

**MOISTURIZER- zinc oxide cream**  
**OXYGEN DEVELOPMENT, 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.*

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**Self Reflect Probiotic Moisturizing Sunscreen Zinc Oxide Broad Spectrum SPF 32**

**Active Ingredients**

Zinc Oxide 22.40%

**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**

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

**Directions**

- Apply liberally 15 minutes before sun exposure.
- Use a water resistant sunscreen if swimming or sweating.
- Reapply at least every 2 hours.
- **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 10am-2pm

- wear long-sleeved shirts, pants hats and sunglasses
- Children under 6 months of age: Ask a doctor.

### **Other Information**

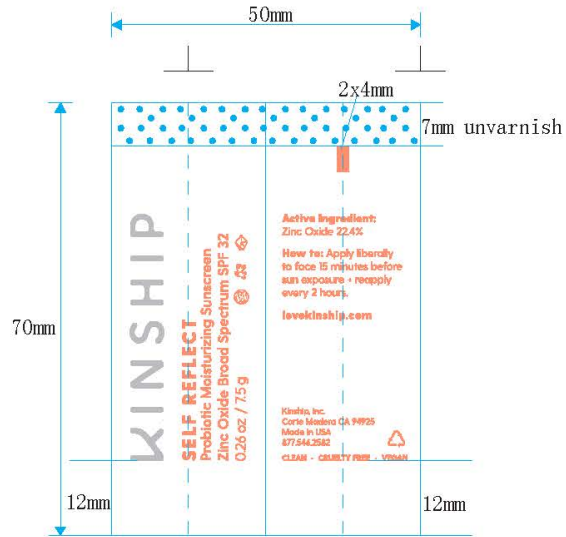
Protect this product from excessive heat and direct sun.

### **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(red Raspberry) Seed oil, Cocos Nucifera(Coconut) Liquid Endosperm, Curcuma Longa (Turmeric) Rhizomes Oil, Butyrospermum parkii nut Extract, Hydrolyzed Jojoba Esters, Tocopherol, Dipotassium Glycyrrhizate, Vanilla Planifolia Fruit Extract, Glycyrrhiza Glabra(Licorice) Root Extract, Butylene Glycol, Isostearic Acid, Lecithin, Polyglyceryl-3 Polyricinoleate, Polyhydroxystearic Acid, Coco-Caprylate/Caprinate, Caprylyl/Capryl 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).

### **Questions or comments?**

Call toll free (877) 546-2582



64144 树脂印 (Offset printing): 170c  
 镭射烫银 (Holographic hot stamping)

- 170c
- 镭射烫银 (Holographic hot stamping)
- die line, does not print
- unvarnished area

产品编号 P/N	64144	制作人 Processed by	Mary	确认签字 Approval	
打样/订单号 Sample/PO #		制作日期 Date	2020/11/02	日期 Date	
附加说明 Remarks					

zinc oxide cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61354-048(NDC:61354-012)
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	22.4 mg in 100 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>COCONUT ALKANES</b> (UNII: 1E5KJY107T)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>APPLE</b> (UNII: B423VGH5S9)	
<b>COCO GLUCOSIDE</b> (UNII: ICS790225B)	
<b>LACTOBACILLUS REUTERI</b> (UNII: 9913I24QEE)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:61354-048-01	7.5 mg in 1 BOTTLE; Type 0: Not a Combination Product	04/29/2022	

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part352	04/29/2022	

**Labeler** - OXYGEN DEVELOPMENT, LLC (137098492)

## Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
OXYGEN DEVELOPMENT, LLC		137098492	repack(61354-048) , manufacture(61354-048)

Revised: 4/2022

OXYGEN DEVELOPMENT, LLC