# SOLARGUARD MD - homosalate oxybenzone octocrylene octisalate avobenzone spray Scarguard Labs, 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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## **Drug Facts**

## **Active Ingredients**

Homosalate 15% Oxybenzone 6% Octocrylene 5% Octisalate 5% Avobenzone 3%

## **Purpose**

Sunscreen

Sunscreen

Sunscreen

Sunscreen

Sunscreen

#### Uses

- helps prevent sunburn
- high SPF provides more sunburn protection
- retains SPF after 30 minutes of activity in the water
- provides maximum protection against the sun

### Warnings

For external use only

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

Do not apply to open wounds.

**Stop use and ask a doctor if** irritation becomes severe or condition worsens.

## Keep out of reach of children

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

### Directions

- apply liberally 20 minutes before sun exposure
- reapply at frequent intervals and after swimming, towel drying or perspiring
- ask a doctor before using on children under 6 months old

#### Other Information

**Sun Alert:** limiting sun exposure, wearing protective clothing and using sunscreens may reduce the risk of skin aging, skin cancer, and other harmful effects of the sun.

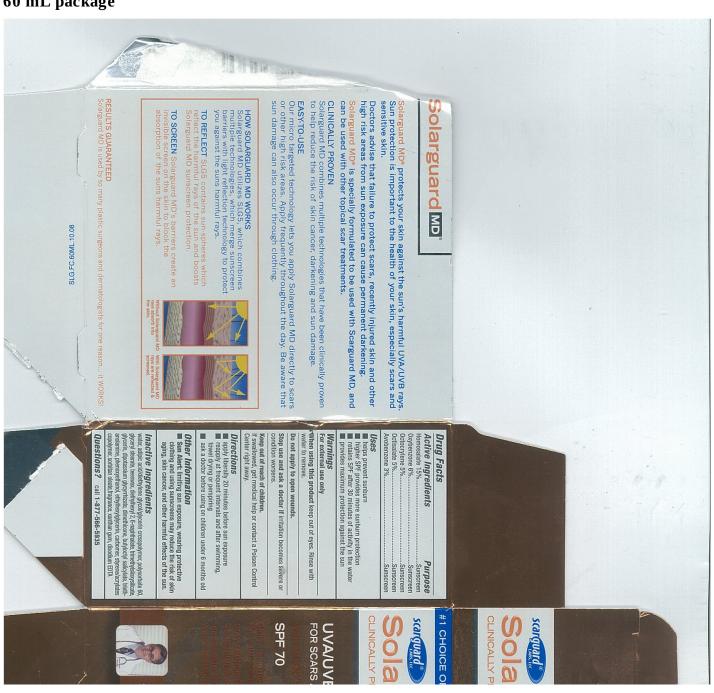
## **Inactive Ingredients**

water, adipic acid/diethylene glycol/glycerin crosspolymer, polysorbate 60, glyceryl stearate, beeswax, diethylhexyl 2,6-naphthalate, trimethylsiloxysilicate, glycerin, dipotassium glycyrrhizate, dimethicone, butyoctyl salicylate, triethanolamine, phenoxyethanol ethylhexylgylcerin, carbomer, styrene/acrylates copolymer, sorbitan oleate, fragrance, xanthan gum, disodium EDTA

### Questions?

call 1-877-566-5935

### 60 mL package





## **SOLARGUARD MD**

homosalate oxybenzone octocrylene octisalate avobenzone spray

Prod	net	Info	rma	tion
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:64269-9907

Route of Administration TOPICAL

#### **Active Ingredient/Active Moiety Basis of Strength Ingredient Name** Strength 15 mL in 100 mL $\textbf{Homosalate} \; (UNII: V06SV4M95S) \; (Homosalate - UNII: V06SV4M95S)$ Ho mo sa la te Oxybenzone (UNII: 9500S7VE0Y) (Oxybenzone - UNII:9500S7VE0Y) Oxybenzone 6 g in 100 mL Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM) Octocrylene 5 mL in 100 mL Octisalate (UNII: 4X49 Y0596W) (Octisalate - UNII:4X49 Y0596W) Octisalate 5 mL in 100 mL Avobenzone (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX) Avobenzone 3 g in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
Polysorbate 60 (UNII: CAL22UVI4M)	

GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)		
YELLOW WAX (UNII: 2ZA36H0S2V)		
GLYCERIN (UNII: PDC6A3C0OX)		
Glycyrrhizinate Dipotassium (UNII: CA2Y0FE3FX)		
Dimethicone (UNII: 92RU3N3Y1O)		
TROLAMINE (UNII: 903K93S3TK)		
Phenoxyethanol (UNII: HIE492ZZ3T)		
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)		
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)		
XANTHAN GUM (UNII: TTV12P4NEE)		
EDETATE DISO DIUM (UNII: 7FLD9 1C8 6 K)		
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)		

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:64269-9907-1	60 mL in 1 BOTTLE, SPRAY				

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part352	04/01/2009			

## Labeler - Scarguard Labs, LLC (842204575)

## Registrant - Scarguard Labs, LLC (842204575)

Revised: 6/2010 Scarguard Labs, LLC