

**LIP SCREEN BROAD SPECTRUM SPF 40- avobenzene, homosalate, octisalate, octocrylene liquid
Taylor James, Ltd.**

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.

Lip Screen Broad Spectrum SPF 40

Avobenzene 3% Sunscreen

Homosalate 5% Sunscreen

Octisalate 5% Sunscreen

Octocrylene 10% 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.

Keep out of reach of children. If product is swallowed, get medical help or contact a poison Control Center right away.

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

Directions

Apply generously and evenly 15 minutes before sun exposure

Use a water-resistant sunscreen if swimming or sweating

Reapply at least every 2 hours.

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 your time in the sun, especially from 10 a.m. – 2 p.m. • wear long-sleeved shirts, pants, hats, and sunglasses • Children under 6 months of age: ask a doctor.

Inactive Ingredients

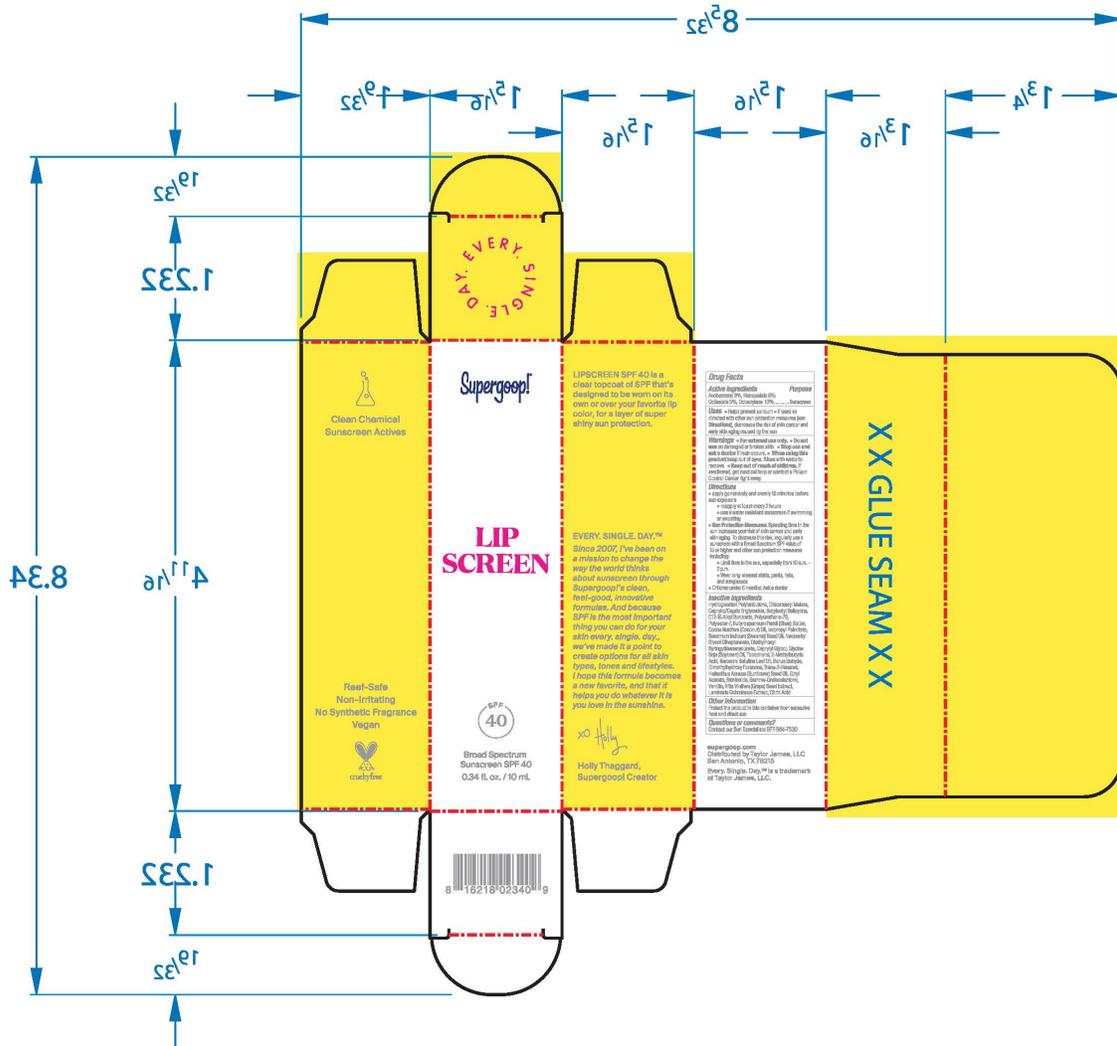
Hydrogenated Polyisobutene, Diisostearyl Malate, Caprylic/Capric Triglyceride, Butyloctyl Salicylate, C12-15 Alkyl Benzoate, Polyurethane-79, Polyester-7, Butyrospermum Parkii (Shea) Butter, Cocos Nucifera (Coconut) Oil, Isopropyl Palmitate, Sesamum Indicum (Sesame) Seed Oil, Neopentyl Glycol Diheptanoate, Diethylhexyl Syringlidene malonate, Caprylyl Glycol, Glycine Soja (Soybean) Oil, Tocopherol, 2-Methylbutyric Acid, Barosma Betulina Leaf Oil, Benzaldehyde, Dimethylhydroxy Furanone, Trans-2-Hexenal, Helianthus Annuus (Sunflower) Seed Oil, Ethyl Acetate, Stevioside, Gamma-Undecalactone, Vanillin, Vitis Vinifera (Grape) Seed Extract, Laminaria Ochroleuca Extract, Citric Acid

Lip Screen

SPF 40

Broad Spectrum SPF 40

0.34 fl. oz. / 10 ml.



- Matte silver foil
- Reflex Blue C
- Cool Gray 7
- PMS 102 U

LIP SCREEN BROAD SPECTRUM SPF 40
 avobenzone, homosalate, octisalate, octocrylene liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75936-257
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
DIETHYLHEXYL SYRINGYLIDENEMALONATE (UNII: 3V5U97P248)	
LAMINARIA OCHROLEUCA (UNII: 4R2124HE76)	
AGATHOSMA BETULINA LEAF OIL (UNII: KOS935A04V)	
VANILLIN (UNII: CHI530446X)	
2-METHYLBUTYRIC ACID (UNII: PX7ZNN5GXX)	
SESAME OIL (UNII: QX10HYY4QV)	
.GAMMA.-UNDECALACTONE (UNII: QB1T0AG2YL)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)	
STEVIO SIDE (UNII: 0YON5MXJ9P)	
VITIS VINIFERA SEED (UNII: C34U15ICXA)	
SHEA BUTTER (UNII: K49155WL9Y)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	
SOYBEAN OIL (UNII: 241ATL177A)	
BENZALDEHYDE (UNII: TA269SD04T)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
ETHYL ACETATE (UNII: 76845O8NMZ)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
POLYESTER-7 (UNII: 0841698D2F)	
TOCOPHEROL (UNII: R0ZB2556P8)	
DIMETHYLHYDROXY FURANONE (UNII: 20PI8YZP7A)	
2-HEXENAL, (2E)- (UNII: 69JX3AIR1I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75936-257-01	10 mL in 1 TUBE; Type 0: Not a Combination Product	04/22/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	04/22/2020	

Labeler - Taylor James, Ltd. (033381850)

Establishment

Name	Address	ID/FEI	Business Operations
Cosway Company, Inc.		620899877	manufacture(75936-257)

Revised: 4/2020

Taylor James, Ltd.