# SUNSCREEN SPF 50- avobenzone 3% homosalate 13% octisalate 5% octocrylene 7% oxybenzone 4% lotion Good Sense

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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## **Drug Facts**

## **Active Ingredients**

3% Avobenzone

13% Homosalate

5% Octisalate

7% Octocrylene

4% Oxybenzone

## **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 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.

## 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

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**

Aluminum Starch Octenylsuccinate, Benzyl Alcohol, Carbomer, Dimethicone, Disodium EDTA, Fragrance, Methylparaben, Polyglyceryl-3 Distearate, Propylparaben, Sorbitan Isostearate, Sorbitol, Stearic Acid, Tocopherol, Triethanolamine, VP/Eicosene Copolymer, Water

### Other Information

- protect this product from excessive heat and direct sun
- may stain fabrics

Questions? 888-309-9030



## BROAD SPECTRUM SPF 50

- Water Resistant (80 Minutes)
- UVA/UVB Protection
- Hypoallergenic

\*Compare to active ingredients of Coppertone®



OXYBENZONE (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)

NET WT 8 OZ (227 g)

# Drug Facts Purpose Active ingredients Purpose Avobenzone 3% Sunscreen Homosalate 13% Sunscreen Octisalate 5% Sunscreen Octocylene 7% Sunscreen Oxybenzone 4% Sunscreen

Uses • helps prevent sunburn • higher SPF gives more sunburn protection • retains SPF after 80 minutes of activity in the water or sweating

#### Warnings

For external use only

Do not use on damaged or broken skin

When using this product • Keep out of eyes. Rinse eyes 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 hours • Sun Protection Measures. Spending time in the sun
increases your risk of skin cancer and early skin aging. To decrease this risk,
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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
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Questions? 888-309-9030

\*This product is not manufactured or distributed by Schering-Plough HealthCare Products, Inc., makers of Coppertone®.

> Distributed by: Geiss, Destin & Dunn, Inc. Peachtree City, GA 30269 www.valuelabels.com 1-866-696-0957

> > OXYBENZONE



4 g in 100 g

#### SUNSCREEN SPF 50

avobenzone 3% homosalate 13% octisalate 5% octocrylene 7% oxybenzone 4% lotion

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:50804-784

Route of Administration TOPICAL

#### Active Ingredient/Active Moiety **Basis of Strength** Strength **Ingredient Name** 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: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W) OCTISALATE 5 g in 100 g OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) OCTOCRYLENE 7 g in 100 g

Inactive Ingredients				
Ingredient Name	Strength			
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: 19 PJ 0 O 6 2 9 4)				
BENZYL ALCOHOL (UNII: LKG8494WBH)				
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)				
<b>DIMETHICO NE</b> (UNII: 92RU3N3Y1O)				
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)				
METHYLPARABEN (UNII: A218 C7HI9 T)				
POLYGLYCERYL-3 DISTEARATE (UNII: ZI1LK470 XV)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)				
SORBITOL (UNII: 506T60A25R)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
TOCOPHEROL (UNII: R0ZB2556P8)				
TROLAMINE (UNII: 903K93S3TK)				
EICOSYL POVIDONE (UNII: XQQ9MKE2BJ)				

Packaging							
#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date			
1	NDC:50804-784-04	113 g in 1 BOTTLE; Type 0: Not a Combination Product	04/05/2012				
2	NDC:50804-784-06	227 g in 1 BOTTLE; Type 0: Not a Combination Product	04/05/2012				

Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC monograph not final	part352	04/05/2012					

# Labeler - Good Sense (076059836)

# Registrant - Product Quest Mfg, LLC (927768135)

Establishment						
Name	Address	ID/FEI	Business Operations			
Product Quest Mfg, LLC		927768135	manufacture(50804-784), label(50804-784)			

Revised: 8/2018 Good Sense