CREAM- zinc oxide cream Oxygen Development LLC

Self Reflect Probiotic Moisturizing Zinc Oxide Sunscreen Broad Spectrum SPF 32

Active ingredient

Zinc Oxide 22.4%

Purpose

Sunscreen

Uses

Help prevent sunburn.

If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin agung caused by the sun.

Warnings

For external use only.

Do not use

Do not use on damaged or broken skin.

When using this product

When using this product keep out of eyes.

Rinse with water to remove.

Stop use and ask a doctor

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.

Use water resistant sunscreen if swimming or sweating.

Reapply at least every 2 hours.

Sun protection measures:

Spending time in the sun increases 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 am-2 pm.
- -wear long-sleeved shirts, pants, hats and sunglasses.
- -children under 6 months of age: Ask a doctor.

Other information

Protect this product from excessive heat and direct sun.

Inactive ingredients

Water(Aqua), Caprylic/Capric Triglyceride, Coconut Alkanes, Cetearyl Alcohol, Glycerin, Aloe Barbadensis Leaf Juice*, Pyrus Malus (Apple) Fruit Extract, Coco-Glucoside, Lactobacillus Ferment, Rubus Idaeus (Raspberry) Seed Oil, Cocos Nucifera (Coconut) Liquid Endosperm, Curcuma Longa (Turmeric) Rhizomes Oil, Butyrospermum Parkii Nut Extract, Hydrolyzed Jojoba Esters, Tocopherol, Dipotassium Glycyrrhizinate, Vanilla Planifolia Fruit Extract, Glycyrrhiza Glabra (Licorice) Root Extract, Butylene Glycol, Isostearic Acid, Lecithin, Polyglyceryl-3 Polyricinoleate, Polyhydroxystearic Acid, Coco-Caprylate/Caprate, Caprylyl/Capryl Glucoside, Glucoside, Sclerotium Gum, Cetearyl Glucoside, Ethylhexylglycerin, Xanthan Gum, Octyldodecanol, Tapioca Starch, Citric Acid, Sorbitan Oleate, Phenoxyethanol, Sodium Benzoate, Potassium Sorbate, May contain +/-Iron Oxides (CI 77491, CI 77492) *Certified Organic.

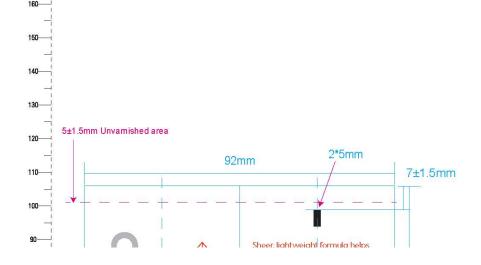


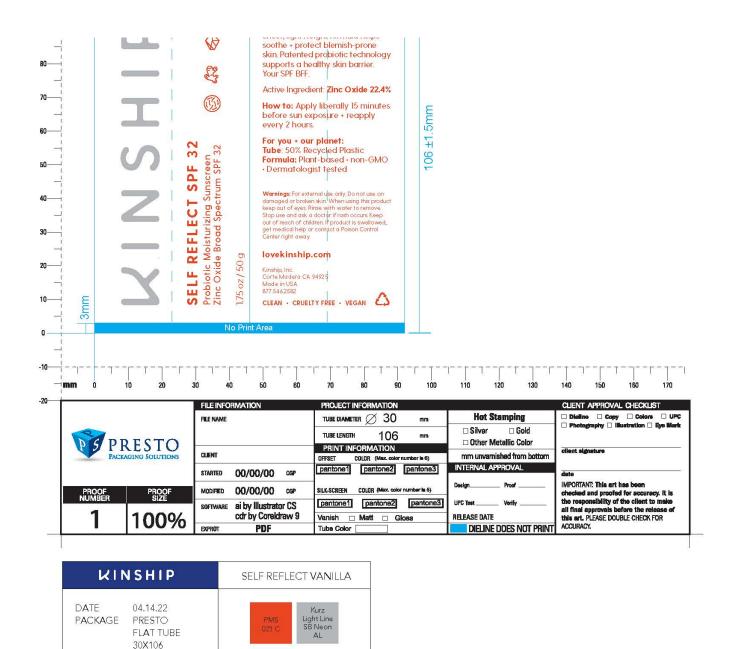
200-

190

170

- Remark:
 1. The scale of dieline must be 1:1;
 2, Artwork must be outlined;
 3, Registration tolerance is +/-1mm for S/S and H/S, +/-0.5mm for offset printing;
- 4, There is 2mm overlap area or blank area at the side for full screen printing





CREAM

zinc oxide cream				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:61354-115
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name				
ingredie	nt Name		Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (Z		54Z)	ZINC OXIDE	Strength 21.76 mg in 100 mg
		54Z)		
		54Z)		

Ingredient Name	Strength
POLYGLYCERYL-3 PENTARICINOLEATE (UNII: 7Q00K5D0T4)	0.96 mg in 100 mg
WATER (UNII: 059QF0KO0R)	36.09 mg in 100 mg
APPLE (UNII: B423VGH5S9)	1.5 mg in 100 mg
COCO GLUCOSIDE (UNII: ICS790225B)	1.05 mg in 100 mg
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	0.96 mg in 100 mg
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)	0.96 mg in 100 mg
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	16.85 mg in 100 mg
COCONUT ALKANES (UNII: 1E5KJY107T)	4.7 mg in 100 mg
RASPBERRY SEED OIL (UNII: 9S8867952A)	0.49 mg in 100 mg
PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.9 mg in 100 mg
LACTOBACILLUS REUTERI F275 STRAIN (UNII: 3K209OP33H)	0.99 mg in 100 mg
GLYCERIN (UNII: PDC6A3C0OX)	4.79 mg in 100 mg
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	4.22 mg in 100 mg
ISOSTEARIC ACID (UNII: X33R8U0062)	0.96 mg in 100 mg

	Packaging			
1	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:61354-115- 02	1 in 1 CARTON	10/26/2023	
	NDC:61354-115- 01	100 mg 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 Drug	M020	10/26/2023	

Labeler - Oxygen Development LLC (137098492)

Establishment				
Name	Address	ID/FEI	Business Operations	
Oxygen Development LLC		137098492	manufacture(61354-115)	

Revised: 10/2023 Oxygen Development LLC