

POUTSCREEN LIP TREATMENT MIDNIGHT KISS- avobenzone, octinoxate, octocrylene liquid
POUTSCREEN LIP TREATMENT LOVE LETTER- avobenzone, octinoxate, octocrylene liquid
POUTSCREEN LIP TREATMENT DARLING- avobenzone, octinoxate, octocrylene liquid
POUTSCREEN LIP TREATMENT CANDY CANE- avobenzone, octinoxate, octocrylene liquid
NAKED SUNDAYS PTY LTD

Poutscreen Lip Treatment

Use:

- Helps prevent sunburn.
- If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin ageing 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 ask a doctor: If rash occurs.

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

Directions:

- Apply liberally and evenly 15 minutes before sun exposure.
- Re-apply at least every 80 minutes or immediately after swimming, sweating or towel drying.
- 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:

- Limit time in the sun, especially from 10.00AM - 2.00PM
- Wear long-sleeved shirts, pants, hats, and sunglasses

Other Information:

- Protect this product from excess heat and direct sun.
- Store below 30°C / 86°F

Questions:

- info@nakedSundays.com

PoutScreen Love Letter

Inactive Ingredients: Polybutene, Isopropyl Myristate, Ethylhexyl Methoxycrylene, Octyldodecanol, Pentaerythrityl Tetraisoostearate, Flavor, Poly C10-30 Alkyl Acrylate, Silica Silylate, Cocos Nucifera (Coconut) Oil, Caprylic/Capric Triglyceride, Simmondsia Chinensis (Jojoba) Seed Oil, Sucralose, Polyglutamic Acid, Squalane, Propylene Carbonate, Stearalkonium Hectorite, Solanum Lycopersicum (Tomato) Fruit Extract, Water, BHT, Sorbitan Oleate, Palmitoyl Hexapeptide-12, Titanium Dioxide (CI 77891), Red 7 (CI 15850), Red 6 Lake (CI 15850), Yellow 5 (CI 19140).

PoutScreen Darling

Inactive Ingredients: Polybutene, Isopropyl Myristate, Ethylhexyl Methoxycrylene, Octyldodecanol, Pentaerythrityl Tetraisoostearate, Flavor, Poly C10-30 Alkyl Acrylate, Silica Silylate, Cocos Nucifera (Coconut) Oil, Caprylic/Capric Triglyceride, Simmondsia Chinensis (Jojoba) Seed Oil, Sucralose, Polyglutamic Acid, Squalane, Propylene Carbonate, Stearalkonium Hectorite, Solanum Lycopersicum (Tomato) Fruit Extract, Water, BHT, Sorbitan Oleate, Palmitoyl Hexapeptide-12, Iron Oxide (CI 77491), Yellow 5 (CI 19140), Red 7 (CI 15850), Iron Oxide (CI 77499), Red 6 Lake (CI 15850), Titanium Dioxide (CI 77891).

PoutScreen Midnight Kiss

Inactive Ingredients: Polybutene, Isopropyl Myristate, Ethylhexyl Methoxycrylene, Octyldodecanol, Pentaerythrityl Tetraisoostearate, Flavor, Poly C10-30 Alkyl Acrylate, Silica Silylate, Cocos Nucifera (Coconut) Oil, Caprylic/Capric Triglyceride, Simmondsia Chinensis (Jojoba) Seed Oil, Sucralose, Polyglutamic Acid, Iron Oxides (CI 77491), Squalane, Propylene Carbonate, Stearalkonium Hectorite, Iron Oxides (CI 77499), Red 7 (CI 15850), Titanium Dioxide (CI 77891), Red 6 Lake (CI 15850), Solanum Lycopersicum (Tomato) Fruit/Leaf/Stem Extract, Water, BHT, Yellow 5 (CI 19140), Sorbitan Oleate, Palmitoyl Hexapeptide-12.

PoutScreen Candy Cane

Inactive Ingredients: Polybutene, Isopropyl Myristate, Ethylhexyl Methoxycrylene, Octyldodecanol, Pentaerythrityl Tetraisoostearate, Flavor, Poly C10-30 Alkyl Acrylate, Silica Silylate, Cocos Nucifera (Coconut) Oil, Caprylic/Capric Triglyceride, Simmondsia Chinensis (Jojoba) Seed Oil, Sucralose, Polyglutamic Acid, Squalane, Propylene Carbonate, Stearalkonium Hectorite, Solanum Lycopersicum (Tomato) Fruit Extract, Water, BHT, Sorbitan Oleate, Palmitoyl Hexapeptide-12, Red 7 (CI 15850), Red 6 Lake (CI 15850).

