SUNSCREEN- homosalate, octinoxate, octisalate, oxybenzone lotion
Safetec of America, Inc.

61010-6103, Sunscreen

Drug Facts

Active Ingredient

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 two 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 – 25 count box

NDC 61010-6103-1

Safetec

Sunscreen
Lotion
SPF 30

PABA Free

25 Packets

3.5 g (1/8 oz.)

Reorder no. 53700

PRINCIPAL DISPLAY PANEL – packet

Safetec

Sunscreen
Lotion
SPF 30•PABA Free
3.5g (1/8 oz.)

Safetec of America, Inc.
Buffalo, NY 14215 800-456-7077
www.safetec.com

Safetec

Sunscreen Lotion

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Drug Facts (continued)

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SUNSCREEN
homosalate, octinoxate, octisalate, oxybenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61010-6103
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)	
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:61010-6103-1	25 in 1 BOX	03/13/2007	
1	NDC:61010-6103-0	3.5 g in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:61010-6103-3	25 in 1 BOX	07/01/2018	
2	NDC:61010-6103-2	2 g in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC Monograph Drug	M020	03/13/2007	

Labeler - Safetec of America, Inc. (874965262)

Establishment

Name	Address	ID/FEI	Business Operations
Safetec of America, Inc.		874965262	manufacture(61010-6103)

Revised: 2/2024 Safetec of America, Inc.