

**GOODSENSE SUNSCREEN SPF 50- avobenzone, homosalate, octisalate, octocrylene, oxybenzone lotion**

**Solskyn Personal Care LLC**

*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.*

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**GoodSense Sunscreen SPF 50**

**Active Ingredients** □

Avobenzone 3%

Homosalate 13%

Octisalate 5%

Octocrylene 7%

Oxybenzone 4%

**Purpose**

Sunscreen

**Use**

• 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**

• Do not use on damaged or broken skin.

**When using this product**

• When using this product keep out of eyes. Rinse with water to remove.

**Stop use and ask a doctor**

Stop use and ask a doctor if rash occurs.

**Keep out of reach of children**

• Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

• Apply liberally 15 minutes before sun exposure

- Re-apply: ■ 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 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-sleeved shirts, pants, hats and sunglasses
- Children under 6 months: ask a doctor

### **Other information**

- Protect the product in this container from excessive heat and direct sun • May stain fabric

### **Inactive Ingredients:**

Water, Glycerin, C28-52 Olefin/Undecylenic Acid Copolymer, Neopentyl Glycol Diheptanoate, Stearic Acid, Polyglyceryl-3 Methylglucose Distearate, Tapioca Starch, Glyceryl Stearate, PEG-100 Stearate, Microcrystalline Cellulose, Phenethyl Benzoate, Cellulose Gum, Tocopheryl Acetate, Fragrance, Polymethylsilsesquioxane, Caprylyl Glycol, Aloe Barbadensis Leaf Juice, Stearyl Alcohol, Dimethicone, Disodium EDTA, Sodium Hydroxide, Phenoxyethanol

### **Questions**

Distributed by: Geiss, Destin & Dunn, Inc, Peachtree City, GA 30269

[www.valuelabels.com/800-715-3485](http://www.valuelabels.com/800-715-3485)

GoodSense is a registered trademark of L. Perrigo Company

\*This product is not manufactured or distributed by Bayer, the owner of the registered trademark Coppertone

### **Principal Display Panel**

GOODSENSE

SUNSCREEN

LOTION

BROAD SPECTRUM

SPF 50

- Water Resistant

(80 Minutes)

- UVA/UVB Protection
- Hypoallergenic

Compare to active ingredients of

Coppertone

100%

Satisfaction

Guaranteed

8 FL OZ (237 mL)

PKLA-41425-GFS1

### Drug Facts

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PKLA-11425-GSR1



## GOODSENSE SUNSCREEN SPF 50

avobenzone, homosalate, octisalate, octocrylene, oxybenzone lotion

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:70281-639

## Route of Administration

TOPICAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	13 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	7 g in 100 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	4 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
STARCH, TAPIOCA (UNII: 24SC3U704I)	
POLYGLYCERYL-3 DISTEARATE (UNII: Z11LK470XV)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PHENETHYL BENZOATE (UNII: 0C143929GK)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
MAGNESIUM DISODIUM EDTA (UNII: NDT563S5VZ)	
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
UNDECYLENIC ACID (UNII: K3D86KJ24N)	
NEOPENTYL GLYCOL (UNII: Q180HXD6S5)	
GLYCERYL STEARATE/PEG-100 STEARATE (UNII: RD25J5V947)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70281-639-24	237 g in 1 CONTAINER; Type 0: Not a Combination Product	04/02/2019	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	04/02/2019	

Labeler - Solskyn Personal Care LLC (080010329)

## Establishment

Name	Address	ID/FEI	Business Operations
Accra Pac, Inc.		024213616	manufacture(70281-639)

Revised: 6/2019

Solskyn Personal Care LLC