

**FLAWLESS BY SONYA ALOE BB CREME SANDY- titanium dioxide cream**  
**Aloe Vera of America, 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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<b>Active Ingredient</b>	<b>Purpose</b>
Titanium dioxide 7.04%.....	Sunscreen

**Uses**

- helps prevent sunburn

**Warnings**

**Skin Cancer/Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn not skin cancer or early skin aging.

**For external use only**

**Do not use** on damages 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 generously and evenly 15 minutes before sun exposure
- reapply at least every 2 hours
- use a water-resistant sunscreen if swimming or sweating
- children under 6 months of age: Ask a doctor

**Inactive ingredients**

water/aqua/eau, dimethicone, coco-caprylate, caprylic/capric tryglyceride, talc, dimethicone/vinyl dimethicone crosspolymer, cetyl peg/ppg 10/1 dimethicone, propanediol, iron oxide (CI 77491, CI 77492, CI 77499), titanium dioxide (CI 77891), sorbitan olivate, glyceryl tribehenate/isostearate/eicosandioate, phenoxyethanol, stearalkonium hectorite, mica, alumina, sodium chloride, triethoxycaprylylsilane, sodium dehydroacetate, propylene carbonate, hydrogen dimethicone, aloe barbadensis leaf extract, spilanthes acmella flower extract, tin oxide, olea europaea (olive) leaf extract, fragrance/parfum, trisodium ethylenediamine disuccinate, alcohol, maltodextrin, tropolone, aluminum hydroxide, olea europaea (olive) fruit extract.

**Other information**

- protect the product in the enclosed container from excessive heat and direct sun
- For your protection, this carton has a clear safety seal on both top and bottom flaps

**Questions or comments?**

Call 1-888-440-2563, Monday-Friday, 9:00 am to 4:00 pm PT.

aloe **BB** crème

HYDRATES • CONCEALS • PERFECTS

**SANDY**  
SPF 20 Sunscreen



Net Wt. 1.5 oz. (45 g)

©2012-2013

SKU 372

flawless<sup>by</sup>  
*Sonya*®

This lightweight aloe enriched BB crème hydrates, conceals, perfects and provides sun protection.

**Active ingredient:** Titanium dioxide 7.04% .....  
**Purpose:** Sunscreen


**Directions:** Apply generously everyday to cleansed skin 15 minutes before sun exposure. Reapply as needed for sun protection. Use alone or as a makeup base. Aloe BB crème generously and evenly applied flawlessly protects and perfects. To remove thoroughly cleanse and tone skin.

**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. If rash occurs, stop use and ask a doctor. Keep out of reach of children.

Manufactured exclusively for  
FOREVER LIVING PRODUCTS®  
Scottsdale, AZ 85258 USA  
©2012-2013 Aloe Vera of America, Inc.  
Made in Italy



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<p><b>Drug Facts</b> (continued)</p> <p><b>Inactive ingredients</b> water/aqua/leau, dimethicone, coco-caprylate, caprylic/capric tryglyceride, talc, dimethicone/vinyl dimethicone crosspolymer, oetyl peg/ppg 10/1 dimethicone, propanediol, iron oxide (CI 77491, CI 77492, CI 77499), titanium dioxide (CI 77891), sorbitan olivate, glyceryl tribehenate/isostearate/eicosandioate, phenoxyethanol, stearylaluminum hectorite, mica, alumina, sodium chloride, triethoxycaprylylsilane, sodium dehydroacetate, propylene carbonate, hydrogen dimethicone, aloe barbadensis leaf extract, spilanthes acmella flower extract, tin oxide, olea europaea (olive) leaf extract, fragrance/parfum, trisodium ethylenediamine disuccinate, alcohol, maltodextrin, tropolone, aluminum hydroxide, olea europaea (olive) fruit extract.</p> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>protect the product in the enclosed container from excessive heat and direct sun</li> <li>For your protection, this carton has a clear safety seal on both top and bottom flaps</li> </ul> <p><b>Questions or comments?</b> Call 1-888-440-2563, Monday-Friday, 9:00 am to 4:00 pm PT.</p>	 <p>aloe <b>BB</b> crème</p> <p>HYDRATES • CONCEALS • PERFECTS</p> <p><b>SANDY</b> SPF 20 Sunscreen</p> <p>Net Wt. 1.5 oz. (45 g)</p> <p>©2012-2013</p>	<p><b>Drug Facts</b></p> <p><b>Active ingredient Purpose</b> Titanium dioxide 7.04%..... Sunscreen</p> <p><b>Uses</b></p> <ul style="list-style-type: none"> <li>helps prevent sunburn</li> </ul> <p><b>Warnings</b></p> <p><b>Skin Cancer/Skin Aging Alert:</b> Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn <b>not</b> skin cancer or early skin aging.</p> <p><b>For external use only</b></p> <p><b>Do not use</b> on damaged or broken skin.</p> <p><b>When using this product</b> keep out of eyes. Rinse with water to remove.</p> <p><b>Stop use and ask a doctor</b> if rash occurs</p> <p><b>Keep out of reach of children.</b> If product is swallowed, get medical help or contact a Poison Control Center right away.</p> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>apply generously and evenly 15 minutes before sun exposure</li> <li>reapply at least every 2 hours</li> <li>use a water-resistant sunscreen if swimming or sweating</li> <li>children under 6 months of age: Ask a doctor</li> </ul>
<p>FOREVER™</p>	<p>FOREVER™</p>	<p>FOREVER™</p>