PoutScreen Love Letter

Active Ingredients: Avobenzone 2.5% , Octinoxate 7.5%, Octocrylene 10%

PoutScreen Darling

Active Ingredients: Avobenzone 2.5% , Octinoxate 7.5%, Octocrylene 10%

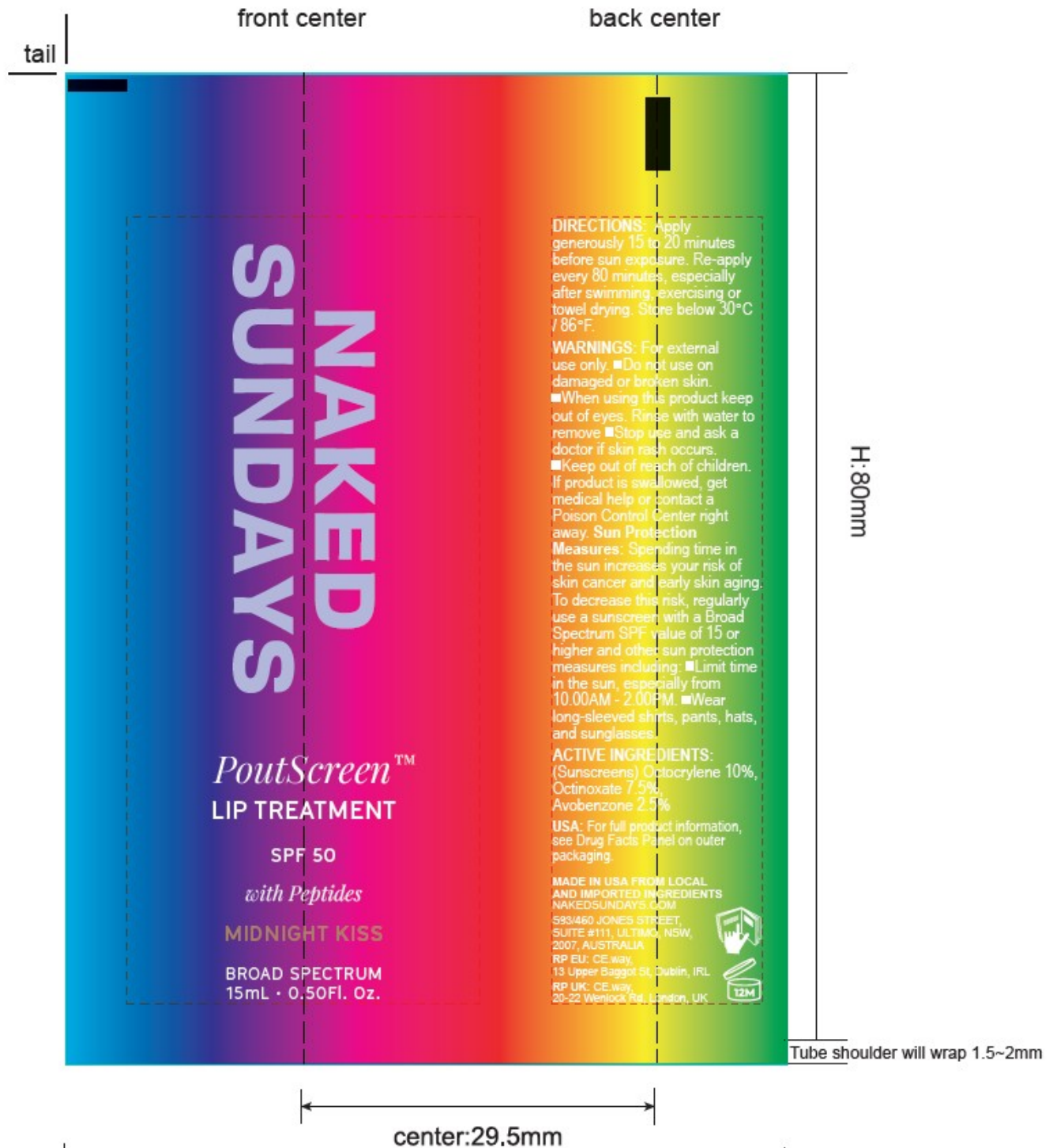
PoutScreen Midnight Kiss

Active Ingredients: Octocrylene 10%, Ethylhexyl Methoxycinnamate 7.5%, Avobenzone 2.5%

