

SPF30 EVERYDAY/YEAR-ROUND SUNSCREEN- titanium dioxide lotion/shampoo ORGANIC & SUSTAINABLE BEAUTY

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.

SPF30 EVERYDAY/YR-ROUND™ SUNSCREEN LOTION

Drug Facts

Active ingredient

Titanium Dioxide 12%

Purpose

Sunscreen

Uses

- helps prevent sunburn
- higher SPF gives more sunburn protection
- retains SPF after 80 minutes of activity in the water

Warnings

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
- Reapply
 - after 80 minutes of swimming or sweating
 - immediately after towel drying
 - at least every 2 hours
- Children under 6 months: 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

Other information

- protect the product in this container from excessive heat and direct sunlight
- report serious adverse reactions to: 5933 Bowcroft St. Los Angeles, CA 90016

Inactive ingredients

Water, isoamyl laurate, coco-caprylate, calendula officinalis extract (calendula), viola tricolor extract (pansy), polyglyceryl-2 dipolyhydroxystearate, euphorbia cerifera (candelilla) wax, glyceryl starch, carthamus tinctorius (safflower) oleosomes, polyglyceryl-3 diisostearate, levulinic acid, glycerin, tapioca starch, rosmarinus officinalis (rosemary) leaf extract, cocos nucifera (coconut) oil, gardenia tahitensis flower extract, squalane, magnesium stearate, p-anisic acid, cymbopogon schoenanthus oil, allantoin, panthenol.

PRINCIPAL DISPLAY PANEL - 82 g Tube Label

CALIF♥RNIA BABY®

TRUSTED SINCE 1995

everyday/year-round™

30+

SUNSCREEN LOTION

HIGH PROTECTION

GARDENIA & LEMONGRASS

BROAD SPECTRUM

SPF 30+ SUNSCREEN

WATER RESISTANT (80 MINUTES)

FOR BABIES, KIDS + ADULTS

WITH SENSITIVE SKIN

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NET WT 82 g/2.9 oz.

ALLERGY

TESTED

Drug Facts

Active ingredient Titanium Dioxide 12% **Purpose** Sunscreen

Uses: Helps prevent sunburn • higher SPF gives more sunburn protection • retains SPF after 80 minutes of activity in the water

Warnings:

For external use only

Do not use: on damaged or broken skin.

Stop use and ask a doctor if • rash or irritation develops and lasts.

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
- 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

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BLENDING, MANUFACTURED & PACKAGED IN OUR FDA REGISTERED & CERTIFIED ORGANIC U.S.A. FACILITY

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titanium dioxide lotion/shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52915-030
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	120 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
isoamyl laurate (UNII: M1SLX00M3M)	
coco-caprylate (UNII: 4828G836N6)	

calendula officinalis flower (UNII: P0M7O4Y7YD)
VIOLA TRICOLOR WHOLE (UNII: 9Q24RAI43V)
polyglyceryl-2 dipolyhydroxystearate (UNII: 9229XJ4V12)
candelilla wax (UNII: WL0328HX19)
starch, rice (UNII: 4DGK8B7I3S)
carthamus tinctorius seed oleosomes (UNII: 9S60Q72309)
polyglyceryl-3 diisostearate (UNII: 46P231IQV8)
levulinic acid (UNII: RYX5QG61EI)
medium-chain triglycerides (UNII: C9H2L21V7U)
starch, tapioca (UNII: 24SC3U704I)
rosemary (UNII: IJ67X351P9)
coconut oil (UNII: Q9L0O73W7L)
squalane (UNII: GW89575KF9)
magnesium stearate (UNII: 70097M6I30)
p-anisic acid (UNII: 4SB6Y7DMM3)
allantoin (UNII: 344S277G0Z)
panthenol (UNII: WW9CM0O67Z)
gardenia taitensis flower (UNII: T0OCU8201Y)
cymbopogon schoenanthus oil (UNII: XE7K568ILO)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52915-030-29	82 g in 1 TUBE; Type 0: Not a Combination Product	08/31/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	08/31/2015	

Labeler - ORGANIC & SUSTAINABLE BEAUTY (020085717)

Revised: 11/2021

ORGANIC & SUSTAINABLE BEAUTY