

**BIG CLOUD SKY MASTER LIP BALM SPF 15- avobenzone, homosalate, octisalate, and octocrylene lipstick**  
**Dollar Shave Club**

*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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**Big Cloud Sky Master Lip Balm SPF 15**

***Drug Facts***

**Active ingredients**

Avobenzone 3%, Homosalate 7%, Octisalate 5%, Octocrylene 2.75%

**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 swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

- apply liberally 15 minutes before sun exposure
- reapply:
  - after 40 minutes of swimming or sweating
  - immediately after towel drying
  - at least every 2 hours
- children under 6 months: Ask a doctor
- **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 the sun, especially from 10 a.m.–2 p.m.
  - wear long-sleeved shirts, pants, hats, and sunglasses

**Other information**

- protect this product from excessive heat and direct sun.

### **Inactive ingredients**

Aloe Barbadensis Leaf Extract, Ascorbyl Palmitate, Beeswax, Butyrospermum Parkii (Shea) Butter, Camellia Sinensis Leaf Extract, Cocos Nucifera (Coconut) Oil, Copernicia Cerifera (Carnauba) Wax, Dehydroacetic Acid, Euphorbia Cerifera (Candelilla) Wax, Flavor, Helianthus Annuus (Sunflower) Seed Oil, Hydrogenated Vegetable Oil, Jojoba Esters, Olea Europaea (Olive) Fruit Oil, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Simmondsia Chinensis (Jojoba) Seed Oil, Tocopherol, Tocopheryl Acetate.

### **PRINCIPAL DISPLAY PANEL - 4.25 g Cylinder Carton**

BIG CLOUD

**SKY MASTER**

**LIP BALM**

*with sunscreen*

– MINT LEAF –

*"SUN SCREEN. NO SHEEN."*

**1 STICK**

BROAD SPECTRUM

SPF 15

FULL SHIELD

SPF

**15**

UVA

UVB

WATER RESISTANT

(40 MINUTES)

NET WT. 4.25 g | 0.15 oz

NO COATING

PARABEN & DYE FREE

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**Other information** • protect this product from excessive heat and direct sun

**Directions** • apply liberally 15 minutes before sun exposure • reapply • after 40 minutes of swimming or sweating • immediately after towel drying • at least every 2 hours • children under 6 months: Ask a doctor • **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 the sun, especially from 10 a.m.-2 p.m. • wear long-sleeved shirts, pants, hats, and sunglasses

**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 swallowed, get medical help or contact a Poison Control Center right away.**

**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

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**Drug Facts**

BIG CLOUD

SKY MASTER

LIP BALM

with sunscreen

MINT LEAF

"SUN SCREEN. NO SHEEN."

1 STICK

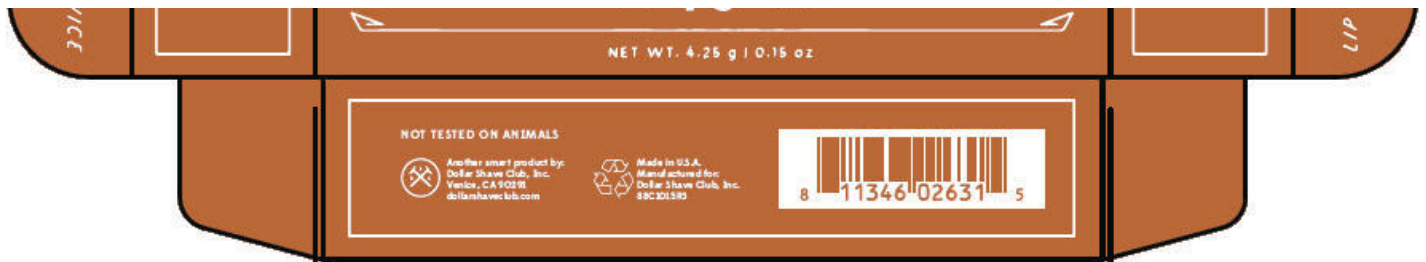
LIP SEAL

BROAD SPECTRUM  
SPF 15

FULL SHIELD  
SPF 15  
UVA  
UVB

WATER RESISTANT  
(40 MINUTES)

SERVICE



## BIG CLOUD SKY MASTER LIP BALM SPF 15

avobenzone, homosalate, octisalate, and octocrylene lipstick

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69522-2315
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	70 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	27.5 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
SHEA BUTTER (UNII: K49155WL9Y)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
COCONUT OIL (UNII: Q9L0O73W7L)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	
CANDELILLA WAX (UNII: WL0328HX19)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
HYDROGENATED JOJOBA OIL, RANDOMIZED (UNII: Q47ST02F58)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
ALMOND OIL (UNII: 66YXD4DKO9)	
JOJOBA OIL (UNII: 724GKU717M)	
.ALPHA.-TOCOPHEROL, DL- (UNII: 7QWA1RIO01)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69522-2315-1	1 in 1 CARTON	04/06/2016	

1		4.25 g in 1 CYLINDER; Type 0: Not a Combination Product		
2	NDC:69522-2315-2	2 in 1 CARTON	04/06/2016	
2		4.25 g in 1 CYLINDER; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
	<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
	OTC monograph not final	part352	04/06/2016	

**Labeler** - Dollar Shave Club (004164494)

Revised: 1/2018

Dollar Shave Club