

## **SUN PROTECT LIP BALM SPF 30- zinc oxide and titanium dioxide cream Stream2Sea, 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.*

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### **Sun Protected Lip Balm SPF 30 +**

#### **Drug Facts**

##### ***Active ingredients***

Non Nano Zinc Oxide 6%, Non Nano Titanium Dioxide 7%

##### ***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.
- **Stop use and ask a doctor if** rash occurs.
- **When using this product,** keep out of eyes. Rinse with water to remove.
- **Keep out of reach of children,** If swallowed, get medical help or contact a poison control centre right away.

##### ***Directions***

- Apply liberally 15 minutes before sun exposure.
- Reapply after 80 minutes of swimming or sweating or immediately after towel drying and at least every 2 hours.
- For children under 6 months of age; ask a doctor.

##### ***Other information***

- This is a personal care item, and should be used by one individual only.
- Protect this product from excessive heat and direct sun.
- Do not use if safety seal is broken prior to purchase.

##### ***Inactive ingredients***

#### **Sun Protected Lip Balm SPF 30 + - Naturally Naked**

Butyrospermum Parkii (Shea Butter), Camellis Sinensis (Green Tea) Leaf, Ocimum Tinuiflorum (Tulsi) Leaf, Alaria Esculenta (Wakame Seaweed), and Olea Europa (Olive) Leaf Extracts in Cocos Nucifera (Coconut) Oil, Candelilla Cera Wax, Caprylic Capric Triglycerides, Copernicia Prunifers (Carnuba) Wax, Cetyl Esters, Glyceryl Caprylate, Helianthus Annuus (Sunflower) Seed Oil, Mica, Mixed Tocopherols (Vitamin E),

Polyhydroxystearic Acid, Rice Starch, Silica, Sorbitan Olivates, Theobroma Cacao(Cocoa) Seed Butter.

### **Sun Protected Lip Balm SPF 30 + - Cherry Vanilla**

Butyrospermum Parkii (Shea Butter), Camellia Sinensis (Green Tea) Leaf, Ocimum Tinuiflorum (Tulsi) Leaf, Alaria Esculenta (Wakame Seaweed), and Olea Europaea(Olive) Leaf Extracts in Cocos Nucifera (Coconut) Oil, Candelilla Cera Wax, Caprylic/Capric Triglycerides, Copernicia Prunifera (Carnauba) Wax, Cetyl esters, Cherry Vanilla Flavor\* Glyceryl Caprylate, Helianthus Annuus (Sunflower) Seed Oil, Mica, Mixed Tocopherols (Vitamin E), Polyhydroxystearic Acid, Rice Starch, Silica, Sorbitan Olivates, Theobroma Cacao(Cocoa) Seed Butter, Stevia Rebaudiana Leaf Extract.

\*Flavor is certified all natural.

### **Sun Protected Lip Balm SPF 30 + - Cucumber Mint**

Butyrospermum Parkii (Shea Butter), Camellia Sinensis (Green Tea) Leaf, Ocimum Tinuiflorum (Tulsi) Leaf, Alaria Esculenta (Wakame Seaweed), and Olea Europaea (Olive) Leaf Extracts in Cocos Nucifera (Coconut) Oil, Candelilla Cera wax, Caprylic/Capric Triglycerides, Copernicia Prunifera (Carnauba) Wax, Cetyl Esters, Cucumber Mint Flavor\* Glyceryl Caprylate, Helianthus Annuus(Sunflower) Seed Oil, Mica, Mixed Tocopherols (Vitamin E), Polyhydroxystearic Acid, Rice starch, Silica, Sorbitan Olivates, Theobroma Cacao(Cocoa) Seed Butter, Stevia Rebaudiana Leaf Extract.

\*Flavor is certified all natural.

### **PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

**SUN PROTECT LIP BALM NATURALLY NAKED SPF 30 + 0.15 OZ - Label - NDC - 69555-036-01**

## Drug Facts (continued)

**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. ■ Stop use and ask a doctor if rash occurs ■ When using this product, keep out of eyes. Rinse with water to remove.

