SOLBAR FIFTY SPF50- solbar fifty spf50 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 Fifty SPF50

WARNINGS AND PRECAUTIONS SECTION

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 - PURPOSE SECTION

Sun screen

INDICATIONS & USAGE SECTION

Helps prevent sunburn. If used as directed with other sun protection measures, decreases the risk of skin cancer and early skin aging caused by the sun.

DOSAGE & ADMINISTRATION SECTION

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.

OTC - KEEP OUT OF REACH OF CHILDREN SECTION

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

OTC - ACTIVE INGREDIENT SECTION

Octocrylene

Ethylhexyl Methoxycinnamate

Oxybenzone

Avobenzone

INACTIVE INGREDIENT SECTION

Purified Water

Propylene Glycol Diethylhexanoate

Dimethicone

PVP/Eicosene Copolymer

Stearic Acid

Cetyl Phosphate

Glycerin

Benzyl Alcohol

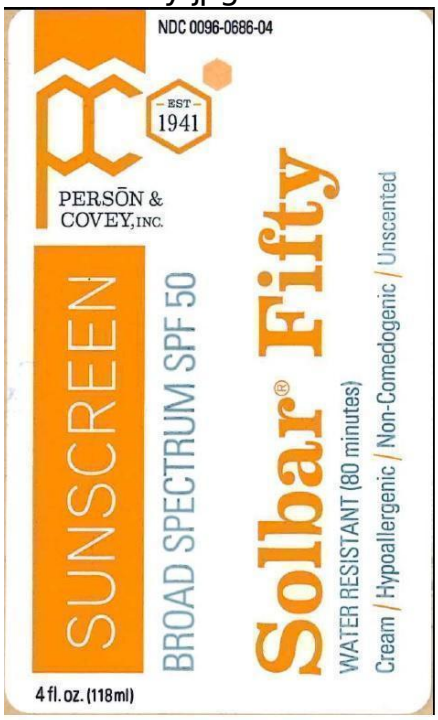
Cetyl Alcohol

Carbomer 1342

Triethanolamine

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Solbar Fifty.jpg



SOLBAR FIFTY SPF50

solbar fifty spf50 cream

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0096-0741
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	0.1 g in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.08 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.06 g in 1 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.011 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL DIETHYLHEXANOATE (UNII: 8D8I9Z0F1Z)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
EICOSYL POVIDONE (2 EICOSYL BRANCHES/REPEAT) (UNII: XQQ9MKE2BJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CETYL PHOSPHATE (UNII: VT07D6X67O)	
GLYCERIN (UNII: PDC6A3C0OX)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CARBOMER 1342 (UNII: 809Y72KV36)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0096-0741-04	128 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(0096-0741)