

**ALOE SOOTHING MOISTURE SPF 15- octisalate, avobenzone, octinoxate, and octocrylene lotion**

**Buth-Na-Bodhaige, 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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**Aloe Soothing Moisture Lotion SPF 15**

**Drug Facts**

<b>Active Ingredients</b>	<b>Purpose</b>
Avobenzone (3.0% w/w)	Sunscreen
Octinoxate (2.9% w/w)	Sunscreen
Octisalate (5.0% w/w)	Sunscreen
Octocrylene (2.2% w/w)	Sunscreen

**Uses**

- helps prevent sunburn.

**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.

▪ **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 value of 15 or higher and other sun protection measures including:

- limit time in sun especially from 10 a.m. – 2 p.m.
- wear long-sleeved shirts, pants, hats and sunglasses.
- reapply this product at least every 2 hours.
- use a water resistant sunscreen if swimming or sweating.
- children under 6 months of age: ask a doctor.

**Other information**

- protect the product in this container from excessive heat and direct sun.

## **Inactive Ingredients**

Water, C12-15 Alkyl Benzoate, Glyceryl Stearate, Glycerin, Butylene Glycol, Caprylic/Capric Triglyceride, Sorbitol, Cetearyl Alcohol, Potassium Cetyl Phosphate, Sesamum Indicum (Sesame) Seed Oil, Dimethicone, Phenoxyethanol, Caprylyl Glycol, Panthenol, Butyrospermum Parkii (Shea) Butter, Aloe Barbadensis Leaf Juice Powder, Xanthan Gum, Carbomer, Bisabolol, Potassium Sorbate, Tetrasodium EDTA, Sodium Hydroxide, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Pentyleneglycol, BHT, Avena Sativa (Oat) Kernel Extract, Citric Acid.

## **PRINCIPAL DISPLAY PANEL - 50 ml Tube Label**

**THE  
BODY  
SHOP**

**THE BODY SHOP  
ALOE**

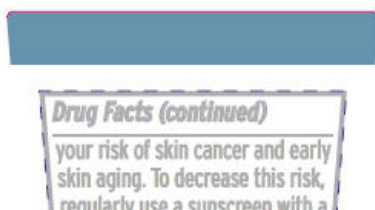
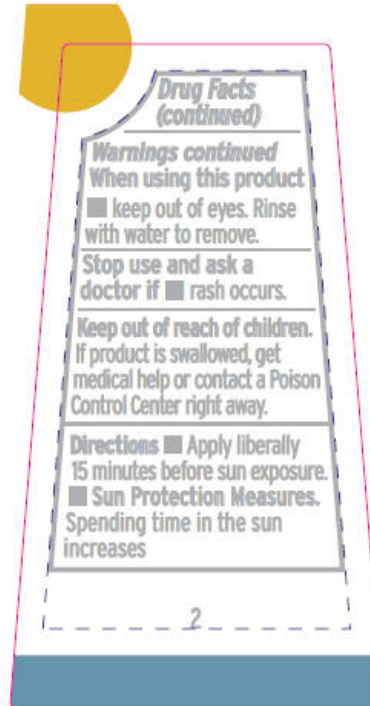
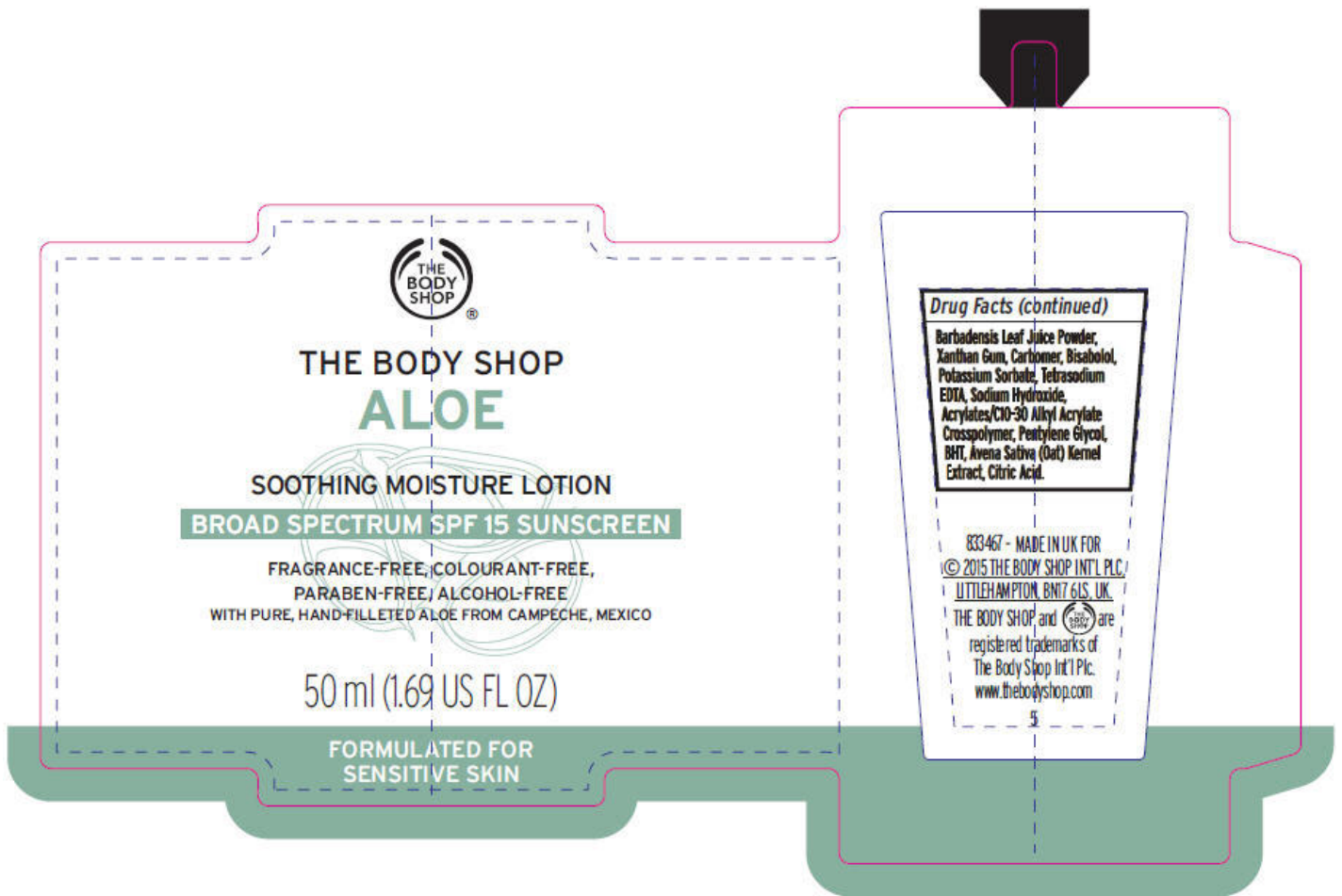
**SOOTHING MOISTURE LOTION**