PoutScreen Candy Cane

Active Ingredients: Avobenzone 2.5% , Octinoxate 7.5%, Octocrylene 10%

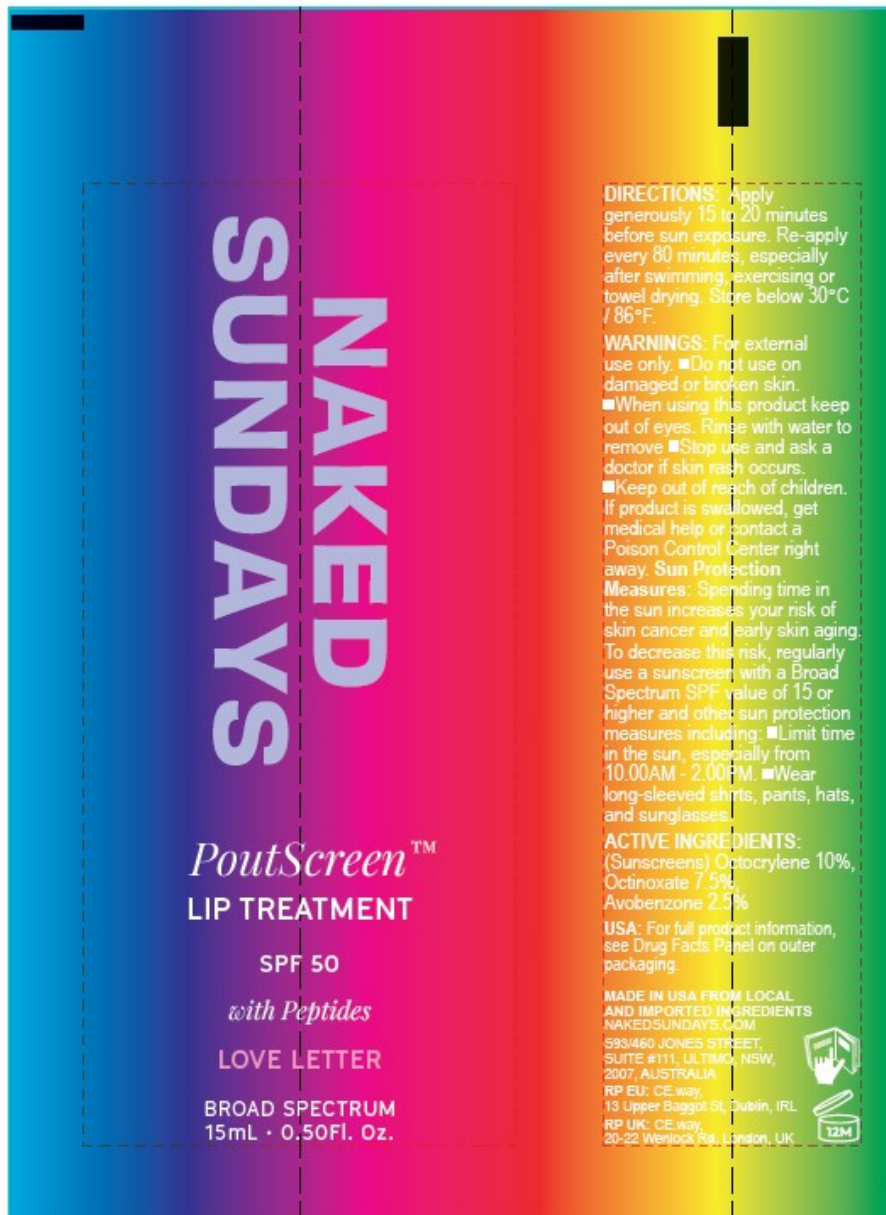
Sunscreen



tail

front center

back center



