

Safety Data Sheet

SECURA™ Antifungal Extra Thick

1. Identification

1.1. Product identifier

Product Identity SECURA™ Antifungal Extra Thick
Alternate Names Triple Care™ Antifungal Extra Thick

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

Intended use Topical skin care
Application Method See Technical Data Sheet.

1.3. Details of the supplier of the safety data sheet

Company Name Smith & Nephew
970 Lake Carillon Drive, Suite 110
St. Petersburg, FL 33716

Emergency

Customer Service: Smith & Nephew 1-800-876-1261

2. Hazard(s) identification

2.1. Classification of the substance or mixture

Skin Irrit. 3;H316 Causes mild skin irritation. (Not adopted by US OSHA)
Eye Irrit. 2;H319 Causes serious eye irritation.
Skin Sens. 1;H317 May cause an allergic skin reaction.
Aquatic Chronic 1;H410 Very toxic to aquatic life with long lasting effects.

2.2. Label elements

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



Warning

H316 Causes mild skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H410 Very toxic to aquatic life with long lasting effects.

[Prevention]:

P261 Avoid breathing dust / fume / gas / mist / vapors / spray.
P264 Wash thoroughly after handling.
P272 Contaminated work clothing should not be allowed out of the workplace.

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P273 Avoid release to the environment.

P280 Wear protective gloves / eye protection / face protection.

[Response]:

P302+352 IF ON SKIN: Wash with plenty of soap and water.

P305+351+338 IF IN EYES: Rinse continuously with water for several minutes. Remove contact lenses if present and easy to do - continue rinsing.

P313 Get medical advice / attention.

P321 Specific treatment (see information on this label).

P333+313 If skin irritation or a rash occurs: Get medical advice / attention.

P337+313 If eye irritation persists: Get medical advice / attention.

P363 Wash contaminated clothing before reuse.

P391 Collect spillage.

[Storage]:

No GHS storage statements

[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
Petrolatum CAS Number: 0008009-03-8	25 - 50	Not Classified	[1]
Zinc oxide CAS Number: 0001314-13-2	25 - 50	Aquatic Acute 1;H400 Aquatic Chronic 1;H410	[1][2]
Karaya CAS Number: 0009000-36-6	1.0 - 10	Not Classified	[1]
Alcohols, C16-18 CAS Number: 0067762-27-0	1.0 - 10	Skin Irrit. 2;H315 Eye Irrit. 2;H319	[1]
D-glucopyranoside methyl 2,6-dioleate CAS Number: 0082933-91-3	1.0 - 10	Not Classified	[1]
Mineral oil (saturated paraffin oil) CAS Number: 0008012-95-1	1.0 - 10	Asp. Tox. 1;H304	[1][2]
Cellulose, carboxymethyl ether, sodium salt CAS Number: 0009004-32-4	1.0 - 10	Not Classified	[1]
Miconazole Nitrate CAS Number: 0075319-48-1	1.0 - 10	Acute Tox. 4;H302 Skin Sens. 1;H317	[1]
1-[1,3-bis(hydroxymethyl)-2,5-dioximidazolidin-4-yl]-1,3-bis(hydroxymethyl)urea CAS Number: 0078491-02-8	0.10 - 1.0	Skin Sens. 1;H317 Eye Irrit. 2;H319	[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 shown in Section 16.

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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	No first aid should be needed.
Ingestion	Dilute with milk or water. Contact a poison control center for instructions.

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

Overview	<u>Acute Effects</u> Ingestion: Can cause abdominal discomfort, nausea, & vomiting. Medical Conditions Aggravated by Long-Term Exposure: Ingestion can cause abdominal discomfort, nausea and vomiting. 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. See section 2 for further details.
Eyes	Causes serious eye irritation.
Skin	May cause an allergic skin reaction. Causes mild skin irritation.

5. Fire-fighting measures

5.1. Extinguishing media

Water spray, carbon dioxide, and dry chemical foam.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition: Thermal decomposition may include carbon dioxide, carbon monoxide, hydrocarbons, chlorides and amines.

Avoid breathing dust / fume / gas / mist / vapors / spray.

5.3. Advice for fire-fighters

Wear self-contained breathing apparatus and protective clothing. Do not release runoff from fire control methods to sewers or waterways.

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).

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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

Sweep up spilled material and discard in DOT-approved disposal container.

7. Handling and storage

7.1. Precautions for safe handling

Wash thoroughly after handling.

See section 2 for further details. - [Prevention]:

7.2. Conditions for safe storage, including any incompatibilities

Handle containers carefully to prevent damage and spillage.

Incompatible materials: Strong oxidizing agents

Store in a cool, dry place between 40°F - 86°F (4°C - 30°C), away from incompatible materials, flames and other sources of ignition.

