SOLSCENTS CLEAR FACE FLOWER BLAST BROAD SPECTRUM SPF 50- octinoxate, octisalate, and zinc oxide lotion
Prime Enterprises, 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.

Active ingredients

Octinozate 7.5% ,Octisalate 5%, and Zinc Oxide 4.5%

Purpose

Sunscreen

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.

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

Directions:

- apply liberally 15 minutes before sun exposure
- reapply:
- immediately after towel drying
- at least every 2 hours
- **Sun Protection Measures:** Spending time in the sun increases your risk of skin cancer & early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher & other sun protection measures including:
- limit time in the sun, especially from 10 a.m. – 2 p.m.
- wear long sleeve shirts, pants, hats, and sunglasses
- Children under 6 months: Ask a doctor

Inactive Ingredients

acrylamide sodium acrylate copolymer, aloe barbadensis leaf juice, camellia sinensis (green tea) leaf extract, caprylic/capric tiglyceride, cetearyl alcohol, ethylhexylglycerin, fragrance, glycerin, glyceryl stearate, helianthus annuus (sunflower) seed oil, mineral oil, phenoxyethanol, propylene glycol, sodium cocoyl glucamate, sodium hydroxide, stearic acid, tocopheryl acetate, trideceth-6, water.

Other information

- protect this product from excessive heat and direct sun
- may stain or damage some fabrics or sufaces

Questions or comments?

SolScents, LLC

2200 N.W. 92nd Avenue.

Miami, FL 33172

PRINCIPAL DISPLAY PANEL - 100 mL Bottle Label

SolScents

SUNSCREEN

CLEAR FACE

SKIN NOUISHING ANTIOXIDANTS

FLOWER BLAST

50

Broad Spectrum SPF50

Paraben Free

Ultra-light

MADE IN TE USA

3.4 FL OZ (100 mL)

SOLSCENTS CLEAR FACE FLOWER BLAST BROAD SPECTRUM SPF 50

octinoxate, octisalate, and zinc oxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58443-0175
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	76.5 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	51 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	45.9 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TRIDECETH-6 (UNII: 3T5PCR2H0C)	
WATER (UNII: 059QF0KO0R)	
CAPRYLIC/CAPRIC MONO/DIGLYCERIDES (UNII: U72Q2I8C85)	
SODIUM ACRYLOYLDIMETHYLTAURATE-ACRYLAMIDE COPOLYMER (1:1; 90000-150000 MPA.S) (UNII: 5F4963KLHS)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
SUNFLOWER SEED OIL GLYCERETH-8 ESTERS (UNII: 358X17CAT0)	
MINERAL OIL (UNII: T5L8T28FGP)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM COCOYL GLUTAMATE (UNII: BMT4RCZ3HG)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0175-3	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	04/01/2015	

Labeler - Prime Enterprises, Inc. (101946028)

Registrant - Prime Enterprises, Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	label(58443-0175) , pack(58443-0175) , manufacture(58443-0175) , analysis(58443-0175)

Revised: 1/2020

Prime Enterprises, Inc.