**POWDER- zinc oxide powder**
**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.*

---

**Hawaiian Tropic mineral translucent powder sunscreen broad spectrum SPF 30**

## Active Ingredient

Zinc oxide 24.5%

Sunscreen Agent

## Uses

Helps prevent sunburn

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

## Warnings

For external use only.

Do not use on damage or broken skin.

When using this product: Avoid inhalation.

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.

Children under 6 months: Ask a docstor

Sun Protection Measures. Spendign time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regulary use a sunscreen with a Board Spectrum SPF value 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-sleeved shirts, pants, hats, and sunglasses

**Inactive Ingredients:**

Calcium Aluminunm Borosilicate, Silica, Ethylhexylglycerin, Sodium Dehydroacetate, Fragrance, Sea Salt, Ceramide NP, Ascorbyl Palmitate, Caprylic/Capric Triglyceride, Triethoxycaprylylsilane, Carica Papaya (Papaya) Fruit Extract, Mangifera Indica (Mango) Fruit Extract, Passiflora Incarnata Fruit Extract, Plumeria Acutifolia Flower Extrat, Psidium Guajava Fruit Extract, Iron Oxides

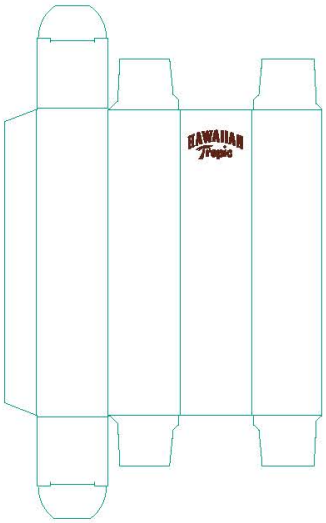
**Other information**

Protect this product from excessive heat and direct sun

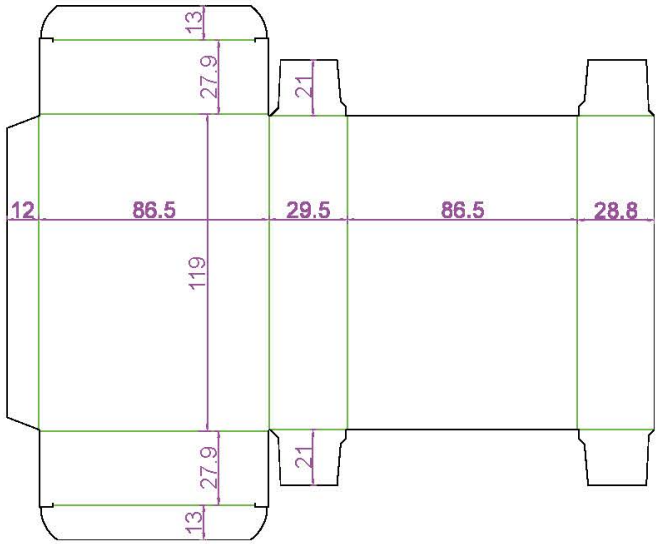
**Package**


HAWAIIAN Tropic
MINERAL
SPF 30

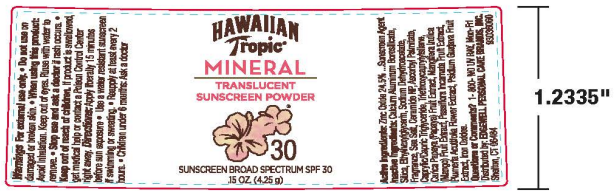

CYAN
MAGENTA
YELLOW
BLACK
PANTONE 700
PANTONE 4695

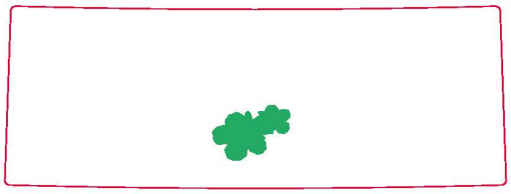

HAWAIIAN Tropic


HOT GOLD


13
27.9
21
12
86.5
29.5
86.5
28.8
119
27.9
21
13

TOP OF COMPONENT



white plate

| | | |
|---|---|---|
| Customer: **Oxygen** | Color Guide: | 50 Marcus Blvd. Hauppauge, NY 11788 tel 631.293.4200 fax 631.293.4203 |
| Folder: **Oxygen•artwork** | dieline does not print | PMS 871 C |
| File: **93036060 US-SC-HT Mineral Powder Brush _15 OZ lbl.ai** | deco area does not print | PMS 4695 C |
| ITEM#: **TBD** PRECISION#: **TBD** | white plate | |
| SIZE: **1.2335" x 3.0114" w/.0312" cr • Tapered** | PMS 197 C | |
| JOB#: **TBD** | PMS 7499 C | |
| UNWIND: **TBD** | PMS 709 C | |
| SUBSTRATE: **Clear BOPP** PREPARED BY: **JR** | | |
| DATE: **6/24/2021** PROOF #: **1** | | |

PRECISION LABEL CORPORATION

**IMPORTANT:** Please review proof for typographical errors, format, style and color breaks. This is a representation of the desired color. Please reference PANTONE® color guide for a more accurate color.

**PLEASE NOTE:** Before proceeding, all proofs and revised proofs MUST be signed and returned.

☐ **Approved** ☐ **Not Approved**

# POWDER

zinc oxide powder

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:61354-017 |
| **Route of Administration** | TOPICAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **ZINC OXIDE** (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE | 24.5 g in 100 g |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **CALCIUM ALUMINUM BOROSILICATE** (UNII: 3JRB8A35M0) | 48.26 g in 100 g |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | 25 g in 100 g |
| **ETHYLHEXYLGLYCERIN** (UNII: 147D247K3P) | 0.5 g in 100 g |
| **SODIUM DEHYDROACETATE** (UNII: 8W46YN971G) | 0.5 g in 100 g |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:61354-017-01 | 1 in 1 CARTON | 10/28/2021 | |
| **1** | | 100 g in 1 BOTTLE; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph final | part352 | 10/28/2021 | |

## Labeler - Oxygen Development LLC (137098492)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Oxygen Development LLC | | 137098492 | manufacture(61354-017) |

Revised: 2/2023 Oxygen Development LLC