

FRESH SKIN ORGANICS- ab nat zinc lotion
Tropical Enterprises International, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Formula: ABNZ2000

Active Ingredients:

Zinc Oxide (18%)

Purpose: Sunscreen

Uses: Our SPF formulas provide both UVA and UVB protection, and are infused with antioxidants and nutrients to help prevent sun damage while keeping the skin well-hydrated.

WARNINGS:

For external use only.

Do not use on damaged or broken skin.

When using this product avoid contact with eyes.


If contact with eyes occurs, flush with water to remove.

Stop use and ask a doctor if irritation or rash develops and persists.

Keep out of reach of children. If product is swallowed, seek immediate medical attention or contact a Poison Control Center right away.

For use on children under 6 months: consult a physician.

Questions? Call 1-800-535-5053

Drug Facts**Active Ingredients** **Purpose**
Zinc Oxide (18%) Sunscreen**Uses:** Our SPF formulas provide both UVA and UVB protection, and are infused with antioxidants and nutrients to help prevent sun damage while keeping the skin well-hydrated.**WARNINGS:****For external use only.****Do not use** on damaged or broken skin.**When using this product** avoid contact with eyes. If contact with eyes occurs, flush with water to remove.**Stop use and ask a doctor** if irritation or rash develops and persists.**Keep out of reach of children.** If product is swallowed, seek immediate medical attention or contact a Poison Control Center right away.**For use on children under 6 months:** consult a physician.**Questions?** Call 1-800-535-5053**Made in USA** 
Distributed by:**Drug Facts** (continued)**Directions:** Apply liberally and evenly prior to sun exposure. **Reapply** after towel drying, or prolonged swimming or sweating.**Inactive Ingredients:** Aloe Barbadensis Leaf Juice, Caprylic/Capric Triglyceride (Fractionated Coconut Oil), Octyl Palmitate, Sorbitan Sesquileate, Cera Alba (Beeswax), Glycerin, Glyceryl Stearate, Butyrospermum Parkii (Shea) Butter, PEG-30 Dipolyhydroxystearate, Helianthus Annuus (Sunflower) Seed Oil, Simmondsia Chinensis (Jojoba) Seed Oil, Punicus Communis (Castor) Seed Oil, Camellia Sinensis (Green & White Tea) Leaf Extract (and) Ilex Paraguariensis (Black Tea) Leaf Extract, Rosmarinus Officinalis (Rosemary) Leaf Oil, Lavandula Angustifolia (Lavender) Oil, Rubus Idaeus (Raspberry) Seed Oil, Rosa Canina (Rose Hips) Fruit Oil, Squalane (Olive Derived), Persea Gratissima (Avocado) Oil, Aleurites Moluccana (Kukui) Seed Oil, Tocopheryl Acetate (Vitamin E), Magnesium Sulfate, Xanthan Gum, Fragrance, Caprylic Acid (and) Lauric Acid (and) Propanediol (and) Potassium Sorbate.**Manufactured in an FDA registered facility.**
TMarketing Tampa, FL Ph. (877) 773-9800 asi/92243**SPF 30 ALL NATURAL**
40 MIN Water Resistant
SUNSCREEN LOTION
1 fl oz. 30 ml**FRESH SKIN ORGANICS**

ab nat zinc lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58418-425
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	6.05 g in 30 mL

Inactive Ingredients

Ingredient Name	Strength
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PROPANEDIOL (UNII: 5965N8W85T)	
CASTOR OIL (UNII: D5340Y2I9G)	
ROSEMARY OIL (UNII: 8LGU7VM393)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
KUKUI NUT OIL (UNII: TP11QR7B8R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
GLYCERIN (UNII: PDC6A3C0OX)	

SHEA BUTTER (UNII: K49155WL9Y)
JOJOBA OIL (UNII: 724GKU717M)
YELLOW WAX (UNII: 2ZA36H0S2V)
LAURIC ACID (UNII: 1160N9NU9U)
CAPRYLIC/CAPRIC/LAURIC TRIGLYCERIDE (UNII: FJ1H6M2JG9)
AVOCADO OIL (UNII: 6VNO72PFC1)
XANTHAN GUM (UNII: TTV12P4NEE)
PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)
ROSA CANINA FRUIT OIL (UNII: CR7307M3QZ)
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)
MAGNESIUM SULFATE, UNSPECIFIED (UNII: DE08037SAB)
CAPRYLIC ACID (UNII: OBL58JN025)
SUNFLOWER OIL (UNII: 3W1JG795YI)
CAMELLIA SINENSIS WHOLE (UNII: C5M4585ZBZ)
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)
RASPBERRY SEED OIL (UNII: 9S8867952A)
SQUALANE (UNII: GW89575KF9)

Product Characteristics

Color	white (zinc lotion)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58418-425-00	15 mL in 1 PACKET; Type 0: Not a Combination Product	03/02/2020	
2	NDC:58418-425-05	15 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/02/2020	
3	NDC:58418-425-01	30 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/02/2020	
4	NDC:58418-425-02	60 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/02/2020	
5	NDC:58418-425-04	120 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/02/2020	
6	NDC:58418-425-08	240 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/02/2020	
7	NDC:58418-425-09	240 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/02/2020	
8	NDC:58418-425-16	480 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/02/2020	
9	NDC:58418-425-12	360 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/02/2020	
10	NDC:58418-425-64	1920 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/02/2020	
11	NDC:58418-425-34	100.55 mL in 1 TUBE; Type 0: Not a Combination Product	03/01/2020	
12	NDC:58418-425-28	3840 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/02/2020	
	NDC:58418-425-			

13	INDU:58418-425-55	211200 mL in 1 DRUM; Type 0: Not a Combination Product	03/01/2020	
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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/01/2020	

Labeler - Tropical Enterprises International, Inc. (091986179)

Registrant - Tropical Enterprises International, Inc. (091986179)

Establishment

Name	Address	ID/FEI	Business Operations
Tropical Enterprises International, Inc.		091986179	repack(58418-425)

Revised: 3/2020

Tropical Enterprises International, Inc.