

BURTS BEES CALMING DAY SPF30- zinc oxide lotion

Burts Bees

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.

Burt's Bees Calming Day Lotion SPF30

Active Ingredient

Zinc Oxide 16.9%

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 broken or damaged 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 product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally 15 minutes before sun exposure
- Reapply

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 sun, especially from 10a.m.-2p.m., wear long-sleeved shirts, pants, hats and sunglasses . **Children under 6 months:** ask a doctor.

Other Information

Protect this product from excessive heat and direct sun.

Inactive Ingredients:

water, caprylic/capric triglyceride, glycerin, polyglyceryl-6 stearate, C13-15 alkane, pentylene glycol, mica, c15-19 alkane, silica, cetearyl nonanoate, inulin, squalane, polyhydroxystearic acid, carthamus tinctorius (safflower) seed oil, simmondsia chinensis (jojoba) seed oil, abe barbadensis leaf juice, honey, argania spinosa kernel oil, saccharomyces ferment, beeswax, oryza sativa (rice) extract, acacia senegal gum, tocopheryl acetate, polyglyceryl-6 behenate, stearyl alcohol, cetyl alcohol, xanthan gum, glyceryl laurate, sodium PCA, sodium citrate, citric acid, sodium phytate, bisabolol, potassium sorbate, fructose, glucose, inositol, sucrose, trehalose, myristyl alcohol, arachidyl alcohol, benzoic acid, sodium benzoate, hydroxyacetophenone

<p>Drug Facts</p> <table border="1"> <thead> <tr> <th>Active Ingredient</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Zinc Oxide 16.5%</td> <td>Sunscreen</td> </tr> </tbody> </table> <p>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.</p> <p>Warnings For external use only. Do not use on broken or damaged skin. When using this product, keep out of eyes. Rinse with water to remove. Stop use and ask a doctor if rash occurs.</p> <p>Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions • Apply liberally 15 minutes before sun exposure. • Reapply at least every 2 hours. • Use water resistant sunscreen if swimming or sweating.</p> <p>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 sun, especially from 10 a.m. – 2 p.m., wear long-sleeved shirts, pants, hats and sunglasses, Children under 6 months: ask a doctor.</p> <p>Other Information: Protect this product from excessive heat and direct sun.</p> <p>Inactive Ingredients: water, caprylic/capric triglyceride, glycerin, polyglyceryl-6 stearate, C13-15 alkane, pentylene glycol, mica, c15-19 alkane, silica, cetearyl nonanoate, inulin, squalane, polyhydroxystearic acid, carthamus tinctorius (safflower) seed oil, simmondsia chinensis (jojoba) seed oil, abe barbadensis leaf juice, honey, argania spinosa kernel oil, saccharomyces ferment, beeswax, oryza sativa (rice) extract, acacia senegal gum, tocopheryl acetate, polyglyceryl-6 behenate, stearyl alcohol, cetyl alcohol, xanthan gum, glyceryl laurate, sodium PCA, sodium citrate, citric acid, sodium phytate, bisabolol, potassium sorbate, fructose, glucose, inositol, sucrose, trehalose, myristyl alcohol, arachidyl alcohol, benzoic acid, sodium benzoate, hydroxyacetophenone</p> <p>Questions? 800-849-7112 or www.burtsbees.com</p>	Active Ingredient	Purpose	Zinc Oxide 16.5%	Sunscreen	<p>Developed with Dermatologists</p> <p>SAFE AND SOFT</p> <p>Get the benefits of mineral sun protection and reinforce your skin's moisture barrier with our SPF 30 Calming Day Lotion.</p> <p>Sensitive skin has a depleted moisture barrier, which may allow irritants to trigger redness. This formula features our Hydrate & Calm Complex to help reinforce the moisture barrier, plus soothing Aloe and lightweight mineral SPF 30. Give sensitive skin the care it needs to leave it looking and feeling healthier.</p>	<p>NEW</p> <p>BURT'S BEES</p> <p>SPF 30 Calming Day Lotion <i>with aloe and rice milk</i></p> <p>SENSITIVE solutions</p> <p>BROAD SPECTRUM SPF 30</p> <p>LIGHTWEIGHT MINERAL SUNSCREEN</p> <p>Net Wt. 1.8 oz / 51 g</p>	<p>BurtsBees.com/Values</p> <p>INGREDIENTS FROM NATURE</p> <p>LEAFING BUNNY CERTIFIED</p> <p>RESPONSIBLE SOURCING</p> <p>RECYCLABLE CARTON</p> <p>Formulated Without Parabens, Phthalates, Petroatum or SLS</p> <p>99.4% NATURAL ORIGIN with nutrient rich botanicals</p> <p>Made in USA of global ingredients. ©2021 Dist. for BURT'S BEES, Inc. Durham, NC 27701, US • 800-849-7112 Burt's Bees is a trademark of The Burt's Bees Products Company. All Rights Reserved. 285184/031</p>
Active Ingredient	Purpose						
Zinc Oxide 16.5%	Sunscreen						

BURTS BEES CALMING DAY SPF30

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:26052-492
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	16.9 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
ACACIA (UNII: 5C5403N260)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
LEVOMENOL (UNII: 24WE03BX2T)	
HEXASODIUM PHYTATE (UNII: ZBX50UG81V)	
HONEY (UNII: Y9H1V576FH)	
RICE GERM (UNII: 7N2B70SFEZ)	
WATER (UNII: 059QF0KO0R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
C13-15 ALKANE (UNII: 114P5I43UJ)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
MICA (UNII: V8A1AW0880)	
C15-19 ALKANE (UNII: CI87N1IM01)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CETEARYL NONANOATE (UNII: F6ZVW2F361)	
INULIN (UNII: JOS53KRJ01)	
SQUALANE (UNII: GW89575KF9)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
JOJOBA OIL (UNII: 724GKU717M)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
ARGAN OIL (UNII: 4V59G5UW9X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALOE (UNII: V5VD430YW9)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
XANTHAN GUM (UNII: TTV12P4NEE)	
POLYGLYCERYL-6 BEHENATE (UNII: 4T2L7QI313)	
GLYCERYL LAURATE (UNII: Y98611C087)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:26052-492-01	1 in 1 CARTON	10/01/2021	
1		51 g in 1 TUBE; Type 0: Not a Combination		

Product			
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	10/01/2021	

Labeler - Burts Bees (613480946)

Revised: 10/2022

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