TALLOW SUNSCREEN- non-nano zinc oxide cream
FOUNDATION COMMERCE INC

Initial Drug Listing - TALLOW SUNSCREEN

Non-Nano Zinc Oxide 25%

Sunscreen

- Helps prevent sunburn
- If used as directed with othersun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun

For external use only

on damaged or broken skin

Keep out of eyes. Rinse with water to remowe.

Ask a doctor if rash occurs.

lf product is swallowed, get medical help or contact a Poison Control Center right away.

- Apply liberally 15 minutes belore sun exposure.
- Reapply: after 80 minutes of swimming or sweating.immediately after towel drying at least every 2 hours.
- **Sun Protection Measures.** Spending time in the sunincreases your risk of skin cancer and eariy skin aging. Todecrease this risk, regularly use a sunscreen wiih a BroadSpectrum SPF value ot 15 or higher and other sunprotection measures including:
  - limit time in the sun,especially from 10 a.m.-2 p.m.
  - wear long-sleeved shirts,pants, hats and sunglasses
  - children under 6 months ofage: Ask a doclor

Protect the product in this container from excessive heat and direct sun

Water, Beef Tallow, Beeswax, Butyrospermum Parkii {Shea)Butter, Vitamin E, Simmondsia Chinensis (Jojoba) seed oll, OleaEuropaea (Olive) Fruit Oil, Lecithin,C12-15 Alkyl Benzoate, Silica,Squalane, Xanthan Gum, Dimethicone, Glyceryl Stearate,Cetearyl Alcohol, lsononyi lsononanoate, Disodium EDTA, RadishRoot Ferment Filtrate, Saururus Chinensis Leaf/root Extract,Taraxacum Offcinale (Dandelion) Leaf Extract

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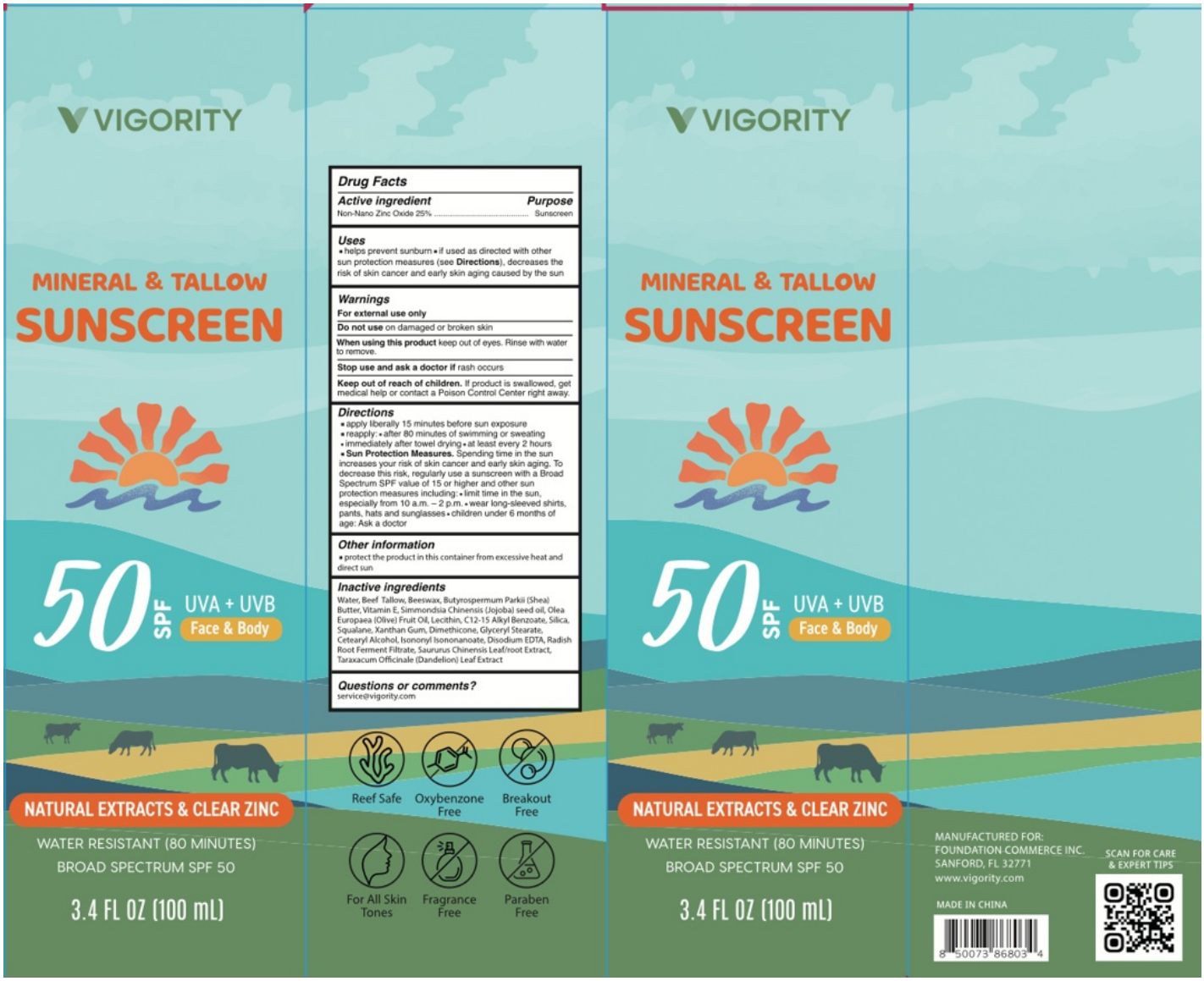

TALLOW SUNSCREEN

non-nano zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:85739-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	25 mg in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
TARAXACUM OFFICINALE (DANDELION) ROOT (UNII: 9DE5YCO0RU)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

XANTHAN GUM (UNII: TTV12P4NEE)	
DIMETHICONE 1000 (UNII: MCU2324216)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
WATER (UNII: 059QF0KO0R)	
OLEA EUROPAEA (OLIVE) FRUIT OIL (UNII: 6UYK2W1W1E)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
CETEARYL ALCOHOL (UNII: 2DMT128M1S)	
CALCIUM DISODIUM EDTA (UNII: 8U5D034955)	
SQUALANE (UNII: GW89575KF9)	
SAURURUS CHINENSIS WHOLE (UNII: 6DRV3D37XS)	
BEEF TALLOW (UNII: 98HPY76U4W)	
BEESWAX (UNII: 2ZA36H0S2V)	
BUTYROSPERMUM PARKII (SHEA) BUTTER (UNII: K49155WL9Y)	
VITAMIN E POLYETHYLENE GLYCOL SUCCINATE (UNII: O03S90U1F2)	
SIMMONDSIA CHINENSIS (JOJOBA) SEED OIL (UNII: 724GKU717M)	
LEUCONOSTOC/RADISH ROOT FERMENT FILTRATE (UNII: D2QHA03458)	
GLYCERYL STEARATE (UNII: 230OU9XXE4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85739-001-01	100 mL in 1 CARTON; Type 0: Not a Combination Product	06/19/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	06/19/2025	

Labeler - FOUNDATION COMMERCE INC (096404242)

Establishment

Name	Address	ID/FEI	Business Operations
Guangzhou Haishi Biological Technology Co., Ltd		421262738	manufacture(85739-001) , label(85739-001)

Revised: 5/2025 FOUNDATION COMMERCE INC