

FACE CREAM 50- homosalate, octisalate, octocrylene, zinc oxide cream
Sun Bum 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.

Face Cream 50

Drug Facts

Active Ingredients

Homosalate 10%, Octisalate 5%

Octocrylene 10%, Zinc oxide 7%

Purpose

Sunscreen

Uses

- helps prevent sunburn
- if used as directed with other sun protection measures (see ***Directions***), decreases the risk of skin cancer and early skin aging caused by the sun

Warnings

For external use only.

Do not use

on damaged or broken skin

When using this product

keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if

rash occurs

Keep out of reach of children.

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

Directions

- shake well before use

- apply liberally 15 minutes before sun exposure
- reapply: • after 80 minutes of swimming or sweating
- immediately after towel drying • at least every 2 hours
- children under 6 months of age: ask a doctor **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
 - limit time in the sun, especially from 10 a.m. - 2 p.m.
 - wear long-sleeved shirts, pants, hats and sunglasses

Inactive Ingredients

water, C12-15 alkyl benzoate, ethylhexyl palmitate, ethylhexyl stearate, cetyl peg/ppg-10/1 dimethicone, glycerin, hydrogenated castor oil, isoamyl cocoate, hydrogenated ethylhexyl olivate, hydrated silica, polyethylene, tocopheryl acetate, theobroma cacao seed butter, aloe barbadensis leaf juice, beeswax, hydrogenated olive oil unsaponifiables, fragrance, sodium chloride, triethoxycaprylylsilane, phenoxyethanol, ethylhexylglycerin

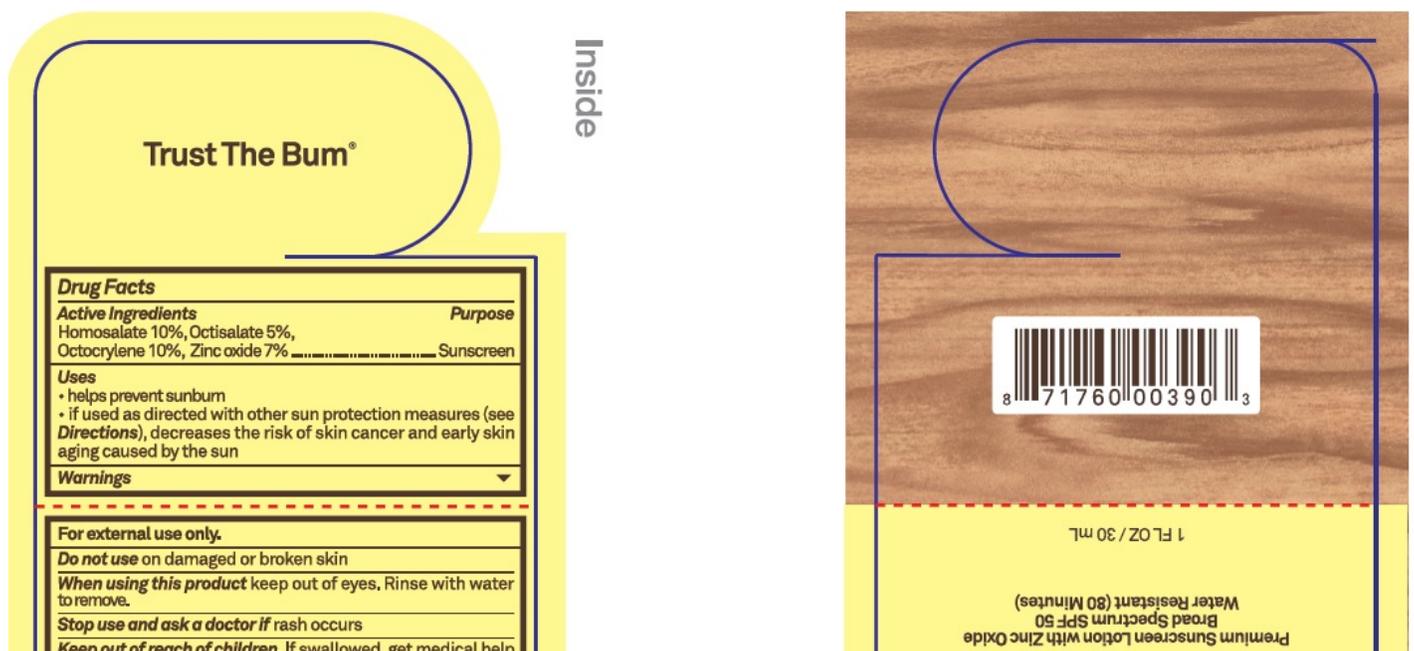
Other Information

- protect this product from excessive heat and direct sun
- keep outer card for complete directions and warnings

Questions?

1-877-978-6286

Package Labeling:



or contact a Poison Control Center immediately.

Directions

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Drug Facts (continued)

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cacao seed butter, aloe barbadensis leaf juice, beeswax, hydrogenated olive oil unsaponifiables, fragrance, sodium chloride, triethoxycaprylsilane, phenoxyethanol, ethylhexylglycerin

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Mfg. for and Dist. by Sun Bum, LLC, PO Box 320598 Cocoa Beach, FL, 32932 USA. ©2019 Sun Bum, LLC. Made in the USA with globally sourced components, R444106.



Face Cream 50

Face Cream 50

Premium Sunscreen Lotion with Zinc Oxide
Broad Spectrum SPF 50
Water Resistant (80 Minutes)

1 FL OZ / 30 mL



Open Here For Drug Facts



Keep outer carton for complete labeling information.

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Face Cream 50

Premium Sunscreen Lotion with Zinc Oxide
Broad Spectrum SPF 50

1 FL OZ / 30 mL

- Water Resistant (80 Minutes)
- Oxybenzone Free
- Rubs In Clear
- Paraben Free
- Gluten Free

Active Ingredients: Homosalate 10%, Octisalate 5%, Octocrylene 10%, Zinc oxide 7%

Suitable for face, nose and ears. Apply liberally 15 minutes before sun exposure. External use only. Avoid contact with eyes.

FACE CREAM 50

homosalate, octisalate, octocrylene, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69039-661
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	100 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	70 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
ETHYLHEXYL STEARATE (UNII: EG3PA2K3K5)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
ISOAMYL COCOATE (UNII: 14OG46E98E)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
HYDROGENATED OLIVE OIL UNSAPONIFIABLES (UNII: B8MIX97W95)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69039-661-00	30 mL in 1 JAR; Type 0: Not a Combination Product	01/06/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/06/2023	