See section 2 for further details. - [Storage]:

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
0001314-13-2	Zinc oxide	OSHA	TWA 5 mg/m ³ (fume) TWA 15 mg/m ³ (total dust) TWA 5 mg/m ³ (resp dust)
		ACGIH	TWA: 2 mg/m ³ STEL: 10 mg/m ³ A1, 1, Revised 2003,
		NIOSH	No Established Limit
		Supplier	No Established Limit
0008009-03-8	Petrolatum	OSHA	No Established Limit
		ACGIH	No Established Limit
		NIOSH	No Established Limit
		Supplier	No Established Limit
0008012-95-1	Mineral oil (saturated paraffin oil)	OSHA	TWA 5 mg/m ³
		ACGIH	No Established Limit
		NIOSH	TWA 5 mg/m ³ ST 10 mg/m ³
		Supplier	No Established Limit
0009000-36-6	Karaya	OSHA	No Established Limit
		ACGIH	No Established Limit

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		NIOSH	No Established Limit
		Supplier	No Established Limit
0009004-32-4	Cellulose, carboxymethyl ether, sodium salt	OSHA	No Established Limit
		ACGIH	No Established Limit
		NIOSH	No Established Limit
		Supplier	No Established Limit
0067762-27-0	Alcohols, C16-18	OSHA	No Established Limit
		ACGIH	No Established Limit
		NIOSH	No Established Limit
		Supplier	No Established Limit
0075319-48-1	Miconazole Nitrate	OSHA	No Established Limit
		ACGIH	No Established Limit
		NIOSH	No Established Limit
		Supplier	No Established Limit
0078491-02-8	1-[1,3-bis(hydroxymethyl)-2,5-dioximidazolidin-4-yl]-1,3-bis(hydroxymethyl)urea	OSHA	No Established Limit
		ACGIH	No Established Limit
		NIOSH	No Established Limit
		Supplier	No Established Limit
0082933-91-3	D-glucopyranoside methyl 2,6-dioleate	OSHA	No Established Limit
		ACGIH	No Established Limit
		NIOSH	No Established Limit
		Supplier	No Established Limit

Carcinogen Data

CAS No.	Ingredient	Source	Value
0001314-13-2	Zinc oxide	OSHA	Select Carcinogen: No
		NTP	Know n: No; Suspected: No
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; Group 4: No;
0008009-03-8	Petrolatum	OSHA	Select Carcinogen: No
		NTP	Know n: No; Suspected: No
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; Group 4: No;
0008012-95-1	Mineral oil (saturated paraffin oil)	OSHA	Select Carcinogen: No
		NTP	Know n: No; Suspected: No
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; Group 4: No;
0009000-36-6	Karaya	OSHA	Select Carcinogen: No
		NTP	Know n: No; Suspected: No
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; Group 4: No;
0009004-32-4	Cellulose, carboxymethyl ether, sodium salt	OSHA	Select Carcinogen: No
		NTP	Know n: No; Suspected: No
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; Group 4: No;
0067762-27-0	Alcohols, C16-18	OSHA	Select Carcinogen: No
		NTP	Know n: No; Suspected: No
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; Group 4: No;
0075319-48-1	Miconazole Nitrate	OSHA	Select Carcinogen: No

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		NTP	Know n: No; Suspected: No
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; Group 4: No;
0078491-02-8	1-[1,3-bis(hydroxymethyl)-2,5-dioximidazolidin-4-yl]-1,3-bis(hydroxymethyl)urea	OSHA	Select Carcinogen: No
		NTP	Know n: No; Suspected: No
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; Group 4: No;
0082933-91-3	D-glucopyranoside methyl 2,6-dioleate	OSHA	Select Carcinogen: No
		NTP	Know n: 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 required for normal use.
Eyes	None required for normal use.
Skin	None required for normal use.
Engineering Controls	Provide adequate ventilation. Where reasonably practicable this should be achieved by the use of local exhaust ventilation and good general extraction. If these are not sufficient to maintain concentrations of particulates and any vapor below occupational exposure limits suitable respiratory protection must be worn.
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. - [Prevention]:

9. Physical and chemical properties

Appearance	White Paste Semi-solid
Odor	Odorless
Odor threshold	Not Measured
pH	6.7 @ 20°C
Melting point / freezing point	73 - 76°C (163 - 169°F)
Initial boiling point and boiling range	Not determined
Flash Point	> 200°F / > 93°C TCC
Evaporation rate (Ether = 1)	> 1 (nBuAc = 1)
Flammability (solid, gas)	Not Applicable
Upper/lower flammability or explosive limits	Lower Explosive Limit: Not known Upper Explosive Limit: Not known
Vapor pressure (Pa)	1.0 mmHg
Vapor Density	Not determined
Specific Gravity	1.20 - 1.35 @ 25°C (H ₂ O = 1)
Solubility in Water	Slight
Partition coefficient n-octanol/water (Log Kow)	Not Measured
Auto-ignition temperature	Not determined
Decomposition temperature	Not available
Viscosity (cSt)	5.00 x 10 ³ - 3.00 x 10 ⁶ cPs
VOC Content	Not available

