

CAY SKIN ISLE LIP BALM SPF 30 CORAL- avobenzene, homosalate, octisalate cream
CAY SKIN ISLE LIP BALM SPF 30 BAD GYAL BERRY- avobenzene, homosalate, octisalate cream
CAY SKIN ISLE LIP BALM SPF 30 NUDE TING- avobenzene, homosalate, octisalate cream
CAY SKIN ISLE LIP BALM SPF 30 COCOA CABANA- avobenzene, homosalate, octisalate cream
CAY SKIN ISLE LIP BALM SPF 30- avobenzene, homosalate, octisalate cream
CAY SKIN ISLE LIP BALM SPF 30 IRIE ROSE- avobenzene, homosalate, octisalate cream
Cay Skin, Inc.

Cay Skin Isle Lip Balm SPF 30

Drug Facts

Active ingredients (w/w)

Avobenzene 3%, Homosalate 10%, Octisalate 5%

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.

When using this product

keep out of eyes. Rinse with water to remove.

Stop use and consult a doctor

if skin rash occurs.

Keep out of reach of children.

If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Adults and children over 6 months of age:
- Apply liberally 15 minutes before sun exposure.
- Reapply: at least every 2 hours or after 40 minutes of 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: limit time in the sun, especially from 10 a.m. - 2 p.m.; wear long-sleeved shirts, pants, hats and sunglasses.

Other information

Protect this product from excessive heat and direct sun.

Inactive ingredients

Hydrogenated Polyisobutene, C18-38 Alkyl Hydroxystearoyl Stearate, Butyrospermum Parkii (Shea) Oil, Butyloctyl Salicylate, VP/Hexadecene Copolymer, Ozokerite, Cetyl Alcohol, Vanillin, Glyceryl Stearate, Phytosteryl/Octyldodecyl Lauroyl Glutamate, Methyl Dihydroabietate, Trihydroxystearin, Erythritol, Aloe Barbadensis Leaf Juice, Water (Aqua), Chondrus Crispus Extract

Cocoa Cabana

Hydrogenated Polyisobutene, C18-38 Alkyl Hydroxystearoyl Stearate, Butyrospermum Parkii (Shea) Oil, Butyloctyl Salicylate, VP/Hexadecene Copolymer, Ozokerite, Cetyl Alcohol, Vanillin, Glyceryl Stearate, Phytosteryl/Octyldodecyl Lauroyl Glutamate, Erythritol, Aqua (Water, Eau), Aloe Barbadensis Leaf Juice, Chondrus Crispus Extract, Tocopherol, Citric Acid, Methyl Dihydroabietate, Trihydroxystearin, Potassium Sorbate, Sodium Benzoate, Vanillin, CI 77891 (Titanium Dioxide), CI 77491/CI 77492/CI 77499 (Iron Oxides), CI 15850 (Red 7 Lake)

Coral

Hydrogenated Polyisobutene, C18-38 Alkyl Hydroxystearoyl Stearate, Butyrospermum Parkii (Shea) Oil, Butyloctyl Salicylate, VP/Hexadecene Copolymer, Ozokerite, Cetyl Alcohol, Vanillin, Glyceryl Stearate, Phytosteryl/Octyldodecyl Lauroyl Glutamate, Erythritol, Aqua (Water, Eau), Aloe Barbadensis Leaf Juice, Chondrus Crispus Extract, Tocopherol, Citric Acid, Methyl Dihydroabietate, Trihydroxystearin, Potassium Sorbate, Sodium Benzoate, Vanillin, CI 77891 (Titanium Dioxide), CI 77491/CI 77492

Nude Ting

Hydrogenated Polyisobutene, C18-38 Alkyl Hydroxystearoyl Stearate, Butyrospermum Parkii (Shea) Oil, Butyloctyl Salicylate, VP/Hexadecene Copolymer, Ozokerite, Cetyl Alcohol, Vanillin, Glyceryl Stearate, Phytosteryl/Octyldodecyl Lauroyl Glutamate,

Erythritol, Aqua (Water, Eau), Aloe Barbadensis Leaf Juice, Chondrus Crispus Extract, Tocopherol, Methyl Dihydroabietate, Trihydroxystearin, Citric Acid, Potassium Sorbate, Sodium Benzoate, CI 77891 (Titanium Dioxide), CI 77491/CI 77492/CI 77499 (Iron Oxides)

Irie Rose

Hydrogenated Polyisobutene, C18-38 Alkyl Hydroxystearoyl Stearate, Butyrospermum Parkii (Shea) Oil, Butyloctyl Salicylate, VP/Hexadecene Copolymer, Ozokerite, Cetyl Alcohol, Vanillin, Glyceryl Stearate, Phytosteryl/Octyldodecyl Lauroyl Glutamate, Erythritol, Aqua (Water, Eau), Aloe Barbadensis Leaf Juice, Chondrus Crispus Extract, Tocopherol, Methyl Dihydroabietate, Trihydroxystearin, Citric Acid, Potassium Sorbate, Sodium Benzoate. May Contain +/-: CI 77891 (Titanium Dioxide), CI 77491/CI 77492/CI 77499 (Iron Oxides), CI 15850 (Red 7 Lake)

Bad Gyal Berry

Hydrogenated Polyisobutene, C18-38 Alkyl Hydroxystearoyl Stearate, Butyrospermum Parkii (Shea) Oil, Butyloctyl Salicylate, VP/Hexadecene Copolymer, Ozokerite, Cetyl Alcohol, Vanillin, Glyceryl Stearate, Phytosteryl/Octyldodecyl Lauroyl Glutamate, Erythritol, Aqua (Water, Eau), Aloe Barbadensis Leaf Juice, Chondrus Crispus Extract, Tocopherol, Methyl Dihydroabietate, Trihydroxystearin, Citric Acid, Potassium Sorbate, Sodium Benzoate. May Contain +/-: CI 77891 (Titanium Dioxide), CI 77491/CI 77492/CI 77499 (Iron Oxides), CI 15850 (Red 7 Lake)

Questions or comments?

cayskin.com (256) 396-8268

Product Packaging

MADE WITH CLEAN
SKINCARE ACTIVES
AND ISLAND-BASED
INGREDIENTS

CAY SIGNATURE INGREDIENTS

Sea Moss,
Aloe Stem Cells,
and Vitamin E

NO COMPROMISES

CLEAN SUNSCREEN
ACTIVES, REEF-SAFE*,
WATER RESISTANT
40 MINUTES, DERMATOL-
OGIST TESTED,
VEGAN, CRUELTY-FREE,
SULFATE, PARABEN
AND SILICONE-FREE

*DOES NOT CONTAIN
OXYBENZONE
OR OCTINOXATE

CAY SKIN — MADE IN USA
FROM GLOBALLY SOURCED MATERIALS
DISTRIBUTED BY SKIN&SUN, INC.,
MIAMI, FL 33140 CAYSKIN.COM CAXLGS-01R-C



CAY SKIN



SUNCARE

Isle Lip Balm
SPF 30

Broad Spectrum
SPF 30
Sunscreen

Water Resistant
(40 minutes)

NET WT 10 G — 0.35 OZ

A hydrating and
protective daily lip
balm with UVA/UVB
protection and a
delicious vanilla
brown sugar flavor
that leaves a clear,
non-sticky finish.

CAY SKIN was
created for every-
one under the
sun to love their
skin — everyday,
everywhere.

Our products are
formulated with a
custom blend of
hydrating, gentle
and island-based
ingredients mixed
with the most
effective skincare-
grade actives to
keep your skin pro-
tected and looking
healthy and glowing.
CAY SKIN works
on all skin tones,
all occasions,
all year round.

Drug Facts

Active ingredients (w/w)	Purpose
Avobenzone 3%, Homosalate 10%, Octisalate 5%	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.

When using this product keep out of eyes.

Rinse with water to remove.

Stop use and consult a doctor if skin rash occurs.

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

Directions • Adults and children over 6 months of age: • Apply liberally 15 minutes before sun exposure. • Reapply: at least every 2 hours or after 40 minutes of 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 protections measures including: limit time in the sun, especially from 10 a.m. - 2 p.m.; wear long-sleeved shirts, pants, hats and sunglasses.

Other information

Protect this product from excessive heat and direct sun.

Inactive ingredients

Hydrogenated Polyisobutene, C18-38 Alkyl Hydroxystearoyl Stearate, Butyrospermum Parkii (Shea) Oil, Butyloctyl Salicylate, VP/Hexadecene Copolymer, Ozokerite, Cetyl Alcohol, Vanillin, Glyceryl Stearate, Phytosteryl/Octylododecyl Lauryl Glutamate, Methyl Dihydroabietate, Trihydroxystearin, Erythritol, Aloe Barbadosensis Leaf Juice, Water (Aqua), Chondrus Crispus Extract

Questions or comments?

cayskin.com (256) 396-8268

Product Packaging - Cocoa Cabana



CAY SKIN



SUNCARE
Isle Lip Balm
SPF 30

COCOA CABANA
Broad Spectrum
SPF 30
Sunscreen

Water Resistant
(40 minutes)

NET WT 10 G — 0.35 OZ

FPO

Drug Facts

Active ingredients (w/w)	Purpose
Azobenzene PA, Homosalate 10PA, Octinoxate 7PA	Sunscreen

Uses • Help 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.

