

IMPACT MELANOMA SPF 30- zinc oxide lotion
RENU LABORATORIES, 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.

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.

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 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

• Rinse with water to remove. • Stop use and consult a 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.

DIRECTIONS: • Apply liberally 15-minutes before sun 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 SPF 15 or higher, along with other sun protection measures including 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 Citrate, 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



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

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|--|------------------|--|----------------------|--------------------|
| Route of Administration | | TOPICAL | | |
| | | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | | ZINC OXIDE | 17.5 g in 1000 g | |
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | | OCTINOXATE | 70 g in 1000 g | |
| OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) | | OCTISALATE | 10 g in 1000 g | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | | TITANIUM DIOXIDE | 12.5 g in 1000 g | |
| | | | | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| ASIAN GINSENG (UNII: CUQ3A77YXI) | | | | |
| MALVA SYLVESTRIS FLOWER (UNII: 12X9JI52BS) | | | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | | |
| MATRICARIA RECUTITA FLOWERING TOP (UNII: 3VNC7T6Z02) | | | | |
| COMFREY LEAF (UNII: DG4F8T839X) | | | | |
| SORBITOL (UNII: 506T60A25R) | | | | |
| POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY) | | | | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | | | | |
| DIMETHICONE 350 (UNII: 2Y53S6ATLU) | | | | |
| CETYL ALCOHOL (UNII: 936JST6JCN) | | | | |
| CARBOMER 934 (UNII: Z135WT9208) | | | | |
| WATER (UNII: 059QF0KO0R) | | | | |
| ISOCETYL STEARATE (UNII: 3RJ7186O9W) | | | | |
| ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | | | | |
| TROLAMINE (UNII: 9O3K93S3TK) | | | | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | | | | |
| POLYESTER-7 (UNII: 0841698D2F) | | | | |
| NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X) | | | | |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) | | | | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | | | | |
| HEXYLENE GLYCOL (UNII: KEH0A3F75J) | | | | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | | | | |
| CALENDULA OFFICINALIS FLOWER (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 not | | not252 | 04/17/2023 | |

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|-------|----------|------------|--|
| final | part 552 | 04/17/2023 | |
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Labeler - RENU LABORATORIES, INC. (945739449)

Registrant - RENU LABORATORIES, INC. (945739449)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|------------------------|
| RENU LABORATORIES, INC. | | 945739449 | manufacture(76348-598) |

Revised: 4/2023

RENU LABORATORIES, INC.