H:80mm

Tube shoulder will wrap 1.5~2mm

center:29.5mm

tail

front center

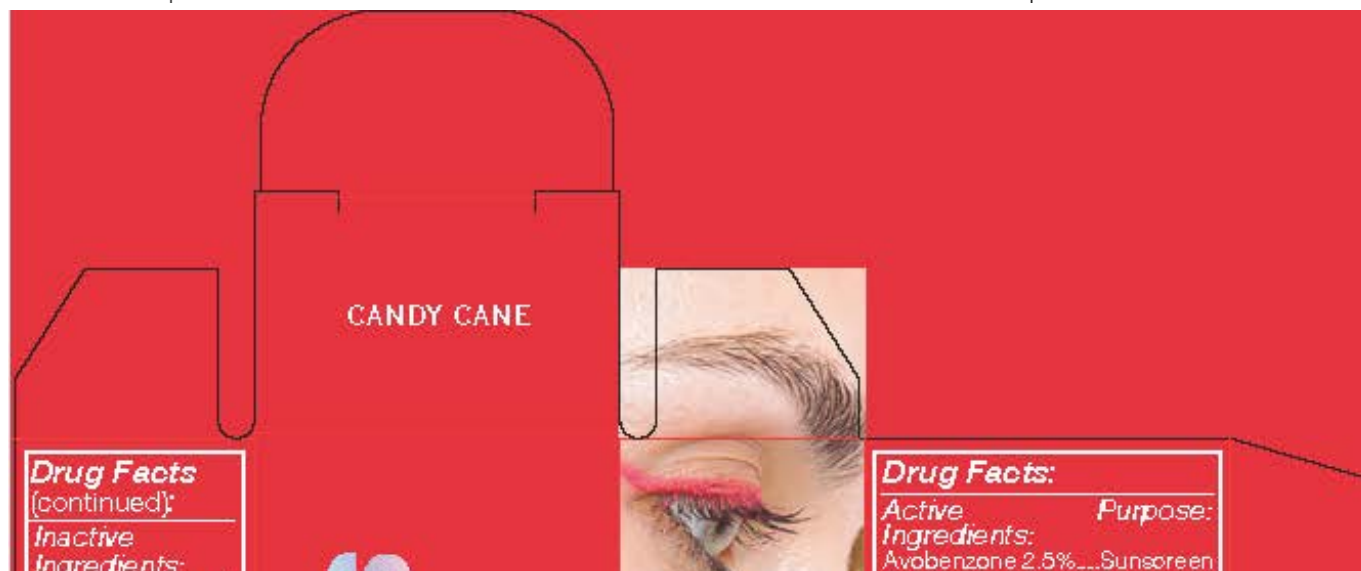
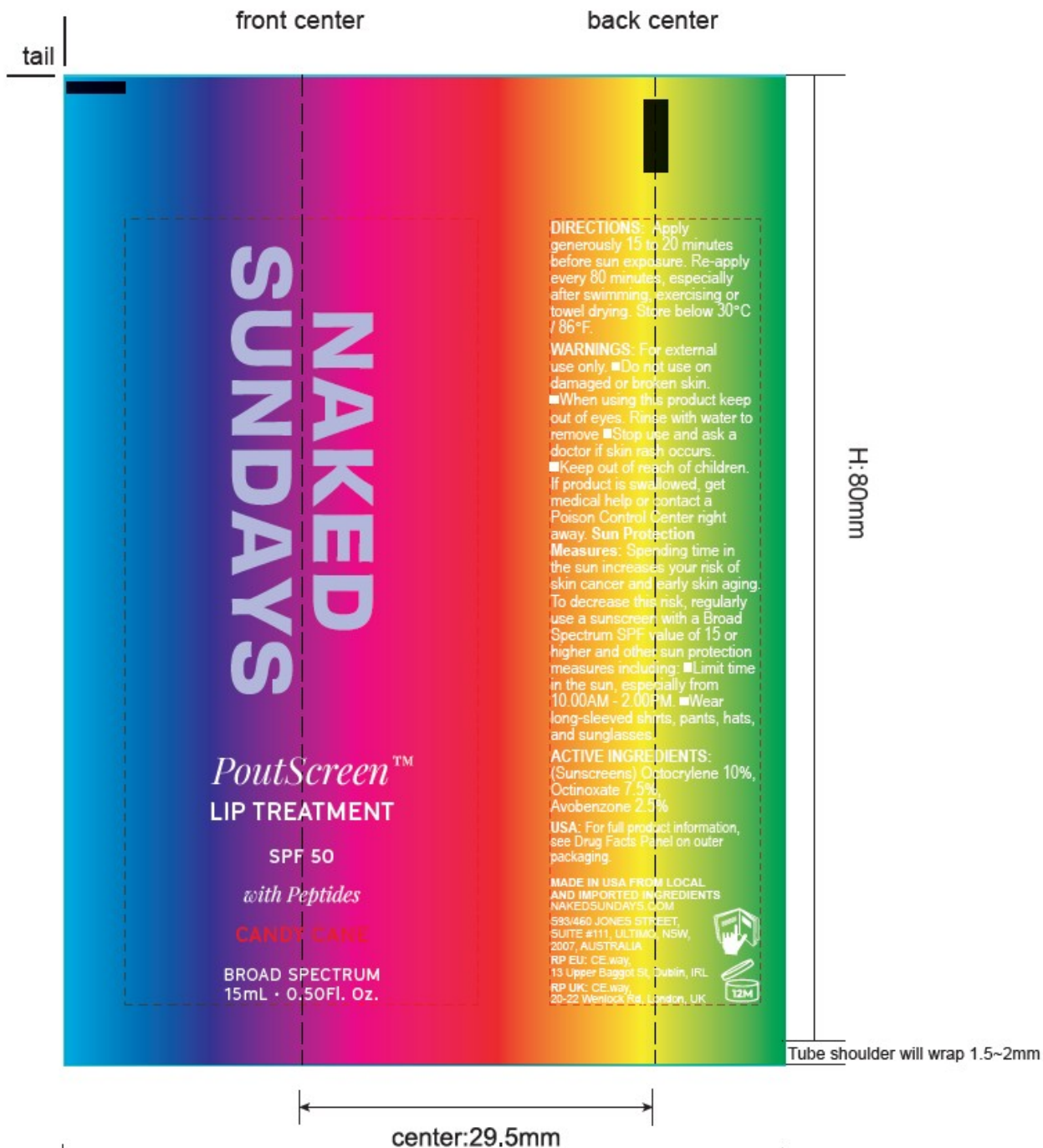
back center



