BURN OUT SPF-30 SUNSCREEN- zinc oxide lotion Sun Research 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.

Burn Out_® SPF-30 Sunscreen

Drug Facts

Active Ingredient

Zinc Oxide (non-nano) 20%

Purpose

sunscreen

Use(s)

- Provides high protection against sunburn.
- Provides broad spectrum (UVA and UVB) protection.
- Retains SPF after 40 minutes of activity in the water or sweating.
- If used as directed with other sun protection measures, decreases the risk of skin cancer and early skin aging caused by the sun.

Warnings

For external use only.

When using this product

- Keep out of eyes. Rinse with water to remove.
- Stop and ask a doctor if rash or irritation occurs.

Keep out of reach of children.

Directions

- Apply liberally 15 minutes before sun exposure
- Reapply:
 - After 40 minutes of swimming or sweating
 - Immediately after towel drying
 - At least every 2 hours
- Children under 6 months: Ask a doctor

Inactive Ingredients

Purified Water, Organic Aloe Barbadensis Leaf Juice¹, Capric/ Caprylic Triglycerides, Sorbitan Stearate, Polyglyceryl-10 Laurate, Cetyl Dimethicone, Magnesium Sulfate, Organic Avocado Oil¹, Virgin Hemp Seed Oil, Organic Cucumber Extract¹, Organic Green Tea Extract¹, Tocopherols, Organic Pomegranate Juice¹, Helionori, Hyaluronic Acid, Ethylhexylglycerin, Hydrogenated Methyl Abiate, Polyaminopropyl Biguanide.

¹ Certified by a USDA third party agency

Other Information

High sun protection product.

Questions?

Call toll free 1-800-798-7970

PRINCIPAL DISPLAY PANEL - 100 ml Tube Label

Burn Out®

BROAD SPECTRUM SPF 30

OCEAN TESTED PHYSICAL SUNSCREEN

No Nanoparticles Petroleum-free, Paraben-free

Enriched with Antioxidants, Organic Avocado Oil & Helionori

Water Resistant (40 min)

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Other Information

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Questions? Call toll free 1-800-798-7970

Press center of cap to close

3.4 fluid oz.

Gluten-free

Made in the U.S.A.

Never tested on animals.

Sun Research LLC Santa Cruz, CA

www.burnoutsun.com



BURN OUT SPF-30 SUNSCREEN

zinc oxide lotion

Product Information

HUMAN OTC DRUG Product Type

Burn Out.

BROAD SPECTRUM

SPF 30

OCEAN TESTED

PHYSICAL.

SUNSCREEN

No Nanoparticles

Petroleum-free, Paraben-free

Enriched with Antioxidants.

Organic Avocado Oil & Helionori

Item Code (Source)

NDC:55777-0100

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

Strength

Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)

Zinc Oxide

20 g in 100 mL

Inactive Ingredients

Ingredient Name

Strength

water (UNII: 059QF0KO0R)	
aloe vera leaf (UNII: ZY81Z83H0X)	
TRICAPRILIN (UNII: 6P92858988)	
sorbitan monostearate (UNII: NVZ4I0H58X)	
polyglyceryl-10 laurate (UNII: MPJ2Q8WI8G)	
cetyl dimethicone 150 (UNII: 5L694Y0T22)	
magnesium sulfate, unspecified form (UNII: DE08037SAB)	
avocado oil (UNII: 6VNO72PFC1)	
cannabis sativa seed oil (UNII: 69 VJ1LPN1S)	
green tea leaf (UNII: W2ZU1RY8B0)	
tocopherol (UNII: R0ZB2556P8)	
pomegranate juice (UNII: 99S671U9KB)	
hyaluronic acid (UNII: S270 N0 TRQY)	
ethylhexylglycerin (UNII: 147D247K3P)	
hydrogenated methyl abietate (UNII: A23O709X8O)	
polihexanide (UNII: 322U039GMF)	

Packaging							
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:55777-0100-1	100 mL in 1 TUBE; Type 0: Not a Combination Product	09/12/2013				
Marketing Information							

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC MONOGRAPH FINAL	part352	09/12/2013				

Labeler - Sun Research LLC (031405272)

Revised: 1/2020 Sun Research LLC