**Directions** ■ Apply liberally 15 min before sun exposure. ■ Reapply after 80 min of swimming or sweating or immediately after towel drying and at least every 2 hrs ■ For children under 6 months of age; ask a doctor.

**Other Info** Protect this product from excessive heat and sunlight.

### Inactive ingredients

Butyrospermum Parkii (Shea Butter), Camellia Sinenis (Green Tea) Leaf, Ocimum Tinuiflorum (Tulsi) Leaf, Alaria Esculenta (Wakame Seaweed), and Olea Europa (Olive) Leaf Extracts in Cocos Nucifera (Coconut) Oil, Candelilla Cera Wax, Caprylic Capric Triglycerides, Copernicia Prunifera (Carnauba) Wax, Cetyl Esters, Glyceryl Caprylate, Helianthus Annuus (Sunflower) Seed Oil, Mica, Mixed Tocopherols (Vitamin E), Polyhydroxystearic Acid, Rice Starch, Silica, Sorbitan Oliviate, Theobroma Cacao (Cocoa) Seed Butter.

SPF 30+



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STREAM2SEA®



Sun Protect  
LIP BALM

30+  
SPF  
UVA/UVB

Naturally Naked



100% PCR, PLEASE RECYCLE AGAIN. NET WT 0.15 oz (4g)

Mfd in the USA by:  
Stream2Sea  
Bowling Green, FL 33834  
Questions/Comments:  
Stream2Sea.com



StreamzSea.com  
855-960-9513

8 51061 00852 4

### Drug Facts

**Active Ingredients:**

Non Nano Zinc Oxide 6%, Non Nano Titanium Dioxide 7%.....Sunscreen

**Purpose**

PEEL HERE FOR MORE DRUG FACTS

NDC# 69555-036-01

**SUN PROTECT LIP BALM CUCUMBER MINT SPF 30 + 0.15 OZ - Label - NDC - 69555-036-02**

## Drug Facts (continued)

**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. ■ Stop use and ask a doctor if rash occurs ■ When using this product, keep out of eyes. Rinse with water to remove.

**Directions** ■ Apply liberally 15 min before sun exposure. ■ Reapply after 80 min of swimming or sweating or immediately after towel drying and at least every 2 hrs ■ For children under 6 months of age; ask a doctor.

**Other Info** Protect this product from excessive heat and sunlight.

### Inactive ingredients

Butyrospermum Parkii (Shea Butter), Camellia Sinenis (Green Tea) Leaf, Ocimum Tinuiflorum (Tulsi) Leaf, Alaria Esculenta (Wakame Seaweed), and Olea Europa (Olive) Leaf Extracts in Cocos Nucifera (Coconut) Oil, Candelilla Cera Wax, Caprylic Capric Triglycerides, Copernicia Prunifera (Carnauba) Wax, Cetyl Esters, Cucumber Mint Flavor\*, Glyceryl Caprylate, Helianthus Annuus (Sunflower) Seed Oil, Mica, Mixed Tocopherols (Vitamin E), Polyhydroxystearic Acid, Rice Starch, Silica, Sorbitan Oliviate, Theobroma Cacao (Cocoa) Seed Butter, Stevia Rebaudiana Leaf Extract.

\*Flavor is certified all natural

SPF 30+



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Sun Protect  
LIP BALM

30+  
SPF  
UVA/UVB

Cucumber Mint



100% PCR, PLEASE RECYCLE AGAIN. NET WT 0.15 oz (4g)

Mfd in the USA by:



Mfg in the USA by:  
Stream2Sea  
Bowling Green, FL 33834  
Questions/Comments:  
Stream2Sea.com  
866-950-9513



**Drug Facts**

<i>Active Ingredients:</i>	<i>Purpose</i>
Non Nano Zinc Oxide 6%, Non Nano Titanium Dioxide 7%.....	Sunscreen

PEEL HERE FOR MORE DRUG FACTS

NDC# 69555-036-02 ▼

**SUN PROTECT LIP BALM CHERRY VANILLA SPF 30 + 0.15 OZ - Label - NDC - 69555-036-03**

## Drug Facts (continued)

**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. ■ Stop use and ask a doctor if rash occurs ■ When using this product, keep out of eyes. Rinse with water to remove.

