

# **SUNSCREEN- homosalate, octinoxate, octisalate, oxybenzone lotion**

## **Total Resources International**

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**Sunscreen**

### ***Drug Facts***

#### **Uses**

- helps prevent sunburn
- higher SPF gives more sunburn protection
- for skin highly sensitive to sunburn

#### **Active Ingredients**

Homosalate (6.0%), Octinoxate (7.5%), Octisalate (5.0%), Oxybenzone (5.0%)

#### **Directions**

- apply liberally 15 minutes before sun exposure
- use a water resistant sunscreen if swimming or sweating
- reapply at least every 2 hours
- children under 6 months: ask a doctor
- protect from excessive heat and direct sun

#### **Warnings**

**Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, not skin cancer or early skin aging.**

**For external use only.**

**Do not use on damaged or broken skin.**

**Stop use and ask a doctor if rash occurs.**

#### **When using this product**

- keep out of eyes
- rinse with water to remove

**Keep out of reach of children.**

if swallowed, contact a poison control center right away

**Do not use on damaged or broken skin.**

**Stop use and ask a doctor if rash occurs.**

#### **When using this product**

- keep out of eyes

- rinse with water to remove

**Keep out of reach of children.**

If swallowed, contact a poison control center right away

**Inactive ingredients**

cetyl alcohol, ganex P-904, germaben II, polyoxyl 40 stearate, polysorbate 60, petrolatum, purified water, sorbitan monostearate, tetrasodium EDTA, titanium dioxide, xanthan gum, zenicone XX

**PRINCIPAL DISPLAY PANEL - packet**

Sunscreen Lotion  
SPF 30

1.5 g. (0.0570 oz.)



**Drug Facts** (continued)

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**Inactive ingredients**  
cetyl alcohol, ganex P-904, germaben II, polyoxyl 40 stearate, polysorbate 60, petrolatum, purified water, sorbitan monostearate, tetrasodium EDTA, titanium dioxide, xanthan gum, zenicone XX

Manufactured for:  
**Total Resource Int'l**  
Walnut, Ca 91789  
909-594-1220

<b>SUNSCREEN</b>			
homosalate, octinoxate, octisalate, oxybenzone lotion			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55550-102
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	6 mg in 1 g
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 mg in 1 g
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 mg in 1 g
<b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	5 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>DIAZOLIDINYL UREA</b> (UNII: H5RIZ3MPW4)	
<b>POLYOXYL 40 STEARATE</b> (UNII: 13A4J4NH9I)	
<b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>SORBITAN MONOSTEARATE</b> (UNII: NVZ4I0H58X)	
<b>EDETATE SODIUM</b> (UNII: MP1J8420LU)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B6978945GQ)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55550-102-01	1.5 g in 1 PACKET; Type 0: Not a Combination Product	01/20/2023	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	01/20/2023	

**Labeler** - Total Resources International (790160535)

**Registrant** - Safetec of America, Inc. (874965262)

**Establishment**

Name	Address	ID/FEI	Business Operations
Safetec of America, Inc.		874965262	manufacture(55550-102)

Revised: 12/2024

Total Resources International