H:80mm

Tube shoulder will wrap 1.5~2mm

center:29.5mm



Polybutene, Isopropyl Myristate, Ethylhexyl Methoxycrylate, Octyldodecanol, Pentaerythrityl Tetraisoostearate, Flavor, Poly C10-30 Alkyl Acrylate, Silica Silylate, Coos Nucifera (Coconut) Oil, Caprylic/Capric Triglyceride, Simmondsia Chinensis (Jojoba) Seed Oil, Sucralose, Polyglutamic Acid, Squalane, Propylene Carbonate, Stearalkonium Hectorite, Solanum Lycopersicum (Tomato) Fruit Extract, Water, BHT, Sorbitan Oleate, Palmitoyl Hexapeptide-12, Red 7 (CI 15850), Red 6 Lake (CI 15850).

Other

Information:

■Protect the product in this container from excessive heat and direct sun.
■Store below 30°C / 86°F

Questions:

info@naked Sundays .com

NAKED SUNDAYS

PoutScreen™ LIP TREATMENT

SPF 40

with Peptides

CANDY CANE

BROAD SPECTRUM
15mL - 0.50FL. Oz.



MADE IN USA FROM
LOCAL AND IMPORTED
INGREDIENTS
NAKEDSUNDAYS.COM
Manufactured for
Naked Sundays Pty Ltd
Distributed by
Lily Harper International Inc.
1940 Fountain View Dr #5206
Houston, TX 77057



Octinoxate 7.5%.....Sunscreen
Octocrylene 10%.....Sunscreen

Use:

■Helps prevent sunburn.
■If used as directed with other sun protection measures (see **directions**), decreases the risk of skin cancer and early skin ageing 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 ask 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:

■Apply generously 15 minutes before sun exposure. ■Reapply at least every 80 minutes or immediately after swimming, sweating or towel drying. ■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

■Limit time in the sun, especially from 10AM - 2PM

■Wear long-sleeved shirts, pants, hats, and sunglasses ▶



6 28120 90066 8

MIDNIGHT KISS



Drug Facts
(continued):

Inactive

Ingredients:

Polybutene, Isopropyl Myristate, Ethylhexyl Methoxycrylate, Octyldodecanol, Pentaerythrityl Tetraisostearate, Flavor, Poly C-10-30 Alkyl Acrylate, Silica Silylate, Cocos Nucifera (Coconut) Oil, Caprylic/Capric Triglyceride, Simmondsia Chinensis (Jojoba) Seed Oil, Sucralose, Polyglutamic Acid, Squalane, Propylene Carbonate, Stearalkonium Hectorite, Solanum Lycopersicum (Tomato) Fruit Extract, Water, BHT, Sorbitan Oleate, Palmitoyl Hexapeptide-12, Iron Oxide (CI 77491), Iron Oxide (CI 77499), Red 7 (CI 15850), Titanium Dioxide (CI 77891), Red 6 Lake (CI 15850), Yellow 6 (CI 19140).

