OCCULUS SOLOXIDE 30 BROAD SPECTRUM SPF 30- avobenzone, homosalate, octisalate, octocrylene, and oxybenzone aerosol
Prime Packaging, 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

Avobenzone 2 %, Homosalate 7.5%, Octisalate 5 %, Octocrylene 2.75 %, and Oxybenzone 2 %

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.

Contents under pressure. Do not puncture or incinerate. Do not store at temperatures above 120°F. Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask a doctor if rash occurs

Flammable: Do not use near heat, flame or while smoking.

Use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.

Directions

- Hold can upright. Shake well before each application.
- Apply liberally and spread evenly by hand 15 minutes before 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 sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF 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-sleeve shirts, pants, hats, and sunglasses
- Children under 6 months: Ask a doctor.

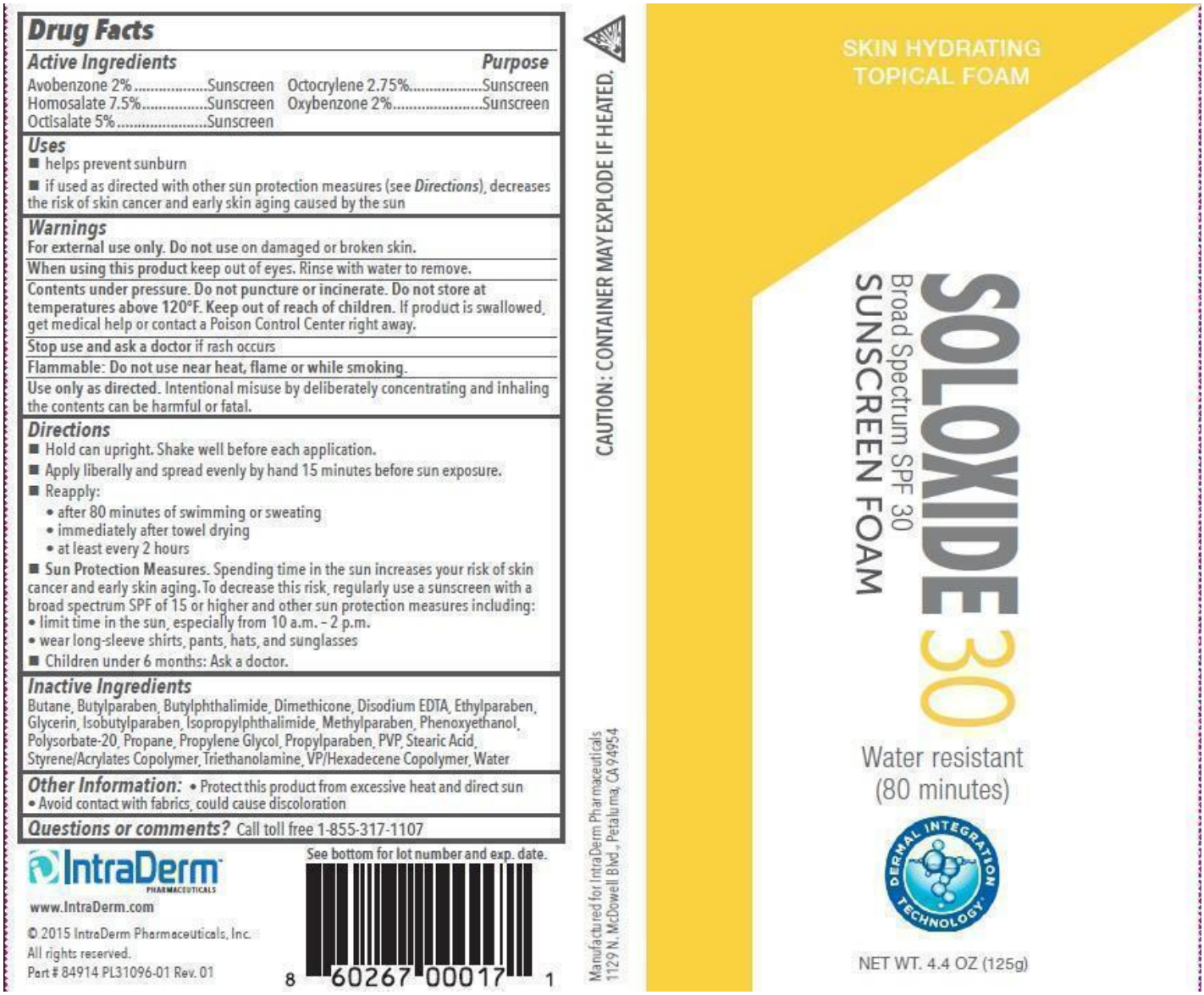
Inactive Ingredients

Butane, Butylparaben, Butylphthalimide, Dimethicone,Disodium EDTA, Ethylparaben, Glycerin, Isobutylparaben, Isopropylphthalimide, Methylparaben, Phenoxyethanol, Polysorbate-20, Propane, Propylene Glycol, Propylparaben, PVP, Stearic Acid, Styrene/Acrylates Copolymer, Triethanolamine, VP/Hexadecene Copolymer, Water

Other Information: •Protect this product from exessive heat and direct sun
•Avoid contact with fabrics, could cause discoloration

Questions or comments? Call toll free 1-855-317-1107

PRINCIPAL DISPLAY PANEL - 125g Can Label



SKIN HYDRATING

TOPICAL FOAM

SOLOXIDE 30

Broad Spectrum SPF 30

SUNSCREEN FOAM

Water resistant

(80 minutes)

NET WT.4.4 OZ (125g)

OCCULUS SOLOXIDE 30 BROAD SPECTRUM SPF 30

avobenzone, homosalate, octisalate, octocrylene, and oxybenzone aerosol

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:13630-0089
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	20 mg in 1 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	75 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	275 mg in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	20 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
N-BUTYLPHTHALIMIDE (UNII: 5TH1DKT35E)	
ISOPROPYLPHTHALIMIDE (UNII: 1J1MM83329)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
ETHYLPARABEN (UNII: 14255EXE39)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ACRYLIC ACID (UNII: J94PBK7X8S)	
TROLAMINE (UNII: 9O3K93S3TK)	
VINYLPYRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	yellow	**Score**	

Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13630-0089-3	125 g in 1 CAN; Type 0: Not a Combination Product	08/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	08/01/2015	

Labeler - Prime Packaging, Inc. (805987059)

Registrant - Prime Packaging, Inc. (805987059)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	manufacture(13630-0089) , analysis(13630-0089)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Packaging, Inc.		805987059	label(13630-0089) , pack(13630-0089)

Revised: 1/2020 Prime Packaging, Inc.