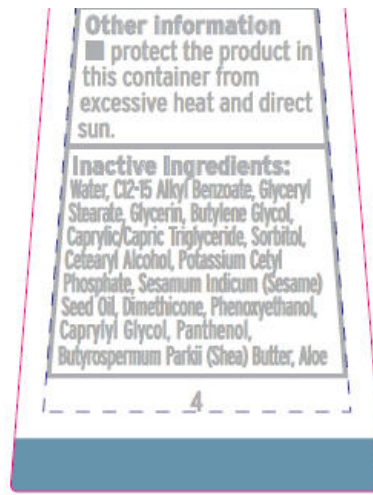
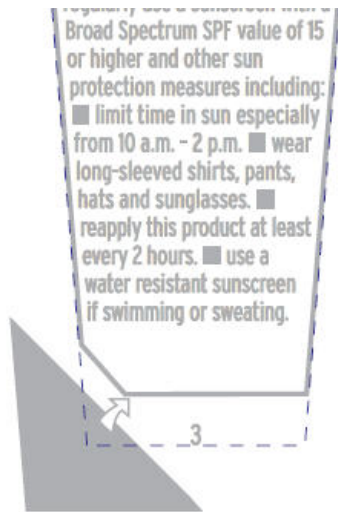
**BROAD SPECTRUM SPF 15 SUNSCREEN**

FRAGRANCE-FREE, COLOURANT-FREE,  
PARABEN-FREE, ALCOHOL-FREE  
WITH PURE, HAND-FILLETED ALOE FROM CAMPECHE, MEXICO

50 ml (1.69 US FL OZ)

**FORMULATED FOR  
SENSITIVE SKIN**





## ALOE SOOTHING MOISTURE SPF 15

octisalate, avobenzone, octinoxate, and octocrylene lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:57691-889
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Octisalate</b> (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	0.05 g in 1 mL
<b>Avobenzone</b> (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX)	Avobenzone	0.03 g in 1 mL
<b>Octinoxate</b> (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.029 g in 1 mL
<b>Octocrylene</b> (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	0.022 g in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>Water</b> (UNII: 059QF0KO0R)	
<b>Alkyl (C12-15) Benzoate</b> (UNII: A9EJ3J61HQ)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>Glycerin</b> (UNII: PDC6A3C0OX)	
<b>Butylene Glycol</b> (UNII: 3XUS85K0RA)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>Sorbitol</b> (UNII: 506T60A25R)	
<b>Cetostearyl Alcohol</b> (UNII: 2DMT128M1S)	
<b>Potassium Cetyl Phosphate</b> (UNII: 03KCY6P7UT)	
<b>SESAME OIL</b> (UNII: QX10HYY4QV)	
<b>Dimethicone</b> (UNII: 92RU3N3Y1O)	
<b>Phenoxyethanol</b> (UNII: HIE492ZZ3T)	
<b>Caprylyl Glycol</b> (UNII: 00YIU5438U)	
<b>Panthenol</b> (UNII: WV9CM0O67Z)	
<b>SHEA BUTTER</b> (UNII: K49155WL9Y)	

<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>Xanthan Gum</b> (UNII: TTV12P4NEE)	
<b>CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED)</b> (UNII: 59TL3WG5CO)	
<b>LEVOMENOL</b> (UNII: 24WE03BX2T)	
<b>Potassium Sorbate</b> (UNII: 1VPU26JZZ4)	
<b>EDETATE SODIUM</b> (UNII: MP1J8420LU)	
<b>Sodium Hydroxide</b> (UNII: 55X04QC32I)	
<b>Pentylene Glycol</b> (UNII: 50C1307PZG)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>OAT</b> (UNII: Z6J799EAJK)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	

<b>Product Characteristics</b>			
<b>Color</b>	WHITE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57691-889-50	50 mL in 1 TUBE; Type 0: Not a Combination Product	04/11/2016	

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	04/11/2016	

**Labeler** - Buth-Na-Bodhaige, Inc., (791071279)