Other

Information:

■Protect the product in this container from excessive heat and direct sun.
■Store below 30°C / 86°F

Questions:

info@nakedundays.com

NAKED
SUNDAYS

PoutScreen™
LIP TREATMENT

SPF 50

with Peptides

MIDNIGHT KISS

BROAD SPECTRUM
15mL • 0.5OFL. Oz.



MADE IN USA FROM
LOCAL AND IMPORTED
INGREDIENTS
NAKEDSUNDAYS.COM
Manufactured for
Naked Sundays Pty Ltd
Distributed by
Lily Harper International Inc.
1940 Fountain View Dr #208
Houston, TX 77057

Drug Facts:

Active

Purpose:

Ingredients:

Avobenzone 2.5%.....Sunscreen
Octinoxate 7.5%.....Sunscreen
Octocrylene 10%.....Sunscreen

Use: ■Helps prevent sunburn.
■If used as directed with other sun protection measures (see **directions**), decreases the risk of skin cancer and early skin ageing 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 ask 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: ■Apply generously 15 minutes before sun exposure. ■Reapply at least every 80 minutes or immediately after swimming, sweating or towel drying. ■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:

■Limit time in the sun, especially from 10AM - 2PM
■Wear long-sleeved shirts, pants, hats, and sunglasses ▶



DARLING

Drug Facts
(continued):

Inactive

Ingredients:

Polybutene, Isopropyl Myristate, Ethylhexyl Methoxycrylate, Octyldodecanol, Pentaerythrityl Tetraisoostearate, Flavor, Poly C10-30 Alkyl Acrylate, Silica Silylate, Cocos Nucifera (Coconut) Oil, Caprylic/Capric Triglyceride, Simmondsia Chinensis (Jojoba) Seed Oil, Sucralose, Polyglutamic Acid, Squalane, Propylene Carbonate, Stearalkonium Hectorite, Solanum Lycopersicum (Tomato) Fruit Extract, Water, BHT, Sorbitan Oleate, Palmitoyl Hexapeptide-12, Iron Oxide (CI 77491), Yellow 6 (CI 19140), Red 7 (CI 16860), Iron Oxide (CI 77499), Red 6 Lake (CI 16860), Titanium Dioxide (CI 77891).

Other Information:

■Protect the product in this container from excessive heat and direct sun.
■Store below 30°C / 86°F

Questions:

info@naked Sundays .com

NAKED SUNDAYS

PoutScreen™ LIP TREATMENT

SPF 50

with Peptides

DARLING

BROAD SPECTRUM
15mL - 0.50FL. Oz.



MADE IN USA FROM
LOCAL AND IMPORTED
INGREDIENTS
NAKEDSUNDAYS.COM

Manufactured by:
Naked Sundays, PT. LLC
Distributors:

Lily Meyer International Inc.
1944 Fountain View Dr #200
Houston, TX 77057

Drug Facts:

Active

Purpose:

Ingredients:

Avobenzone 2.5%.....Sunsoreen
Octinoxate 7.5%.....Sunsoreen
Octocrylene 10%.....Sunsoreen

Use: ■Helps prevent sunburn.

■If used as directed with other sun protection measures (**see directions**), decreases the risk of skin cancer and early skin ageing 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 ask 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: ■Apply generously 15 minutes before sun exposure. ■Reapply at least every 80 minutes or immediately after swimming, sweating or towel drying. ■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:

■Limit time in the sun, especially from 10AM - 2 PM
■Wear long-sleeved shirts, pants, hats, and sunglasses ▶



LOVE LETTER

Drug Facts
(continued):

Inactive

Ingredients:

Polybutene, Isopropyl Myristate, Ethylhexyl Methoxycrylate, Octyldodecanol, Pentaerythrityl Tetraisostearate, Flavor, Poly C10-30 Alkyl Acrylate, Silica Silylate, Coos Nucifera (Coconut) Oil, Caprylic/Capric Triglyceride, Simmondsia Chinensis (Jojoba) Seed Oil, Sucralose, Polyglutamic Acid, Squalane, Propylene Carbonate, Stearalkonium Hectorite, Solanum Lycopersicum (Tomato) Fruit Extract, Water, BHT, Sorbitan Oleate, Palmitoyl Hexapeptide-12, Titanium Dioxide (CI 77891), Red 7 (CI 15850), Red 6 Lake (CI 15850), Yellow 5 (CI 19140).

Other

Information:

■Protect the product in this container from excessive heat and direct sun.
■Store below 30°C / 86°F

Questions:

info@naked Sundays .com

SUNDAYS
NAKED

PoutScreen™
LIP TREATMENT

SPF 50

with Peptides

LOVE LETTER

BROAD SPECTRUM
15mL • 0.5OFL. Oz.



