SUNSCREEN- homosalate, octinoxate, octisalate, oxybenzone lotion
Total Resources International

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.

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, conatct 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

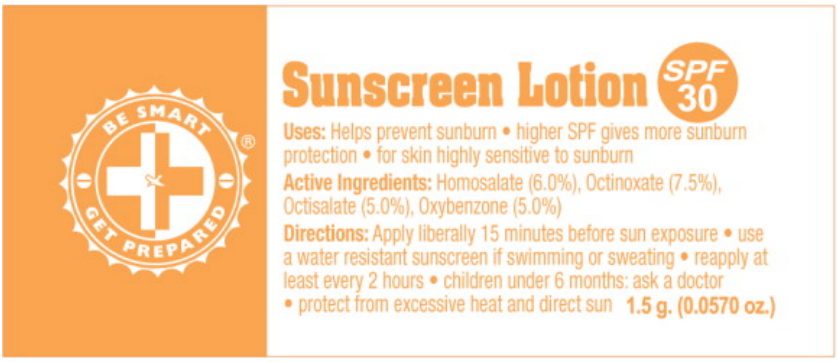
Inactive ingredients

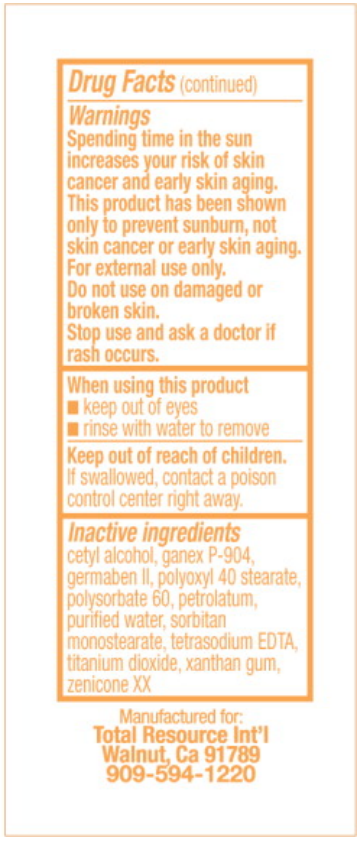
cetyl alcohol, ganex P-904, germaben II, polyoxyl 40 stearate, polysorbate 60, petrolatum, purified water, sorbitan monostearate, tetrasodium EDTA, titanium dioxide, xanthan gum, zenicone XX

PRINCIPAL DISPLAY PANEL – packet

Sunscreen Lotion
SPF 30

1.5 g. (0.0570 oz.)





SUNSCREEN
homosalate, octinoxate, octisalate, oxybenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55550-102
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
CETYL ALCOHOL (UNII: 936JST6JCN)	
POVIDONE K30 (UNII: U725QWY32X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
POLYOXYL 40 STEARATE (UNII: 13A4J4NH9I)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
PETROLATUM (UNII: 4T6H12BN9U)	
WATER (UNII: 059QF0KO0R)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
EDETATE SODIUM (UNII: MP1J8420LU)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XANTHAN GUM (UNII: TTV12P4NEE)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
DIMETHICONE (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 not final	part352	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)