**Directions** ■ Apply liberally 15 min before sun exposure. ■ Reapply after 80 min of swimming or sweating or immediately after towel drying and at least every 2 hrs ■ For children under 6 months of age; ask a doctor.

**Other Info** Protect this product from excessive heat and sunlight.

### Inactive ingredients

Butyrospermum Parkii (Shea Butter), Camellia Sinensis (Green Tea) Leaf, Ocimum Tinuiflorum (Tulsi) Leaf, Alaria Esculenta (Wakame Seaweed), and Olea Europa (Olive) Leaf Extracts in Cocos Nucifera (Coconut) Oil, Candelilla Cera Wax, Caprylic Capric Triglycerides, Copernicia Prunifera (Carnauba) Wax, Cetyl Esters, Cherry Vanilla Flavor\*, Glyceryl Caprylate, Helianthus Annuus (Sunflower) Seed Oil, Mica, Mixed Tocopherols (Vitamin E), Polyhydroxystearic Acid, Rice Starch, Silica, Sorbitan Oliviate, Theobroma Cacao (Cocoa) Seed Butter, Stevia Rebaudiana Leaf Extract.

\*Flavor is certified all natural

SPF 30+



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STREAM2SEA®



Sun Protect  
LIP BALM

30+  
SPF  
UVA/UVB

Cherry Vanilla



100% PCR, PLEASE RECYCLE AGAIN. NET WT 0.15 oz (4g)

Mfd in the USA by:



Stream2Sea  
Bowling Green, FL 33834  
Questions/Comments:  
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866-960-9513



## Drug Facts

**Active Ingredients:** Non Nano Zinc Oxide 6%, Non Nano Titanium Dioxide 7%.....**Purpose** Sunscreen

PEEL HERE FOR MORE DRUG FACTS

NDC# 69555-036-03 ▼

## SUN PROTECT LIP BALM SPF 30

zinc oxide and titanium dioxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69555-036
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	280 mg in 4 g
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	240 mg in 4 g

### Inactive Ingredients

Ingredient Name	Strength
<b>ALARIA ESCULENTA</b> (UNII: EJ9JK8J58D)	
<b>OLEA EUROPAEA LEAF</b> (UNII: MJ95C3OH47)	
<b>CANDELILLA WAX</b> (UNII: WL0328HX19)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>CETYL ESTERS WAX</b> (UNII: D072FFP9GU)	
<b>GLYCERYL CAPRYLATE</b> (UNII: TM2TZD4G4A)	
<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)	
<b>MICA</b> (UNII: V8A1AW0880)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)	
<b>STARCH, RICE</b> (UNII: 4DGK8B7I3S)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SORBITAN OLIVATE</b> (UNII: MDL271E3GR)	
<b>COCOA BUTTER</b> (UNII: 512OYT1CRR)	
<b>STEVIA REBAUDIUNA LEAF</b> (UNII: 6TC6NN0876)	
<b>HOLY BASIL LEAF</b> (UNII: SCJ765569P)	



<b>SHEA BUTTER</b> (UNII: K49155WL9Y)	
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)	

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT (Cucumber Mint) , CHERRY (Cherry Vanilla)	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69555-036-04	4 g in 1 TUBE; Type 0: Not a Combination Product	07/10/2021	
2	NDC:69555-036-05	4 g in 1 TUBE; Type 0: Not a Combination Product	07/10/2021	
3	NDC:69555-036-06	4 g in 1 TUBE; Type 0: Not a Combination Product	07/10/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	07/10/2021	

**Labeler** - Stream2Sea, LLC (052920828)

**Registrant** - Stream2Sea, LLC (052920828)

### Establishment

Name	Address	ID/FEI	Business Operations
Stream2Sea, LLC		052920828	manufacture(69555-036)

Revised: 1/2023

Stream2Sea, LLC