

**CHAPSTICK- avobenzone, octinoxate, and white petrolatum  
GlaxoSmithKline Consumer Healthcare Holdings (US) 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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**Drug Facts**

**Moisturizer | Original**

**Active Ingredients**

Avobenzone 3%

Octinoxate 7.5%

White petrolatum 42.3%

**Purposes**

Sunscreens

Skin protectant

**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
- helps prevent and temporarily protects chafed, chapped or cracked lips
- helps prevent and protect from the drying effects of wind and cold weather

**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 Center right away.

**Directions**

- apply liberally 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
- **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:

- limited time in the sun, especially from 10 a.m. – 2 p.m.
- wear long-sleeved shirts, pants, hats, and sunglasses

### ***Other information***

- store at 20-25°C (68-77°F)
- protect this product from excessive heat and direct sun

### ***Inactive ingredients***

aloe barbadensis leaf extract, carnauba wax, cetyl alcohol, fragrance, isocetyl stearate, isopropyl lanolate, lanolin, mineral oil, paraffin, saccharin, tocopheryl linoleate/oleate, vitamin E acetate, white wax

### ***Questions or comments?***

call weekdays from 9 AM to 5 PM EST at **1-877-227-3421**

## **Classic | Original . Cherry . Strawberry**

### ***Active ingredient***

White petrolatum 45%

### ***Purpose***

Skin Protectant

### ***Uses***

- helps prevent and temporarily protects chafed, chapped or cracked lips
- helps prevent and protect from the drying effects of wind and cold weather

### ***Warnings***

**For external use only**

**Keep Out of Reach of Children**

### ***Directions***

apply as needed

### ***Other Information***

store at 20-25°C (68-77°F)

### ***Inactive ingredients (Classic Original)***

arachidyl propionate, camphor, carnauba wax, cetyl alcohol, fragrance, isopropyl lanolate, isopropyl myristate, lanolin, light mineral oil, octyldodecanol, oleyl alcohol, paraffin, phenyl trimethicone, red 6 lake, titanium dioxide, white wax, yellow 5 lake

***Inactive Ingredients (Classic Cherry)***

arachidyl propionate, camphor, carnauba wax, cetyl alcohol, fragrance, isopropyl lanolate, isopropyl myristate, lanolin, light mineral oil, menthol, octyldodecanol, paraffin, phenyl trimethicone, red 6 lake, saccharin, white wax

***Inactive Ingredients (Classic Strawberry)***

arachidyl propionate, camphor, carnauba wax, cetyl alcohol, fragrance, isopropyl lanolate, isopropyl myristate, lanolin, lemon oil, light mineral oil, maltol, octyldodecanol, paraffin, phenyl trimethicone, red 6 lake, saccharin, white wax

***Additional Information***

Paraben Free

Distributed by: GSK Consumer Healthcare, Warren, NJ 07059

For most recent product information, visit [www.chapstick.com](http://www.chapstick.com)

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**PRINCIPAL DISPLAY PANEL**

**NDC 0573-2028-02**

**ChapStick®**

PUT YOUR LIPS FIRST®

**8 HOUR MOISTURE**

**SPF15**

- 9 Classic Cherry/Skin Protectant
- 9 Classic Original/Skin Protectant
- 9 Classic Strawberry/Skin Protectant
- 9 Moisturizer Original Skin/Sunscreen/Broad Spectrum SPF 15

NET WT 0.15 OZ

(4 g) EACH

72 INDIVIDUAL STICKS

PAA171900 – Front Carton



## CHAPSTICK

avobenzone, octinoxate, and white petrolatum kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0573-2028
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-2028-02	1 in 1 PACKAGE; Type 0: Not a Combination Product	06/28/2021	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	18 CYLINDER	72 g
Part 2	18 CYLINDER	72 g
Part 3	18 CYLINDER	72 g
Part 4	18 CYLINDER	72 g

## Part 1 of 4

### CHAPSTICK MOISTURIZER ORIGINAL

avobenzone, octinoxate, and white petrolatum stick

#### Product Information

Route of Administration TOPICAL

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	423 mg in 1 g

#### Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ISOCETYL STEARATE (UNII: 3RJ7186O9W)	
LANOLIN (UNII: 7EV65EAW6H)	
MINERAL OIL (UNII: T5L8T28FGP)	
PARAFFIN (UNII: I9O0E3H2ZE)	
SACCHARIN (UNII: FST467XS7D)	
.ALPHA.-TOCOPHEROL LINOLEATE, D- (UNII: G0N132Q0ED)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WHITE WAX (UNII: 7G1J5DA97F)	

#### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		4 g in 1 CYLINDER; Type 0: Not a Combination Product		

#### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	06/28/2021	

## Part 2 of 4

# CHAPSTICK CLASSIC STRAWBERRY

white petrolatum stick

## Product Information

**Route of Administration** TOPICAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	450 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
ARACHIDYL PROPIONATE (UNII: QV5DAH3MSB)	
CAMPHOR (NATURAL) (UNII: N20HL7Q941)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
LANOLIN (UNII: 7EV65EAW6H)	
LEMON OIL (UNII: I9GRO824LL)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
MALTOL (UNII: 3A9RD92BS4)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
D&C RED NO. 6 (UNII: 481744AI4O)	
SACCHARIN (UNII: FST467XS7D)	
WHITE WAX (UNII: 7G1J5DA97F)	

## Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	STRAWBERRY	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		4 g in 1 CYLINDER; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	06/28/2021	

## Part 3 of 4

### CHAPSTICK CLASSIC CHERRY

white petrolatum stick

#### Product Information

Route of Administration TOPICAL

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	450 mg in 1 g

#### Inactive Ingredients

Ingredient Name	Strength
ARACHIDYL PROPIONATE (UNII: QV5DAH3MSB)	
CAMPHOR (NATURAL) (UNII: N20HL7Q941)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
LANOLIN (UNII: 7EV65EAW6H)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
LEVOMENTHOL (UNII: BZ1R15MTK7)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
D&C RED NO. 6 (UNII: 481744AI4O)	
SACCHARIN (UNII: FST467XS7D)	
WHITE WAX (UNII: 7G1J5DA97F)	

#### Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

#### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	4 g in 1 CYLINDER; Type 0: Not a Combination Product		
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## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	04/30/2021	

## Part 4 of 4

### CHAPSTICK CLASSIC ORIGINAL

white petrolatum stick

## Product Information

**Route of Administration** TOPICAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	450 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
ARACHIDYL PROPIONATE (UNII: QV5DAH3MSB)	
CAMPHOR (NATURAL) (UNII: N20HL7Q941)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
LANOLIN (UNII: 7EV65EAW6H)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
D&C RED NO. 6 (UNII: 481744AI4O)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WHITE WAX (UNII: 7G1J5DA97F)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	4 g in 1 CYLINDER; Type 0: Not a Combination Product		
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### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	04/30/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	06/28/2021	

**Labeler** - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)

Revised: 6/2021

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC