

VACATION WORLD CLASSIC WHIP SPF 30- dimethicone spray
Prime Packaging 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.

Vacation World Classic Whip Broad Spectrum SPF 30

Active Ingredients

Homosalate 7.5%, Octisalate 5%, Octocrylene 5%, Avobenzone 3%

Purpose

Sunscreen

Uses

- Helps prevent sunburn
- If used as directed with other sun protection measures (Directions), decreases the risk of skin cancer and early skin aging caused by the sun.

Warnings

- **For external use only**
- Contents under pressure. Do not puncture or incinerate can.

Do not use on damaged or broken skin.

Stop use and ask a doctor if rash occurs

When using this product

- Keep out of eyes. Rinse with water to remove.
- Do not store at temperatures above 120 F.
- **Keep out of reach of children.** In case of ingestion, get medical help or contact a Poison Control Center right away.

Use only as directed. intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.

Directions

- Apply liberally 15 minutes before sun exposure. Dispense a ping pong ball size amount and apply to a single area (arm, leg, chest, or back). Repeat up to 4 times (roughly a tennis ball size amount) for a whole body application.
- Do not spray product directly on face. Spray onto hands and rub onto face.
- Reapply:

- after 80 minutes of swimming or sweating
- immediately after towel drying
- 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 the risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including
- limit time in the sun, especially from 10 a.m.- 2 p.m.
- wear long-sleeve shirts, pants, hats, and sunglasses
- Children under 6 months of age: ask a physician

Inactive Ingredients

Aloe Barbadensis Leaf Juice, Aminomethyl Propanol, Butyloctyl Salicylate, Cocos Nucifera (Coconut) Oil, Dimethicone, Ethylhexylglycerin, Fragrance, Glycerin, Microcrystalline Cellulose, Musa Sapientum (Banana) Fruit Extract, Niacinamide, PVP/Hexadecene Copolymer, Phenoxyethanol, Polymethylsilsesquioxane, Polysorbate 20, Sodium Hyaluronate, Stearic Acid, Tapioca Starch, Tetrafluoropropene, Tetrasodium Glutamate Diacetate, Tocopheryl Acetate, Water

Other information

- Protect this product from excessive heat and direct sun

Vacation World Classic Whip Broad Spectrum SPF 30 Sunscreen Mousse

"For True Connoisseurs of Leisure"

✓ OXYBENZONE FREE ✓ OCTISOALATE FREE ✓ CRUELTY FREE ✓ VEGAN
 ✓ PARABEN AND PEG FREE ✓ NON-OZONE DEPLETING PROPPELLANT

| Drug Facts | Purpose |
|--|-----------|
| Active ingredients Homosalate (7.5%), Octisalate (5%), Octocrylene (5%), Avobenzone (3%) | Sunscreen |
| Uses • Helps prevent sunburn • If used as directed with other sun protection measures (see <i>Directions</i>), decreases the risk of skin cancer and early skin aging caused by the sun. | |
| Warnings • For external use only. • Contents under pressure. Do not puncture or incinerate can. • Do not use on damaged or broken skin. • Stop use and ask a doctor if rash occurs. • When using this product • Keep out of eyes. Rinse with water to remove. • Do not store at temperatures above 120 F. • Keep out of reach of children. In case of ingestion, get medical help or contact a Poison Control Center right away. • Use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal. | |
| Directions • Apply liberally 15 minutes before sun exposure. Dispense a ping pong ball size amount and apply to a single area (arm, leg, chest, or back). Repeat up to 4 times (roughly a tennis ball size amount) for a whole body application. • Do not spray product directly on face. Spray onto hands and rub onto face. • Reapply: • after 80 minutes of swimming or sweating • immediately after towel drying • 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 the risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including: • limit time in the sun, especially from 10 a.m. - 2 p.m. • wear long-sleeve shirts, pants, hats, and sunglasses • Children under 6 months of age: ask a physician. | |
| Inactive ingredients Aloe Barbadensis (Aloe Vera) Leaf Juice, Aminomethyl Propanol, Butyloctyl Salicylate, Cocos Nucifera (Coconut) Oil, Dimethicone, Ethylhexylglycerin, Fragrance, Glycerin, Microcrystalline Cellulose, Musa Sapientum (Banana) Fruit Extract, Niacinamide (Vitamin B3), PVP/Hexadecene Copolymer, Phenoxyethanol, Polymethylsilsesquioxane, Polysorbate 20, Sodium Hyaluronate, Stearic Acid, Tapioca Starch, Tetrafluoropropene, Tetrasodium Glutamate Diacetate, Tocopheryl Acetate (Vitamin E), Water | |
| Other information • Protect this product from excessive heat and direct sun | |

**BROAD-SPECTRUM SPF 30
SUNSCREEN MOUSSE**
 WATER RESISTANT (80 MINUTES)
 4 OZ / 113 G

Distributed by Vacation Inc.
 936 SW 1st Ave #888 Miami, FL 33130
 © 2022 Vacation Inc.

WARNING! THIS PRODUCT SMELLS MUCH BETTER THAN IT TASTES—DO NOT EAT.

To Use:

- ① SHAKE VIGOROUSLY.
- ② TURN CAN UPSIDE DOWN AND TILT NOZZLE WITH FINGER.
- ③ START WITH PING PONG BALL SIZE INCREMENTS. (A FULL BODY WILL REQUIRE A TENNIS BALL SIZE AMOUNT)
- ④ RINSE & WIPE OFF ANY EXCESS PRODUCT BEFORE PLACING CAP BACK ON.

VACATION WORLD CLASSIC WHIP SPF 30

dimethicone spray

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:13630-0232 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|-----------------|
| OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) | OCTISALATE | 50.5 mg in 1 mL |
| HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S) | HOMOSALATE | 75.8 mg in 1 mL |
| OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE | 50.5 mg in 1 mL |
| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | AVOBENZONE | 50.5 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| COCONUT OIL (UNII: Q9L0O73W7L) | |
| AMINOMETHYLPROPANOL (UNII: LU49E6626Q) | |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| POLYSORBATE 20 (UNII: 7T1F30V5YH) | |
| NIACINAMIDE (UNII: 25X51I8RD4) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3) | |
| STARCH, TAPIOCA (UNII: 24SC3U704I) | |
| TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY) | |
| ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| WATER (UNII: 059QF0KO0R) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| BANANA (UNII: 4AJZ4765R9) | |
| HYALURONATE SODIUM (UNII: YSE9PPT4TH) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |

Product Characteristics

| | | | |
|-----------------|-------------------|---------------------|--|
| Color | white (Off-White) | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------|--|----------------------|--------------------|
| 1 | NDC:13630- | 112 mL in 1 CAN; Type 0: Not a Combination | 01/08/2022 | |

| 0232-3 | Product | 04/08/2022 | |
|------------------------------|--|----------------------|--------------------|
| Marketing Information | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph final | part352 | 04/08/2022 | |

Labeler - Prime Packaging Inc. (805987059)

Registrant - Prime Packaging Inc. (805987059)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------|---------|-----------|--|
| Prime Enterprises Inc | | 101946028 | analysis(13630-0232) , manufacture(13630-0232) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------|---------|-----------|--------------------------------------|
| Prime Packaging Inc. | | 805987059 | pack(13630-0232) , label(13630-0232) |

Revised: 4/2022

Prime Packaging Inc.