HILTON SPF 30 MINERAL SUNSCREEN- zinc oxide cream
ORIOR SPF 30 MINERAL SUNSCREEN- zinc oxide cream
Body One, LLC

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.

SPF 30 Mineral Sunscreen

Drug Facts

Active Ingredient

Zinc Oxide 21.6%

Purpose

Sunscreen

Uses

* Helps prevent sunburn.
* higher SPF five more sunburn protection
* retains SPF after 40 minutes of activity in the water
* If used as directed with other sun protection measures, decreases the risk of skin cancer and early skin aging caused by the sun.

Warnings

Skin Cancer/Skin Aging Alert

Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, **not** skin cancer of early skin aging.

For External Use Only

Do not use on damaged or broken skin.

When using this product keep out of eyes. Rinse with water to removed. Stop use and ask a doctor if rash of irritation develops and lasts.

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

Directions

* Apply liberally and evenly 15 minutes before sun exposure.

* Reapply after 40 minutes of swimming or sweating, immediately after towel drying, at least every 2 hours.

Children under 6 months of age: Ask a doctor.

Other Information

Protect this product from excessive heat and direct sun.

Inactive ingredients

Aqua/water, ButylOctyl Salicylate, C12-15 Alkyl Benzoate, Caprylic/Capric Triglyceride, Disteardimmonium Hectorite, EthylHexylglycerin, EthylhexylMethoxycrylene, Fragrance, Glycerine, Isostearic Acid, Lecithin, Magnesium Sulfate, Phenoxyethanol, Polyglyceryl-3 Diisostearate, Polyglyceryl-2 Dipolyhydroxystearate, Polyglyceryl-3 Polyricinoleate, Polyhydroxystearic Acid.

Questions or comments?

1-833-263-9663

PRINCIPAL DISPLAY PANEL - 59 ml. Bottle Label

Hilton
WAIKOLOA VILLAGE®

MINERAL
SUNSCREEN

SPF 30
BROAD SPECTRUM

2 fl. oz. (59 ml.)
www.hiltonwaikoloavillage.com

PRINCIPAL DISPLAY PANEL - 150 mL Bottle Label

ORIOR

MINERAL
SUNSCREEN
LOTION

SPF 30
BROAD SPECTRUM

5.0 fl.oz. 150 mL

HILTON SPF 30 MINERAL SUNSCREEN

zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:73563-335
Route of Administration	CUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	21.6 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
GLYCERIN (UNII: PDC6A3C0OX)	

PHENOXYETHANOL (UNII: HIE492ZZ3T)	
GUAIETOLIN, (S)- (UNII: L7635M8189)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
C13-15 Alkane (UNII: 114P5I43UJ)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
ETHYLHEXYL METHOXYCRYLENE (UNII: S3KFG6Q5X8)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
POLYGLYCERYL-3 PENTARICINOLEATE (UNII: 7Q0OK5DOT4)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
LINALYL ACETATE (UNII: 5K47SSQ51G)	
PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)	
ETHYL LINALOOL (UNII: SF2JS9GF5T)	
TETRAHYDROLINALOOL (UNII: UM4XS5M134)	

Product Characteristics

Color	WHITE	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73563-335-02	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2023	
2	NDC:73563-335-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	08/01/2023	

ORIOR SPF 30 MINERAL SUNSCREEN

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:73563-638
Route of Administration	CUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	21.6 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
GUAIETOLIN, (S)- (UNII: L7635M8189)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
C13-15 Alkane (UNII: 114P5I43UJ)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
ETHYLHEXYL METHOXYCRYLENE (UNII: S3KFG6Q5X8)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
POLYGLYCERYL-3 PENTARICINOLEATE (UNII: 7Q0OK5DOT4)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
LINALYL ACETATE (UNII: 5K47SSQ51G)	
PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)	
ETHYL LINALOOL (UNII: SF2JS9GF5T)	
TETRAHYDROLINALOOL (UNII: UM4XS5M134)	

Product Characteristics

Color	WHITE	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73563-638-05	150 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/01/2023	
2	NDC:73563-638-02	50 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph not final	part352	08/01/2023	

Labeler - Body One, LLC (117376115)

Registrant - Solo Laboratories Inc (078831987)

Establishment

Name	Address	ID/FEI	Business Operations
Solo Laboratories Inc		078831987	MANUFACTURE(73563-335, 73563-638) , LABEL(73563-335, 73563-638) , PACK(73563-335, 73563-638)

Revised: 5/2023 Body One, LLC