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. Stop use and consult a doctor if skin rash occurs. Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions • Adults and children over 6 months of age: • Apply liberally 15 minutes before sun exposure. • Reapply at least every 2 hours or after 40 minutes of swimming or sweating. • Continue under 6 months of age with a doctor. • Sun Protection Measurement: • 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.

Other information
Protect the product from excessive heat and direct sun.

Inactive ingredients
Hydrogenated Polyisobutene, C18-38 Alkyl Polydimethylsilyloxy Crosspolymer, Pentaerythrityl Diethylhexyl Selenate, VP/Hexadecene Copolymer, Octyltriaerythryl Ether, Vanillin, Glycerol Stearate, Polyacrylate/Copolymer/Lauryl Glutamate, Erythritol, Aqua (Water, Eau), Aloe Barbadensis Leaf Juice, Chondrus Crispus Extract, Tocopherol, Citric Acid, Methyl Dihydroxyacetate, Trihydroxyacetone, Potassium Sorbate, Sodium Benzoate, Vanillin, CI 77261 (Titanium Dioxide), CI 77491/CI 77492/CI 77499 (Iron Oxides), CI 15850 (Red 7 Lake)

Questions or comments?
cayskin.com 1-888-800-1181

A hydrating, non-sticky and protective daily lip balm with UVA/UVB protection and a delicious vanilla brown sugar flavor that gives lips a sheer rich brown tint and looks gorgeous on all skin tones.

Product Packaging - Coral



Product Packaging - Nude Ting



Product Packaging - Irie Rose



Product Packaging - Bad Gyal Berry



CAY SKIN ISLE LIP BALM SPF 30 CORAL

avobenzone, homosalate, octisalate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82657-011
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

OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
CI 77492 (UNII: EX438O2MRT)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SHEANUT OIL (UNII: O88E196QRF)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ERYTHRITOL (UNII: RA96B954X6)	
CHONDRUS CRISPUS (UNII: OQS23HUA1X)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CERESIN (UNII: Q1LS2UJO3A)	
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)	
PHYTOSTERYL/OCTYLDODECYL LAUROYL GLUTAMATE (UNII: 65954KGO9Q)	
METHYL DIHYDROABIETATE (UNII: 7666FJOJ9F)	
TRIHYDROXYSTEARIN (UNII: 06YD7896S3)	
WATER (UNII: 059QF0KO0R)	
C18-38 ALKYL HYDROXYSTEAROYL STEARATE (UNII: WW4FVB2PEM)	
VINYLPYRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)	
VANILLIN (UNII: CHI530446X)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TOCOPHEROL (UNII: R0ZB2556P8)	
CI 77491 (UNII: 1K09F3G675)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82657-011-01	1 in 1 CARTON	01/01/2025	
1		10 g in 1 TUBE, WTH APPLICATOR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	01/01/2025	

CAY SKIN ISLE LIP BALM SPF 30 BAD GYAL BERRY

avobenzone, homosalate, octisalate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82657-014
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
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
CI 15850 (UNII: 481744AI4O)	
CI 77492 (UNII: EX438O2MRT)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SHEANUT OIL (UNII: O88E196QRF)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ERYTHRITOL (UNII: RA96B954X6)	
CHONDRUS CRISPUS (UNII: OQS23HUA1X)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CERESIN (UNII: Q1LS2UJO3A)	
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)	
PHYTOSTERYL/OCTYLDODECYL LAUROYL GLUTAMATE (UNII: 65954KGO9Q)	
METHYL DIHYDROABIETATE (UNII: 7666FJ0J9F)	
TRIHYDROXYSTEARIN (UNII: 06YD7896S3)	
WATER (UNII: 059QF0KO0R)	
C18-38 ALKYL HYDROXYSTEAROYL STEARATE (UNII: WW4FVB2PEM)	
VINYLPYRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TOCOPHEROL (UNII: R0ZB2556P8)	
CI 77491 (UNII: 1K09F3G675)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CI 77499 (UNII: XM0M87F357)	
VANILLIN (UNII: CHI530446X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82657-014-01	1 in 1 CARTON	01/01/2023	
1		10 g in 1 TUBE, WTH APPLICATOR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	01/01/2023	

