

**IMPACT MELANOMA SPF 30- zinc oxide lotion**  
**RENU LABORATORIES, LLC**

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**Impact Melanoma SPF 30**

**IMPACT MELANOMA SPF 30**

sunscreen is broad spectrum, water  
resistant (80 minutes), free of parabens  
and made for all skin types

***Active Ingredients***

Octyl Methoxy Cinnamate 7.00% Sunscreen

Titanium Dioxide 1.25% Sunscreen

Zinc Oxide 1.25% Sunscreen

Octyl Salicylate 1.00% Sunscreen

***Purpose***

Octyl Methoxy Cinnamate 7.00% Sunscreen

Titanium Dioxide 1.25% Sunscreen

Zinc Oxide 1.25% Sunscreen

Octyl Salicylate 1.00% 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 damaged or broken skin.
- **When using this product** keep out of eyes. Rinse with water to remove.
- **Stop use and consult physician** if irritation or rash develops.
- **Keep out of reach of children.**
- If product is swallowed, get medical attention or contact poison control center immediately.

**Keep out of reach of children.**

## **DIRECTIONS**

- Apply liberally 15 minutes before sun exposure
- Reapply after 80 minutes of swimming or sweating.
- reapply immediately after towel drying.
- 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 sunscreen with broad spectrum protection and an SPF rating of 15 or higher, along with other sun protection measures including:
  - Limited time in the sun, especially between 10am and 2pm.
  - Wear long sleeve shirts, pants, hats and sunglasses.
  - For children under 6 months, consult a physician.

## **OTHER INGREDIENTS**

Aloe Barbadensis (Aloe Vera) Leaf Juice, Calendula Officinalis (Marigold) Flower Extract, Caprylyl Glycol, Carbopol, Cetareth-20, Cetearyl Alcohol, Deionized Water, Dimethicone, Glycerin, Hexylene Glycol, Isocetyl Stearate, Malva Sylvestris (Mallow) Flower Extract, Panax Ginseng Root Extract, Phenoxyethanol, Polyester-7, Neopentyl Glycol, Diheptanoate, Sorbitol, Stearic Acid,

Symphytum Officinale (Comfrey) Leaf Extract, Triethanolamine, Tocopheryl Acetate (Vitamin E)

## **Other information**

- Protect this product from excessive heat and direct sunlight.
- May stain some fabrics.

## **Questions or Comments?**

Visit [www.BrightGuard.com](http://www.BrightGuard.com) or call (310) 589-4116

## **DRUG FACTS**

### **Active Ingredients**

Octyl Methoxy Cinnamate	7% .....
Octyl Salicylate	1.00% .....
Titanium Dioxide	1.25% .....
Zinc Oxide	1.25% .....

**USES:** • Helps prevent sunburn. • If used as direct sun protection measures (see directions), decreases skin cancer and early skin aging caused by the sun.

**WARNINGS:** • For external use only. • DO NOT USE on broken skin. • When using this product keep out of eyes. • Rinse with water to remove. • Stop use and consult physician if irritation or rash develops. • Keep out of reach of children.

irritation or rash develops. Keep out of reach of child.  
If product is swallowed, get medical attention or contact  
poison control center immediately.

**DIRECTIONS:** • Apply liberally 15-minutes before  
exposure • Reapply: At least every two hours • Sun protection  
measures: Spending time in the sun increases your risk of skin  
cancer and early skin aging. To decrease this risk, regular use of  
sunscreen with broad spectrum protection and an SPF of 30 or  
higher, along with other sun protection measures such as wearing  
limited time in the sun, especially between 10am -2pm, wearing  
long sleeve shirts, pants, hats and sun glasses. • For children under  
6-months, consult a physician.

**OTHER INGREDIENTS:** Aloe Barbadensis (Aloe Vera) Leaf  
Extract, Calendula Officinalis (Marigold) Flower Extract, Caprylyl Glycol,  
Cetearyl Alcohol, Cetyl Alcohol, Chamomilla Recutita (Matricaria)  
Flower Extract, Deionized Water, Dimethicone, Glycerin, Hexyl  
Stearate, Malva Sylvestris (Mallow) Flower Extract, Panax Ginseng  
Root Extract, Phenoxyethanol, Polyester-7 (and) Neopentyl Glycol Diheptanoate,  
Stearic Acid, Symphytum Officinale (Comfrey) Leaf Extract, Triethyl  
Tocopherol Acetate

### Other Information:

Protect this product from excessive heat and direct sunlight.

**IMPACT  
MELANOMA**

IMPACT Melanoma Corporation  
To reorder call or visit  
800-557-6352 [www.impactmelanoma.com](http://www.impactmelanoma.com)



LABEL FOR IMPACT MELANOMA SPF

## IMPACT MELANOMA SPF 30

zinc oxide lotion

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76348-598
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	17.5 g in 1000 g
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	70 g in 1000 g
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	10 g in 1000 g
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	12.5 g in 1000 g

Inactive Ingredients	
Ingredient Name	Strength
<b>MALVA SYLVESTRIS FLOWER</b> (UNII: 12X9JI52BS)	
<b>ASIAN GINSENG</b> (UNII: CUQ3A77YXI)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>MATRICARIA RECUTITA FLOWERING TOP</b> (UNII: 3VNC7T6Z02)	
<b>COMFREY LEAF</b> (UNII: DG4F8T839X)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>POLYOXYL 20 CETOSTEARYL ETHER</b> (UNII: YRC528SWUY)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>DIMETHICONE 350</b> (UNII: 2Y53S6ATLU)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>CARBOMER 934</b> (UNII: Z135WT9208)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ISOCETYL STEARATE</b> (UNII: 3RJ7186O9W)	
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>POLYESTER-7</b> (UNII: 0841698D2F)	
<b>NEOPENTYL GLYCOL DIHEPTANOATE</b> (UNII: 5LKW3C543X)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>HEXYLENE GLYCOL</b> (UNII: KEH0A3F75J)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>CALENDULA OFFICINALIS FLOWER</b> (UNII: P0M7O4Y7YD)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76348-598-01	1000 g in 1 JUG; Type 0: Not a Combination Product	04/17/2023	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	04/17/2023	

**Labeler** - RENU LABORATORIES, LLC (119451815)

**Registrant** - RENU LABORATORIES, LLC (119451815)

**Establishment**

Name	Address	ID/FEI	Business Operations
RENU LABORATORIES, LLC		119451815	manufacture(76348-598)

Revised: 3/2025

RENU LABORATORIES, LLC