**FLAWLESS BY SONYA ALOE BB CREME SANDY**

titanium dioxide cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:11697-372
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	3.1680 g in 45.0000 g

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	18.8696 g in 45.0000 g
DIMETHICONE (UNII: 92RU3N3Y1O)	4.5923 g in 45.0000 g
CO CO-CAPRYLATE (UNII: 4828G836N6)	2.9250 g in 45.0000 g
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	2.8359 g in 45.0000 g
TALC (UNII: 7SEV7J4R1U)	1.8630 g in 45.0000 g
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	1.7438 g in 45.0000 g
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 3) (UNII: G300307ZXP)	1.3500 g in 45.0000 g
PROPANEDIOL (UNII: 5965N8W85T)	1.3500 g in 45.0000 g
FERRIC OXIDE RED (UNII: 1K09F3G675)	0.3859 g in 45.0000 g
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	0.3859 g in 45.0000 g
FERROSFERRIC OXIDE (UNII: XM0M87F357)	0.3859 g in 45.0000 g
SORBITAN OLIVATE (UNII: MDL271E3GR)	0.9000 g in 45.0000 g
GLYCERYL TRIBEHENATE/ISOSTEARATE/EICOSANDIOATE (UNII: 3Y9NJ5Z7E5)	0.9000 g in 45.0000 g
PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.4365 g in 45.0000 g
STEARALKONIUM HECTORITE (UNII: O LX698AH5P)	0.3375 g in 45.0000 g
MICA (UNII: V8A1AW0880)	0.3195 g in 45.0000 g
ALUMINUM OXIDE (UNII: LM26O6933)	0.2340 g in 45.0000 g
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.2250 g in 45.0000 g
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	0.1620 g in 45.0000 g
SODIUM DEHYDROACETATE (UNII: 8W46YN971G)	0.1350 g in 45.0000 g
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	0.1125 g in 45.0000 g
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.0450 g in 45.0000 g
ACMELLA OLERACEA FLOWER (UNII: 2794N5KM0K)	0.0441 g in 45.0000 g
STANNIC OXIDE (UNII: KM7N50LOS6)	0.0315 g in 45.0000 g
OLEA EUROPAEA LEAF (UNII: MJ95C30H47)	0.0313 g in 45.0000 g
TRISODIUM ETHYLENEDIAMINE DISUCCINATE (UNII: YA22H34H9Q)	0.0167 g in 45.0000 g
ALCOHOL (UNII: 3K9958V90M)	0.0135 g in 45.0000 g
MALTODEXTRIN (UNII: 7CVR7L4A2D)	0.0135 g in 45.0000 g
TROPOLONE (UNII: 7L6DL16P1T)	0.0135 g in 45.0000 g
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	0.0134 g in 45.0000 g
BLACK OLIVE (UNII: 2M6QWV94OC)	0.0005 g in 45.0000 g

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11697-372-02	1 in 1 CARTON		
1	NDC:11697-372-01	45 g in 1 TUBE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/01/2015	

**Labeler** - Aloe Vera of America, Inc. (049049463)

**Registrant** - Aloe Vera of America, Inc. (049049463)

## Establishment

Name	Address	ID/FEI	Business Operations
Aloe Vera of America, Inc.		049049463	manufacture(11697-372)

Revised: 1/2015

Aloe Vera of America, Inc.