CAY SKIN ISLE LIP BALM SPF 30 NUDE TING

avobenzone, homosalate, octisalate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82657-012
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
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
CI 77492 (UNII: EX438O2MRT)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SHEANUT OIL (UNII: O88E196QRF)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ERYTHRITOL (UNII: RA96B954X6)	
CHONDRUS CRISPUS (UNII: OQS23HUA1X)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CERESIN (UNII: Q1LS2UJO3A)	
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)	
PHYTOSTERYL/OCTYLDODECYL LAUROYL GLUTAMATE (UNII: 65954KGO9Q)	
METHYL DIHYDROABIETATE (UNII: 7666FJ0J9F)	
TRIHYDROXYSTEARIN (UNII: 06YD7896S3)	
WATER (UNII: 059QF0KO0R)	
C18-38 ALKYL HYDROXYSTEAROYL STEARATE (UNII: WW4FVB2PEM)	
VINYLPYRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TOCOPHEROL (UNII: R0ZB2556P8)	
CI 77491 (UNII: 1K09F3G675)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CI 77499 (UNII: XM0M87F357)	

VANILLIN (UNII: CHI530446X)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82657-012-01	1 in 1 CARTON	01/01/2024	
1		10 g in 1 TUBE, WTH APPLICATOR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	01/01/2024	

CAY SKIN ISLE LIP BALM SPF 30 COCOA CABANA

avobenzone, homosalate, octisalate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82657-010
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
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CI 77499 (UNII: XM0M87F357)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
CI 77492 (UNII: EX438O2MRT)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SHEANUT OIL (UNII: O88E196QRF)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ERYTHRITOL (UNII: RA96B954X6)	
CHONDRUS CRISPUS (UNII: OQS23HUA1X)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CERESIN (UNII: Q1LS2UJO3A)	
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)	
PHYTOSTERYL/OCTYLDODECYL LAUROYL GLUTAMATE (UNII: 65954KGO9Q)	

METHYL DIHYDROABIETATE (UNII: 7666FJ0J9F)
TRIHYDROXYSTEARIN (UNII: 06YD7896S3)
WATER (UNII: 059QF0KO0R)
C18-38 ALKYL HYDROXYSTEAROYL STEARATE (UNII: WW4FVB2PEM)
VINYLPYRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)
VANILLIN (UNII: CHI530446X)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
CI 15850 (UNII: 481744AI4O)
TOCOPHEROL (UNII: R0ZB2556P8)
CI 77491 (UNII: 1K09F3G675)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82657-010-01	1 in 1 CARTON	09/13/2024	
1		10 g in 1 TUBE, WTH APPLICATOR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	09/13/2024	

CAY SKIN ISLE LIP BALM SPF 30

avobenzone, homosalate, octisalate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82657-001
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
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SHEANUT OIL (UNII: O88E196QRF)	

BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
ERYTHRITOL (UNII: RA96B954X6)
CHONDRUS CRISPUS (UNII: OQS23HUA1X)
CETYL ALCOHOL (UNII: 936JST6JCN)
CERESIN (UNII: Q1LS2UJO3A)
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)
PHYTOSTERYL/OCTYLDODECYL LAUROYL GLUTAMATE (UNII: 65954KGO9Q)
METHYL DIHYDROABIETATE (UNII: 7666FJ0J9F)
TRIHYDROXYSTEARIN (UNII: 06YD7896S3)
WATER (UNII: 059QF0KO0R)
C18-38 ALKYL HYDROXYSTEAROYL STEARATE (UNII: WW4FVB2PEM)
VINYLPYRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)
VANILLIN (UNII: CHI530446X)
ALOE VERA LEAF (UNII: ZY81Z83H0X)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82657-001-01	1 in 1 CARTON	03/29/2022	
1		10 g in 1 TUBE, WTH APPLICATOR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	03/29/2022	

CAY SKIN ISLE LIP BALM SPF 30 IRIE ROSE

avobenzone, homosalate, octisalate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82657-013
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
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CI 15850 (UNII: 481744AI4O)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
CI 77492 (UNII: EX438O2MRT)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SHEANUT OIL (UNII: O88E196QRF)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ERYTHRITOL (UNII: RA96B954X6)	
CHONDRUS CRISPUS (UNII: OQS23HUA1X)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CERESIN (UNII: Q1LS2UJO3A)	
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)	
PHYTOSTERYL/OCTYLDODECYL LAUROYL GLUTAMATE (UNII: 65954KGO9Q)	
METHYL DIHYDROABIETATE (UNII: 7666FJ0J9F)	
TRIHYDROXYSTEARIN (UNII: 06YD7896S3)	
WATER (UNII: 059QF0KO0R)	
C18-38 ALKYL HYDROXYSTEAROYL STEARATE (UNII: WW4FVB2PEM)	
VINYLPYRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TOCOPHEROL (UNII: R0ZB2556P8)	
CI 77491 (UNII: 1K09F3G675)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CI 77499 (UNII: XM0M87F357)	
VANILLIN (UNII: CHI530446X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82657-013-01	1 in 1 CARTON	01/01/2023	
1		10 g in 1 TUBE, WTH APPLICATOR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	01/01/2023	

Labeler - Cay Skin, Inc. (118574309)