

**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.

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

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PRINCIPAL DISPLAY PANEL

NDC 0573-2028-01

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

36 INDIVIDUAL STICKS

PAA171900 – Front Carton



CHAPSTICK

avobenzone, octinoxate, and white petrolatum kit

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:0573-2028

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-2028-01	1 in 1 PACKAGE; Type 0: Not a Combination Product	06/28/2021	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	9 CYLINDER	36 g
Part 2	9 CYLINDER	36 g
Part 3	9 CYLINDER	36 g
Part 4	9 CYLINDER	36 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

Color		Score	
Shape		Size	
Flavor	STRAWBERRY	Imprint Code	
Contains			

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
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	04/30/2021	

Part 4 of 4

CHAPSTICK CLASSIC ORIGINAL

white petrolatum stick

Product Information

Route of Administration	TOPICAL
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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
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	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