data Sheet (SDS)

SDS Revision Date:

03 JUN 2016

1. Identification

1.1. Product identifier

Product Identity

Naftin 1% Cream

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

Intended use

Naftin Cream, 1% is indicated for the topical treatment of tinea pedis, tinea cruris, and tinea corporis caused by the organisms Trichophyton rubrum, Trichophyton mentagrophytes, and 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

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.

[Prevention]:

No GHS prevention statements

[Response]:

No GHS response statements

[Storage]:

No GHS storage statements

[Disposal]:

No GHS disposal statements

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.



Naftin 1% Cream Safety Data Sheet (SDS)

SDS Revision Date:

03 JUN 2016

Ingredient/Chemical Designations	Weight %	GHS Classification	Notes
Benzyl alcohol CAS Number: 0000100-51-6	1.0 - 10	Acute Tox. 4;H332 Acute Tox. 4;H302	[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:

H302 Harmful if swallowed.

H332 Harmful if inhaled.

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	Inhalation: Not expected to be an inhalation hazard with prescribed use. Eye Contact: Causes eye irritation. Contact with eye causes irritation, redness, and burning. Skin Contact: Causes skin irritation. Absorbed through the skin. May cause allergic reactions in some individuals. Exposure causes redness, itching and inflammation. Ingestion: Not expected to be an ingestion hazard with prescribed use. Ingestion may be harmful and cause nausea, vomiting, diarrhea, or other systemic effects. Contraindications: Individuals sensitive to naftifine hydrochloride or hypersensitivity to any of the components in the formulation. Chronic Health Effects: Hypersensitization to naftifine hydrochloride or to formulation.
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5. Fire-fighting measures

5.1. Extinguishing media

Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire.



Naftin 1% Cream Safety Data Sheet (SDS)

SDS Revision Date:

03 JUN 2016

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition: Carbon oxides, nitrogen oxides, hydrogen chloride

5.3. Advice for fire-fighters

Firefighters should wear self-contained breathing apparatus and full protective gear. Water can be used to cool, protect exposed material and knock down fumes.

ERG Guide No. ----

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.

6.3. Methods and material for containment and cleaning up

Small liquid spill: Wipe up and place into a container for disposal.

Large liquid spill: Wipe up and place into a container for disposal. Prevent runoff from entering drains, sewers or streams.

7. Handling and storage

7.1. Precautions for safe handling

Avoid contact with eyes, skin, and clothing. Do not taste or swallow. Wash thoroughly after handling.

7.2. Conditions for safe storage, including any incompatibilities

Handle containers carefully to prevent damage and spillage.

Incompatible materials: Contact with strong oxidizing agents. Hazardous polymerization does not occur.

Keep container closed. Store in tight, light-resistant container at a temperature between 15 - 30°C.

7.3. Specific end use(s)

No data available.

8. Exposure controls and personal protection

8.1. Control parameters

Exposure

CAS No.	Ingredient	Source	Value
0000100-51-6	Benzyl alcohol	OSHA	No Established Limit
		ACGIH	No Established Limit
		NIOSH	No Established Limit



Naftin 1% Cream Safety Data Sheet (SDS)

SDS Revision Date:

03 JUN 2016

		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
0000100-51-6	Benzyl alcohol	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

If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn.

Eyes

Wear safety glasses with side shields (or goggles) if risk of splashing or spraying. Having an eyewash station nearby is recommended.

Skin

Wear protective gloves and appropriate clothing to minimize skin contact.

Engineering Controls

Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

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.



Naftin 1% Cream Safety Data Sheet (SDS)

SDS Revision Date:

03 JUN 2016

9. Physical and chemical properties

Appearance	White Cream
Odor	None
Odor threshold	Not Measured
pH	4.5 - 5.5
Melting point / freezing point	Not Measured
Initial boiling point and boiling range	Not Measured
Flash Point	Not Measured
Evaporation rate (Ether = 1)	Not Measured
Flammability (solid, gas)	Not Applicable
Upper/lower flammability or explosive limits	Lower Explosive Limit: Not Measured Upper Explosive Limit: Not Measured
Vapor pressure (Pa)	Not Measured
Vapor Density	Not Measured
Specific Gravity	Not Measured
Solubility in Water	Not Measured
Partition coefficient n-octanol/water (Log Kow)	Not Measured
Auto-ignition temperature	Not Measured
Decomposition temperature	Not Measured
Viscosity (cSt)	Not Measured
Other information	
No other relevant information.	

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

Keep away from heat, sparks and flame.

10.5. Incompatible materials

Contact with strong oxidizing agents. Hazardous polymerization does not occur.

10.6. Hazardous decomposition products

Carbon oxides, nitrogen oxides, hydrogen chloride



Naftin 1% Cream Safety Data Sheet (SDS)

SDS Revision Date:

03 JUN 2016

11. Toxicological information

Acute toxicity

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
Benzyl alcohol - (100-51-6)	1,230.00, Rat - Category: 4	2,000.00, Rabbit - Category: 4	No data available	4.178, Rat - Category: 4	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



Naftin 1% Cream Safety Data Sheet (SDS)

SDS Revision Date:

03 JUN 2016

12. Ecological information

12.1. 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
Benzyl alcohol - (100-51-6)	10.00, Lepomis macrochirus	55.00, Daphnia magna	700.00 (72 hr), Algae
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.



Naftin 1% Cream Safety Data Sheet (SDS)

SDS Revision Date:

03 JUN 2016

14. Transport information

	DOT (Domestic Surface Transportation)	IMO / IMDG (Ocean Transportation)	ICAO/IATA
14.1. UN number	Not Applicable	Not Regulated	Not Regulated
14.2. UN proper shipping name	Not Regulated	Not Regulated	Not Regulated
14.3. Transport hazard class(es)	DOT Hazard Class: Not Applicable	IMDG: Not Applicable Sub Class: Not Applicable	Air Class: Not Applicable
14.4. Packing group	Not Applicable	Not Applicable	Not Applicable
14.5. Environmental hazards			
IMDG	Marine Pollutant: No		
14.6. Special precautions for user	No further information		



Naftin 1% Cream Safety Data Sheet (SDS)

SDS Revision Date:

03 JUN 2016

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	Not Regulated

US EPA Tier II Hazards	Fire: No
	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.

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%) :

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

Pennsylvania RTK Substances (>1%):

Benzyl alcohol

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.



Naftin 1% Cream Safety Data Sheet (SDS)

SDS Revision Date:

03 JUN 2016

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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