SOLBAR ZINC SPF38- solbar zinc spf38 cream
Person and Covey

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.

Solbar Zinc

Indications and use

Helps prevent sunburn.

Purpose

Sunscreen

Keep out of the reach of children

Yes. If swallowed, get medical help or contact a Poison Control Center right away.

Dosage and Administration

Apply liberally and evenly to all sun exposed areas of DRY skin 15 minutes before sun exposure. Reapply after 80 minutes of swimming or sweating and immediately after towel drying. Apply at least every 2 hours. For children under 6 months, ask a physician.

Warnings

For external use only. Do not use on damaged or broken skin. Keep out of eyes. Rinse eyes thoroughly with water to remove. Stop use and ask a physician if rash or irritation develops and lasts. Store away from excessive heat and direct sun.

OTC - ACTIVE INGREDIENT SECTION

Homosalate

Octinoxate

Zinc Oxide

INACTIVE INGREDIENT SECTION

Water

Isobutyl Stearate

PEG-100 Stearate

Glycerin

Dimethicone

PVP/Eicosene Copolymer

Glyceryl Dilaurate

Cetyl Alcohol

DEA Cetyl Phosphate

Benzyl Alcohol

Cyclomethicone

Stearyl Alcohol

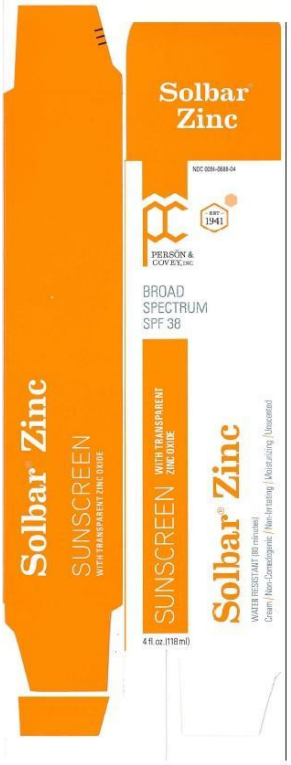
Xanthan Gum

Disodium EDTA

Citric Acid

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Solbar Zinc.jpg



SOLBAR ZINC SPF38

solbar zinc spf38 cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0096-0688
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	0.1015 in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.077 in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	0.077 in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
ISOBUTYL STEARATE (UNII: V8DPR6HNX3)	
PEG-100 STEARATE (UNII: YD01N1999R)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
EICOSYL POVIDONE (2 EICOSYL BRANCHES/REPEAT) (UNII: XQQ9MKE2BJ)	
GLYCERYL DILAURATE (UNII: MFL3ZIE8SK)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIETHANOLAMINE CETYL PHOSPHATE (UNII: 4UG0316V9S)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
XANTHAN GUM (UNII: TTV12P4NEE)	
EDETATE SODIUM (UNII: MP1J8420LU)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0096-0688-04	115 g in 1 BOTTLE; Type 0: Not a Combination Product	06/01/1996	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	06/01/1996	

Labeler - Person and Covey (008482473)

Establishment

Name	Address	ID/FEI	Business Operations
Person and Covey		008482473	manufacture(0096-0688)

Revised: 1/2020 Person and Covey