ULTA SUNSCREEN SPF 45- octinoxate, octisalate, octocrylene, and oxybenzone 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

Octinoxate 7.5%, Octisalate 5 %, Octocrylene 8%, and Oxybenzone 6 %

Purpose

Sunscreen

Uses

- Helps prevent sunburn

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 prevent sunburn, **not** skin cancer or 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 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:
  - after 80 minutes of swimming or sweating
  - immediately after towel drying
  - at least every 2 hour
- children under 6 months: Ask a doctor

Inactive Ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Allantoin, Aloe Barbadensis Leaf Juice, Ammonium Hydroxide, Butylphthalimide, Carrageenan, Citric Acid, Diazolidinyl Urea, Disodium EDTA, Glyceryl Stearate, Isopropyl Myristate, Isopropylphthalimide, Magnesium Aluminum Silicate, Methylparaben, Polyethylene, Propylparaben, Soluble Collagen, Sorbitol, Stearic Acid, Stearyl Alcohol, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Triethanolamine, Water

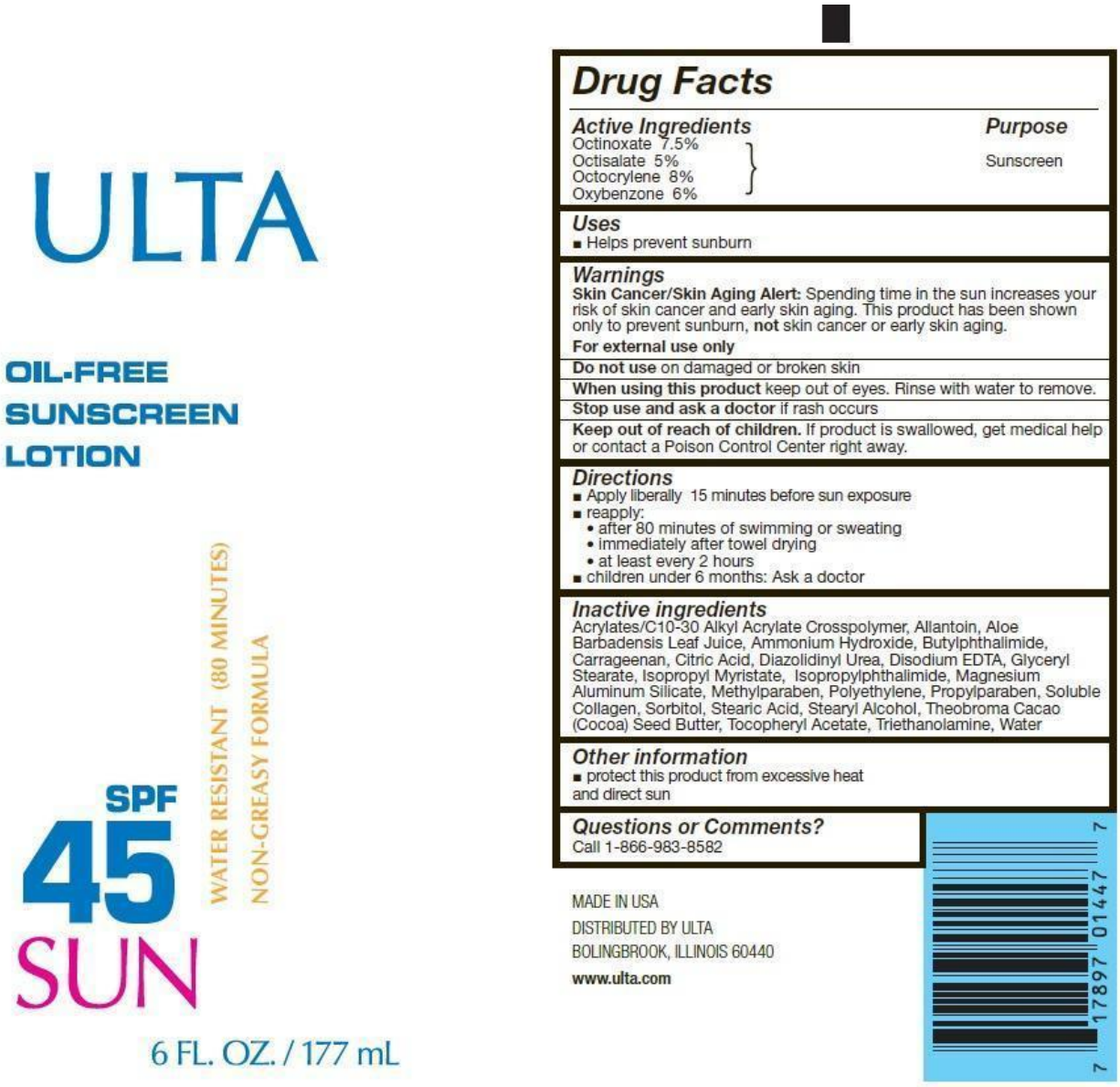
Other information

- protect this product from excesive heat and direct sun

Questions or Comments?:

Call- 1-866-983-8582

PRINCIPAL DISPLAY PANEL - 177 mL Tube Label



ULTA

OIL-FREE

SUNSCREEN

LOTION

SPF

45

SUN

WATER RESISTANT (80 MINUTES)

NON-GREASY FORMULA

6 FL.OZ./177mL

ULTA SUNSCREEN SPF 45

octinoxate, octisalate, octocrylene, and oxybenzone lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58443-0129
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	71.25 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	47.5 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	76 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	57 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
(C10-C30)ALKYL METHACRYLATE ESTER (UNII: XH2FQZ38D8)	
ALLANTOIN (UNII: 344S277G0Z)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
TETRAETHYLAMMONIUM HYDROXIDE (UNII: RA8VU41B1F)	
N-BUTYLPHTHALIMIDE (UNII: 5TH1DKT35E)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
CITRIC ACID ACETATE (UNII: DSO12WL7AU)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERYL STEARATE CITRATE (UNII: WH8T92A065)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
ISOPROPYLPHTHALIMIDE (UNII: 1J1MM83329)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
COLLAGEN, SOLUBLE, FISH SKIN (UNII: 8JC99XGU4W)	
SORBITOL (UNII: 506T60A25R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
COCOA BUTTER (UNII: 512OYT1CRR)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0129-4	177 mL in 1 TUBE; Type 0: Not a Combination Product	03/12/2007	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/12/2007	

Labeler - Prime Enterprises, Inc. (101946028)

Registrant - Prime Enterprises, Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	label(58443-0129) , pack(58443-0129) , manufacture(58443-0129) , analysis(58443-0129)

Revised: 1/2020 Prime Enterprises, Inc.