

# **KARAVITA FACE ESSENTIAL WITH SPF 15- oxybenzone, avobenzone, octinoxate, and octisalate lotion**

**Kara Vita, 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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## **Karavita Face Essential with SPF 15**

### **Drug Facts**

#### **Active ingredients**

Benzophenone-3 6.0%

Butyl Methoxydibenzoylmethane 3.0%

Ethylhexyl Methoxycinnamate 7.5%

Ethylhexyl Salicylate 5.0%

#### **Purpose**

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 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
- 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 this 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: Ask a doctor

**Inactive ingredients**

Purified Water, Potassium Cetyl Phosphate, Sorbitol, Dicapryl Maleate, Alcohol, Lecithin, Dimethicone, Cetyl Alcohol, Tocopheryl Acetate, Aloe Barbadensis Leaf Juice, Carbomer, Methylparaben, Propylparaben, Triethanolamine

Manufactured by:

**Dermazone Solutions, Inc.**

2440 30th Avenue North

St. Petersburg, FL 33713 USA

Distributed by:

**Kara Vita®**

St. Petersburg, FL 33713

**PRINCIPAL DISPLAY PANEL - 57 g Bottle Carton**

**KARA VITA**

**face**

**essential**

**with SPF15**

**4**

**Broad**

**Spectrum**

**Protection**

**WATER RESISTANT**

**(80 MINUTES)**

**Clinical Skin**

**Care with**

**Lyphazome®**

**Technology**

Net Wt. 2 oz. (57 g)

KARA VITA

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**DESCRIPTION:**

This lightweight, moisturizing sunscreen lotion provides durable protection from the harmful effects of UVA and UVB rays. Long-lasting benefits for all skin types, including sensitive skin with:

- Time-released all-natural Lyphazome nanotechnology
- Oil free, PABA free, and fragrance free
- Broad spectrum protection
- Water resistant for 80 minutes
- Safe for all skin types

**BENEFITS:**

- Reduces the risk of skin cancer and early skin aging, as well as helps prevent sunburn, if used as directed with other sun protection measures

KARA VITA

face essential with SPF 15

4

Broad Spectrum Protection

WATER RESISTANT (80 MINUTES)

Clinical skin Care with Lyphazome® Technology

Net Wt. 2 oz. (57 g)

Produced at Pharmaceutical Standards with Lyphazome® Technology

Manufactured by: **Dermazone Solutions, Inc.** 2440 30th Avenue North St. Petersburg, FL 33713 USA

Distributed by: **Kara Vita®** St. Petersburg, FL 33713 727-456-7560 www.karavita.com

U.S. Patent No. 5,879,703 Made in U.S.A.

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# KARAVITA FACE ESSENTIAL WITH SPF 15

oxybenzone, avobenzone, octinoxate, and octisalate lotion

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68572-3005
Route of Administration	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	60 mg in 1 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
SORBITOL (UNII: 506T60A25R)	
ALCOHOL (UNII: 3K9958V90M)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
METHYLPARABEN (UNII: A2I8C7H9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
TROLAMINE (UNII: 9O3K93S3TK)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68572-3005-2	1 in 1 CARTON	10/15/2015	
1		57 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	10/15/2015	

Labeler - Kara Vita, Inc. (140693388)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Dermazone Solutions, LLC		136116865	MANUFACTURE(68572-3005)

Revised: 11/2018

Kara Vita, Inc.