9.2. Other information

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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

Open flames, excessive heat (> 200°F), or cold

10.5. Incompatible materials

Strong oxidizing agents

10.6. Hazardous decomposition products

Thermal decomposition may include carbon dioxide, carbon monoxide, hydrocarbons, chlorides and amines.

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
Petrolatum - (8009-03-8)	> 5,000.00, Rat - Category: NA	> 5,000.00, Rabbit - Category: NA	No data available	No data available	No data available
Zinc oxide - (1314-13-2)	5,000.00, Rat - Category: 5	No data available	No data available	2.50, Mouse - Category: 4	No data available
Karaya - (9000-36-6)	No data available	No data available	No data available	No data available	No data available
Alcohols, C16-18 - (67762-27-0)	No data available	No data available	No data available	No data available	No data available
D-glucopyranoside methyl 2,6-dioleate - (82933-91-3)	No data available	No data available	No data available	No data available	No data available
Mineral oil (saturated paraffin oil) - (8012-95-1)	No data available	No data available	No data available	No data available	No data available
Cellulose, carboxymethyl ether, sodium salt - (9004-32-4)	No data available	No data available	No data available	No data available	No data available
Miconazole Nitrate - (75319-48-1)	No data available	No data available	No data available	No data available	No data available
1-[1,3-bis(hydroxymethyl)-2,5-dioximidazolidin-4-yl]-1,3-bis(hydroxymethyl)urea - (78491-02-8)	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).

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Classification	Category	Hazard Description
Acute toxicity (oral)	---	Not Applicable
Acute toxicity (dermal)	---	Not Applicable
Acute toxicity (inhalation)	---	Not Applicable
Skin corrosion/irritation	3	Causes mild skin irritation. (Not adopted by US OSHA)
Serious eye damage/irritation	2	Causes serious eye irritation.
Respiratory sensitization	---	Not Applicable
Skin sensitization	1	May cause an allergic skin reaction.
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

12. Ecological information

12.1. Toxicity

Very toxic to aquatic life with long lasting effects.

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	Er C50 algae, mg/l
Petrolatum - (8009-03-8)	Not Available	Not Available	Not Available
Zinc oxide - (1314-13-2)	1.10, Oncorhynchus mykiss	0.098, Daphnia magna	0.042 (72 hr), Pseudokirchneriella subcapitata
Karaya - (9000-36-6)	Not Available	Not Available	Not Available
Alcohols, C16-18 - (67762-27-0)	Not Available	Not Available	Not Available
D-glucopyranoside methyl 2,6-dioleate - (82933-91-3)	Not Available	Not Available	Not Available
Mineral oil (saturated paraffin oil) - (8012-95-1)	Not Available	Not Available	Not Available
Cellulose, carboxymethyl ether, sodium salt - (9004-32-4)	Not Available	Not Available	Not Available
Miconazole Nitrate - (75319-48-1)	Not Available	Not Available	Not Available
1-[1,3-bis(hydroxymethyl)-2,5-dioximidazolidin-4-yl]-1,3-bis(hydroxymethyl)urea - (78491-02-8)	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

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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.

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: Yes (Zinc oxide)		
14.6. Special precautions for user	No further information		

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)	All components of this material are either listed or exempt from listing on the TSCA Inventory.
WHMIS Classification	D2B
US EPA Tier II Hazards	Fire: No Sudden Release of Pressure: No Reactive: No Immediate (Acute): Yes 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.

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EPCRA 313 Toxic Chemicals:

Zinc oxide

Proposition 65 - Carcinogens (>0.0%):

Arsenic

Cadmium

Ethane, 1,1'-oxybis[2-chloro-

Lead Compounds (as Pb)

Propylene oxide

Proposition 65 - Developmental Toxins (>0.0%):

Lead Compounds (as Pb)

Toluene

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

Lead Compounds (as Pb)

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

Cadmium

Lead Compounds (as Pb)

New Jersey RTK Substances (>1%):

Mineral oil (saturated paraffin oil)

Zinc oxide

Pennsylvania RTK Substances (>1%):

Mineral oil (saturated paraffin oil)

Zinc oxide

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.

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

H302 Harmful if swallowed.

H304 May be fatal if swallowed and enters airways.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

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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