

SUNFREE SUNSCREEN- homosalate, octinoxate, octisalate, oxybenzone lotion Afassco

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.

Drug Facts

Active ingredients

Homosalate (6.0%)

Octinoxate (7.5%)

Octisalate (5.0%)

Oxybenzone (5.0%)

Purpose

Sunscreens

Uses

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

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, get medical help or contact a poison control center right away.

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

Inactive ingredients

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

Principal Display Panel - Packet Label

SUNFREE™
SUNSCREEN

SPF 30 PABA Free

Net contents 3.5g (1/8 oz.)

Mfd for:

Afassco::®

Minden, NV 89423

800-441-6774

SUNFREE™ SUNSCREEN

SPF 30 • PABA Free

Net contents 3.5g (1/8 oz.)

Mfd for: **Afascoco**®
Minden, NV 89423
800-441-6774

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| <i>Active ingredients</i> | <i>Purpose</i> |
|---------------------------|----------------|
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Drug Facts (continued)

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SUNFREE SUNSCREEN

homosalate, octinoxate, octisalate, oxybenzone lotion

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:51532-6103 |
| 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) | |
| ETHYL PYRROLIDONE (UNII: H0229SX1CW) | |
| 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) | |
| PEG-8 Dimethicone (UNII: GIA7T764OD) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|--|-----------------------------|---------------------------|
| 1 | NDC:51532-6103-1 | 3.5 g in 1 PACKET; Type 0: Not a Combination Product | 10/01/2014 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| OTC monograph not final | part352 | 10/01/2014 | |

Labeler - Afassco (609982723)

Registrant - Safetec of America, Inc (874965262)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|----------------|---------------|----------------------------|
| Safetec of America, Inc | | 874965262 | MANUFACTURE(51532-6103) |

Revised: 12/2021

Afassco