

MINT CONDITION LIP SHIELD SPF 30 SUPERGOOP- avobenzene, octisalate, homosalate, octinoxate stick

T AYLO R JAMES, LT D.

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.

Mint Condition Lip Shield Broad Spectrum SPF 30

Active Ingredients	Purpose
Avobenzene 2%	Sunscreen
Octisalate 5%	Sunscreen
Homosalate 15%	Sunscreen
Octinoxate 7.5%	Sunscreen

Uses Helps prevent and temporarily protect chafed, chapped, cracked, or windburned lips

- Helps prevent sunburns
- 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

Keep out of reach of children

Stop use and ask a doctor if rash occurs

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
- If swallowed, get medical help or contact a Poison Control Center right away
- If condition worsens or does not improve within 7 days, consult a doctor

Directions Apply liberally 15 minutes before sun exposure

- Reapply: after 80 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:

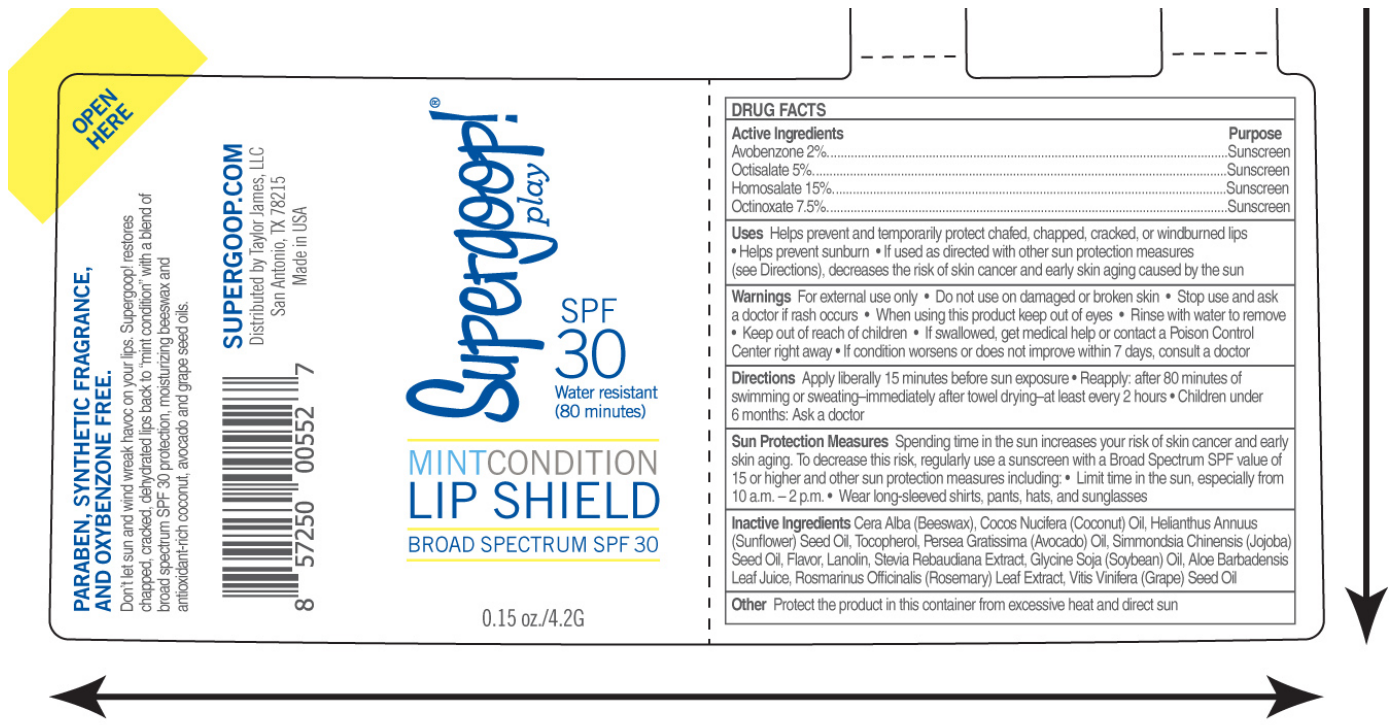
- Limit time in the sun, especially from 10a.m. - 2p.m.
- Wear long-sleeved shirts, pants, hats, and sunglasses

Cera Alba (Beeswax), Cocos Nucifera (Coconut) Oil, Helianthus Annuus (Sunflower) Seed Oil, Tocopherol, Persea Gratissima (Avocado) OIL, Simmondsia Chenensis (Jojoba) Seed Oil, Flavor, Lanolin, Stevia Rebaudiana Extract, Glycine Soja (Soybean) Oil, Aloe Barbadensis Leaf Juice, Rosmarinus Officinalis (Rosemary) Leaf Extract, Vitis Vinifera (Grape) Seed Oil

Mint Condition Lip Shield

Broad Spectrum SPF 30

0.15oz./4.2G



DRUG FACTS	
Active Ingredients	Purpose
Avobenzone 2%.....	Sunscreen
Octisalate 5%.....	Sunscreen
Homosalate 15%.....	Sunscreen
Octinoxate 7.5%.....	Sunscreen
Uses Helps prevent and temporarily protect chafed, chapped, cracked, or windburned lips • 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 Center right away • If condition worsens or does not improve within 7 days, consult a doctor	
Directions Apply liberally 15 minutes before sun exposure • Reapply: after 80 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	
Inactive Ingredients Cera Alba (Beeswax), Cocos Nucifera (Coconut) Oil, Helianthus Annuus (Sunflower) Seed Oil, Tocopherol, Persea Gratissima (Avocado) Oil, Simmondsia Chinensis (Jojoba) Seed Oil, Flavor, Lanolin, Stevia Rebaudiana Extract, Glycine Soja (Soybean) Oil, Aloe Barbadensis Leaf Juice, Rosmarinus Officinalis (Rosemary) Leaf Extract, Vitis Vinifera (Grape) Seed Oil	
Other Protect the product in this container from excessive heat and direct sun	

MINT CONDITION LIP SHIELD SPF 30 SUPERGOOP

avobenzone, octisalate, homosalate, octinoxate stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75936-201
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2 g in 100 g
OCTISALATE (UNII: 4X49 Y0 596 W) (OCTISALATE - UNII:4X49 Y0 596 W)	OCTISALATE	5 g in 100 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	15 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WHITE WAX (UNII: 7G1J5DA97F)	
COCONUT OIL (UNII: Q9L0O73W7L)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
TOCOPHEROL (UNII: R0ZB2556P8)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
JOJOBA OIL (UNII: 724GKU717M)	
LANOLIN (UNII: 7EV65EAW6H)	
STEVIA REBAUDIUNA LEAF (UNII: 6TC6NN0876)	
SOYBEAN OIL (UNII: 241ATL177A)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

ROSEMARY (UNII: IJ67X351P9)

GRAPE SEED OIL (UNII: 930MLC8XGG)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75936-201-01	4.2 g in 1 CYLINDER; Type 0: Not a Combination Product	08/08/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	08/08/2016	

Labeler - T AYLO R JAMES, LT D. (033381850)

Registrant - T AYLO R JAMES, LT D. (033381850)

Establishment

Name	Address	ID/FEI	Business Operations
Filltech USA, LLC		965596435	manufacture(75936-201)

Revised: 1/2017

T AYLO R JAMES, LT D.