

**SPF30- zinc oxide lotion**  
**Cosmetic Specialty Labs, Inc.**

*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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**Active Ingredient**

Zinc Oxide

**Purpose**

Sunscreen

**Sun Alert:**

Limiting sun exposure, wearing protective clothing, and using broad spectrum sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun.

**Uses**

Helps prevent sunburn. Used as directed with other sun protection measures, decreases skin cancer risk and early skin aging, caused by the sun.

**Caution**

Keep out of direct sunlight and excessive heat. Some natural separation may occur. Shake well before using.

**Warnings**

For external use only. Do not ingest. Keep out of eyes; rinse with water to remove. Keep out of reach of children. If swallowed, get medical help or contact poison control.

**Other Information**

Protect this product from excessive heat or direct sun.

**Directions: FDA Recommends**

- Applying 15 minutes before sun exposure
- Using a water resistant sunscreen if swimming or sweating
- Reapplying at least every 2 hours
- For children under 6 months: consult pediatrician

## **Inactive Ingredients**

Aloe Barbadensis Leaf Extract, Beeswax, Butyrospermum parkii (Shea) Butter, C12-15 Alkyl Benzoate, Candelilla (Euphorbia Cerifera) Wax, Carthamus tinctorius (Safflower) Seed Oil, Chamomilla recutita (Matricaria) Flower Extract, Cocos nucifera (Coconut) Oil, Glyceryl Caprylate, Glyceryl Undecylenate, Helianthus annuus (Sunflower) Seed Oil, Lavandula angustifolia (Lavender) Oil, Mangifera indica (Mango) Seed Butter, Olea europaea (Olive) Fruit Oil, Persea gratissima (Avocado) Oil, Symphytum officinale (Comfrey) Leaf Extract, Theobroma cacao (Cocoa) Seed Butter, Tocopherol, Triethoxycaprylylsiloxane

# Rubber Ducky<sup>®</sup>

## NO-OX<sup>®</sup> SUNSCREEN

100% Natural • Chemical Free



"Like Water Off A Duck's Back"

un-tinted  
paraben free  
extensive clinicals  
non-nano zinc oxide 22.75%  
broad spectrum  
uva/uvb - blue light

3.3 oz /100ml

**Approved for All  
Globally Restricted Dive Sites  
Won't Sweat into Eyes**

### Drug Facts

Active Ingredients:	Purpose
Zinc Oxide 22.75%	Sunscreen

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Made in USA NDC 56133-652-33

Distributed by:  
Carefree Skincare  
DBA Rubber Ducky  
Sunscreens  
Austin, TX 78641  
512-827-2433  
www.sunblocks.com  
info@sunblocks.com

Item #423



# SPF30

zinc oxide lotion

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58133-652
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	22.75 g in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
YELLOW WAX (UNII: 2ZA36H0S2V)	
COCONUT OIL (UNII: Q9L0073W7L)	
COCOA BUTTER (UNII: 512OYT1CRR)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
GLYCERYL 1-UNDECYLENATE (UNII: B68LJT9544)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CHAMOMILE (UNII: FGL3685T2X)	
MANGIFERA INDICA SEED BUTTER (UNII: 4OXD9M35X2)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SHEA BUTTER (UNII: K49155WL9Y)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
ALMOND OIL (UNII: 66YXD4DKO9)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CANDELILLA WAX (UNII: WL0328HX19)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
COMFREY (UNII: D05HXX6R3G)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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<b>1</b>	NDC:58133-652-33	100 mL in 1 TUBE; Type 0: Not a Combination Product	11/04/2021	
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part352		11/04/2021	

**Labeler** - Cosmetic Specialty Labs, Inc. (032973000)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Cosmetic Specialty Labs, Inc.		032973000	label(58133-652) , manufacture(58133-652) , pack(58133-652)

Revised: 11/2021

Cosmetic Specialty Labs, Inc.