

**SUNSCREEN- sunscreen, zinc oxide lotion
NATURAL AND ORGANIC FORMULATIONS (PTY) LTD**

Drug Facts

Active Ingredients ***Purpose***

Zinc oxide 20%.....Sunscreen

Warnings

For external use only

Do not use on damaged or broken skin

When using this product keep out of eyes.
Rinse with water to remove.

Stop use and ask a doctor if rash occurs

Keep out of reach of children. If swallowed,
get medical help or contact a Poison Control
Center right away.

Drug Facts

Active Ingredients ***Purpose***

Zinc oxide 20%.....Sunscreen

Directions

- apply liberally 15 minutes before sun exposure
- children under 6 months of age: Ask a doctor
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
 - limit time in the sun, especially from 10 a.m. – 2 p.m.
 - wear long-sleeved shirts, pants, hats, and sunglasses

Drug Facts (continued)

Directions

- reapply at least every two hours
- use a water resistant sunscreen if swimming or sweating

Warnings

For external use only

Do not use on damaged or broken skin

When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash occurs

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Inactive ingredients

Aloe Vera (Aloe Barbadensis) Leaf Extract[†], Caprylic/Capric Triglyceride, Isoamyl Laurate, Jojoba (Simmondsia Chinensis) Seed Oil[†], Polyglyceryl-2 Dipolyhydroxystearate, Polyglyceryl-3 Diisostearate, Shea (Butyrospermum Parkii) Butter[†], Zinc Sulfate, Resurrection Bush (Myrothamnus Flabellifolia) Extract, Rooibos (Aspalathus Linearis) Leaf Extract[†], Olive (Olea Europaea) Leaf Extract, Polyhydroxystearic Acid, Polyglyceryl-3 Polyricinoleate, Isostearic Acid, Sunflower (Helianthus Annuus) Seed Oil, Sunflower (Helianthus Annuus) Seed Wax, Olive (Olea Europaea) Oil Unsaponifiables, Berrywax (Rhus Verniciflua) Peel Wax, Japan (Rhus Succedanea) Fruit Wax, Sal (Shorea Robusta) Resin, Glyceryl Oleate, Ascorbyl Palmitate, Dehydroacetic Acid, Benzyl Alcohol, Water, Tocopherol, Lecithin, Hydrogenated Lecithin, Iron Oxides

[†]Organic

Uses

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

1 fl oz (30ml)

The logo for 'esse' is displayed in a light blue, lowercase, sans-serif font. The letters are stylized with rounded, leaf-like shapes, particularly the 'e's. The logo is centered within a solid yellow rectangular background.

Sunscreen
Broad Spectrum SPF 30

30mL Sunscreen

label Principal Display Panel

SUNSCREEN

sunscreen, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83748-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	20 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
SHOREA ROBUSTA RESIN (UNII: XUK1106UBO)	
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
ZINC SULFATE (UNII: 89DS0H96TB)	
ASPALATHUS LINEARIS LEAF (UNII: H7UGK1GJCU)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
OLEA EUROPAEA (OLIVE) OIL UNSAPONIFIABLES (UNII: XO45V955LT)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
TOXICODENDRON VERNICIFLUUM FRUIT RIND WAX (UNII: 6RG2461FCH)	
MYROTHAMNUS FLABELLIFOLIA LEAF (UNII: 6Y9E0R40J5)	
POLYGLYCERYL-3 PENTARICINOLEATE (UNII: 7Q0OK5DOT4)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
TOXICODENDRON SUCCEDANEUM FRUIT WAX (UNII: 684PA7HRMI)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
JOJOBA OIL (UNII: 724GKU717M)	
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TOCOPHEROL (UNII: R0ZB2556P8)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
GLYCERYL OLEATE (UNII: 4PC054V79P)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
ISOAMYL LAURATE (UNII: M1SLX00M3M)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
SHEA BUTTER (UNII: K49155WL9Y)	
OLEA EUROPAEA LEAF (UNII: MJ95C3OH47)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83748-001-01	1 in 1 CARTON	12/13/2023	
1		30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	12/13/2023	

Labeler - NATURAL AND ORGANIC FORMULATIONS (PTY) LTD (598865809)

Establishment

Name	Address	ID/FEI	Business Operations
NATURAL AND ORGANIC FORMULATIONS (PTY) LTD		598865809	manufacture(83748-001)

Revised: 10/2023

NATURAL AND ORGANIC FORMULATIONS (PTY) LTD