6 28120 90062 0



Drug Facts:

Active

Purpose:

Ingredients:

Avobenzone 2.5%... Sunscreen
Octinoxate 7.5%... Sunscreen
Octocrylene 10%... Sunscreen

Use: ■Helps prevent sunburn.

■If used as directed with other sun protection measures (**see directions**), decreases the risk of skin cancer and early skin ageing 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 ask 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: ■Apply generously 15 minutes before sun exposure. ■Reapply at least every 80 minutes or immediately after swimming, sweating or towel drying. ■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:

■Limit time in the sun, especially from 10AM - 2PM

■Wear long-sleeved shirts, pants, hats, and sunglasses ►



MADE IN USA FROM
LOCAL AND IMPORTED
INGREDIENTS
NAKEDSUNDAYS.COM

Manufactured for
Naked Sundays Pty Ltd
Distributed by
Uly Harper International, Inc.
1940 Fountain View Dr #208
Houston, TX 77057

POUTSCREEN LIP TREATMENT MIDNIGHT KISS

avobenzene, octinoxate, octocrylene liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81104-596
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)		OCTINOXATE	7.5 g in 100 mL
AVOBENZENE (UNII: G63QQF2NOX) (AVOBENZENE - UNII:G63QQF2NOX)		AVOBENZENE	2.5 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)		OCTOCRYLENE	10 g in 100 mL

Inactive Ingredients		Strength
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)		
COCOS NUCIFERA (COCONUT) OIL (UNII: Q9L0O73W7L)		
STEARALKONIUM HECTORITE (UNII: O LX698AH5P)		
PALMITOYL HEXAPEPTIDE-12 (UNII: HO4ZT5S86C)		
CI 19140 (UNII: I753WB2F1M)		
SOLANUM LYCOPERSICUM (TOMATO) FRUIT (UNII: Z4KHF2C175)		
POLYGLUTAMIC ACID (1200 MW) (UNII: MGE3733FR2)		
SUCRALOSE (UNII: 96K6UQ3ZD4)		
WATER (UNII: 059QF0KO0R)		
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)		
POLYBUTENE (1400 MW) (UNII: 1NA5AO9GH7)		
ETHYLHEXYL METHOXYCRYLENE (UNII: S3KFG6Q5X8)		
SORBITAN OLEATE (UNII: 06XEA2VD56)		
CI 77891 (UNII: 15FIX9V2JP)		
SQUALANE (UNII: GW89575KF9)		
PROPYLENE CARBONATE (UNII: 8D08K3S51E)		
PENTAERYTHRITYL TETRAISOSTEARATE (UNII: 9D7IK5483F)		
OCTYLDODECANOL (UNII: 461N1O614Y)		
BEHENYL ACRYLATE POLYMER (UNII: D64PM5UT4U)		
CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)		
SIMMONDSIA CHINENSIS (JOJOBA) SEED OIL (UNII: 724GKU717M)		
CI 15850 (UNII: 481744AI4O)		
CI 77491 (UNII: 1K09F3G675)		
CI 77499 (UNII: XM0M87F357)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC 81104			

1	NDC:81104-596-02	1 in 1 CARTON	12/18/2025	
1	NDC:81104-596-01	15 mL 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		12/18/2025	

POUTSCREEN LIP TREATMENT LOVE LETTER

avobenzone, octinoxate, octocrylene liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81104-595
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)		OCTINOXATE	7.5 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)		OCTOCRYLENE	10 g in 100 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)		AVOBENZONE	2.5 g in 100 mL
Inactive Ingredients			
Ingredient Name			Strength
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)			
COCOS NUCIFERA (COCONUT) OIL (UNII: Q9L0O73W7L)			
STEARALKONIUM HECTORITE (UNII: O LX698AH5P)			
PALMITOYL HEXAPEPTIDE-12 (UNII: HO4ZT5S86C)			
CI 19140 (UNII: I753WB2F1M)			
SOLANUM LYCOPERSICUM (TOMATO) FRUIT (UNII: Z4KHF2C175)			
SORBITAN OLEATE (UNII: 06XEA2VD56)			
POLYGLUTAMIC ACID (1200 MW) (UNII: MGE3733FR2)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			
WATER (UNII: 059QF0KO0R)			
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)			
POLYBUTENE (1400 MW) (UNII: 1NA5AO9GH7)			
ETHYLHEXYL METHOXYCRYLENE (UNII: S3KFG6Q5X8)			
CI 77891 (UNII: 15FIX9V2JP)			
SQUALANE (UNII: GW89575KF9)			
PROPYLENE CARBONATE (UNII: 8D08K3S51E)			
PENTAERYTHRITYL TETRAISOSTEARATE (UNII: 9D7IK5483F)			
OCTYLDODECANOL (UNII: 461N1O614Y)			
BEHENYL ACRYLATE POLYMER (UNII: D64PM5UT4U)			

CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)				
SIMMONDSIA CHINENSIS (JOJOBA) SEED OIL (UNII: 724GKU717M)				
CI 15850 (UNII: 481744AI4O)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81104-595-02	1 in 1 CARTON	12/18/2025	
1	NDC:81104-595-01	15 mL 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	12/18/2025	

POUTSCREEN LIP TREATMENT DARLING

avobenzone, octinoxate, octocrylene liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81104-597
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)		OCTINOXATE	7.5 g in 100 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)		AVOBENZ ONE	2.5 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)		OCTOCRYLENE	10 g in 100 mL
Inactive Ingredients			
Ingredient Name			Strength
CI 77491 (UNII: 1K09F3G675)			
CI 77499 (UNII: XM0M87F357)			
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)			
COCOS NUCIFERA (COCONUT) OIL (UNII: Q9L0O73W7L)			
STEARALKONIUM HECTORITE (UNII: OLX698AH5P)			
PALMITOYL HEXAPEPTIDE-12 (UNII: HO4ZT5S86C)			
CI 19140 (UNII: I753WB2F1M)			
SOLANUM LYCOPERSICUM (TOMATO) FRUIT (UNII: Z4KHF2C175)			
POLYGLUTAMIC ACID (1200 MW) (UNII: MGE3733FR2)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			
WATER (UNII: 059QF0KO0R)			

SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
POLYBUTENE (1400 MW) (UNII: 1NA5AO9GH7)	
ETHYLHEXYL METHOXYCRYLENE (UNII: S3KFG6Q5X8)	
SORBITAN OLEATE (UNII: 06XEA2VD56)	
CI 77891 (UNII: 15FIX9V2JP)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
SQUALANE (UNII: GW89575KF9)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
PENTAERYTHRITYL TETRAISOSTEARATE (UNII: 9D7IK5483F)	
BEHENYL ACRYLATE POLYMER (UNII: D64PM5UT4U)	
CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)	
SIMMONDSIA CHINENSIS (JOJOBA) SEED OIL (UNII: 724GKU717M)	
CI 15850 (UNII: 481744AI4O)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81104-597-02	1 in 1 CARTON	12/18/2025	
1	NDC:81104-597-01	15 mL 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	12/18/2025	

POUTSCREEN LIP TREATMENT CANDY CANE

avobenzone, octinoxate, octocrylene liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81104-598
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2.5 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
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ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
COCOS NUCIFERA (COCONUT) OIL (UNII: Q9L0O73W7L)	
STEARALKONIUM HECTORITE (UNII: O LX698AH5P)	
PALMITOYL HEXAPEPTIDE-12 (UNII: HO4ZT5S86C)	
CI 19140 (UNII: I753WB2F1M)	
SOLANUM LYCOPERSICUM (TOMATO) FRUIT (UNII: Z4KHF2C175)	
POLYGLUTAMIC ACID (1200 MW) (UNII: MGE3733FR2)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
WATER (UNII: 059QF0KO0R)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
POLYBUTENE (1400 MW) (UNII: 1NA5AO9GH7)	
ETHYLHEXYL METHOXYCRYLENE (UNII: S3KFG6Q5X8)	
SORBITAN OLEATE (UNII: 06XEA2VD56)	
CI 77891 (UNII: 15FIX9V2JP)	
SQUALANE (UNII: GW89575KF9)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
PENTAERYTHRITYL TETRAISOSTEARATE (UNII: 9D7IK5483F)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
BEHENYL ACRYLATE POLYMER (UNII: D64PM5UT4U)	
CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)	
SIMMONDSIA CHINENSIS (JOJOBA) SEED OIL (UNII: 724GKU717M)	
CI 15850 (UNII: 481744AI4O)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81104-598-02	1 in 1 CARTON	12/18/2025	
1	NDC:81104-598-01	15 mL 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	12/18/2025	

Labeler - NAKED SUNDAYS PTY LTD (746918845)