

**SHEER TINT SPF20 - LIGHT- zinc oxide and octinoxate lotion**  
**SHEER TINT SPF20 - MEDIUM- zinc oxide and octinoxate lotion**  
**SHEER TINT SPF20 - DARK- zinc oxide and octinoxate lotion**  
**Dermalogica, Inc.**

*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.*

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**Sheer Tint**  
**SPF20**

***Drug Facts***

**Active Ingredients**

Octinoxate 4.5%,  
Zinc Oxide 9.5%

**Purpose**

Sunscreen

**Uses**

- helps prevent sunburn.
- if used as directed with other sun protection measures (see **Directions**), helps decrease 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 ask a Doctor**

- if rash occurs

**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 two hours
- use a water resistant sunscreen if swimming or sweating
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To help decrease this risk, regularly use a sunscreen with a broad spectrum SPF 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-sleeve shirts, pants, hats and sunglasses
- Children under 6 months: ask a doctor

### **Other information**

- Protect this product from excessive heat and direct sun

### **Inactive ingredients**

Water/Aqua, Caprylic/Capric Triglyceride, Dimethicone, Dimethyl Isosorbide, Methyl Gluceth-20, Glyceryl Stearate, PEG-100 Stearate, Stearic Acid, Cetearyl Alcohol, Hydrolyzed Pearl, Juglans Regia (Walnut) Seed Extract, Sodium Hyaluronate Crosspolymer, Silanetriol, Lavandula Spica (Lavender) Flower Oil, Lavandula Hybrida Oil, Eucalyptus Globulus Leaf Oil, Lavandula Angustifolia (Lavender) Flower/Leaf/Stem Extract, Hydroxyethyl Acrylate/ Sodium Acryloyldimethyl Taurate Copolmer, Polyhydroxystearic Acid, Squalane, Triethoxycaprylylsilane, Polysorbate 60, Cetyl Alcohol, Silica Dimethyl Silylate, Magnesium Aluminum Silicate, Pentylene Glycol, Ethylhexylglycerin, Disodium EDTA, Silica, Phenoxyethanol, Tin Oxide, Iron Oxides (CI 77491, CI 77492, CI 77499), Titanium Dioxide (CI 77891).

### **Questions?**

**1-800-831-5150** in USA

### **PRINCIPAL DISPLAY PANEL - 40 mL Tube Carton - Light**

sheer  
tint

spf  
20

broad  
spectrum

light

1.3 US FL OZ / 40 mL e

**dermalogica®**

sheer  
tint



light

Lightly-tinted moisturizer provides an all-day sheer wash of color. Natural, light-diffusing Iron Oxides provide translucent color for radiant skin, while Broad Spectrum sunscreens shield against damaging UV rays. Hydrolyzed Pearl amino acids, hydrating Hyaluronic Acid and antioxidant Walnut Seed extracts help improve skin texture and reduce the appearance of fine dehydration lines.

*Formulated without artificial fragrances, colors or parabens. Product guaranteed when professionally recommended.*

© Dermalogica, Inc.  
Dermalogica, Dist.  
Los Angeles, CA 90009 USA  
1-800-831-5150  
Europe: London KT22 8JL UK Made in the USA

**dermalogica**  
dermalogica.com



### Drug Facts

#### Active Ingredients

Octinoxate 4.5%  
Zinc Oxide 9.5%

**Purpose** Sunscreen

#### Uses

- helps prevent sunburn.
- if used as directed with other sun protection measures (see Directions), helps decrease the risk of skin cancer and early skin aging caused by the sun.

#### Warnings

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- if rash occurs

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#### Directions

- apply liberally 15 minutes before sun exposure
- reapply at least every two hours
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- Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To help decrease this risk, regularly use a sunscreen with a broad spectrum SPF 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-sleeve shirts, pants, hats and sunglasses
- Children under 6 months: ask a doctor

sheer  
tint  
light

sheer  
tint



light

**dermalogica**<sup>®</sup>

a skin care system researched and developed by The International Dermal Institute

### Drug Facts (continued)

#### Other Information

- Protect this product from excessive heat and direct sun

#### Inactive ingredients


Water/Aqua, Caprylic/Capric Triglyceride, Dimethicone, Dimethyl Isosorbide, Methyl Gluceth-20, Glyceryl Stearate, PEG-100 Stearate, Stearic Acid, Cetearyl Alcohol, Hydrolyzed Pearl, Juglans Regia (Walnut) Seed Extract, Sodium Hyaluronate Crosspolymer, Silanetriol, Lavandula Spica (Lavender) Flower Oil, Lavandula Hybrid Oil, Eucalyptus Globulus Leaf Oil, Lavandula Angustifolia (Lavender) Flower/Leaf/Stem Extract, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Polyhydroxystearic Acid, Squalane, Triethoxycaprylylsilane, Polysorbate 60, Cetyl Alcohol, Silica Dimethyl Silylate, Magnesium Aluminum Silicate, Pentylene Glycol, Ethylhexylglycerin, Disodium EDTA, Silica, Phenoxyethanol, Tin Oxide, Iron Oxides (CI 77491, CI 77492, CI 77499), Titanium Dioxide (CI 77891).

**Questions?**  
1-800-831-5150  
in USA

1.3 US FL OZ / 40 mL e

(D1121-01)

111126-01



**PRINCIPAL DISPLAY PANEL - 40 mL Tube Carton - Medium**

sheer  
tint

spf  
20

broad  
spectrum

medium

1.3 US FL OZ / 40 mL e

**dermalogica**<sup>®</sup>

sheer tint



medium

Lightly-tinted moisturizer provides an all-day sheer wash of color. Natural, light-diffusing Iron Oxides provide translucent color for radiant skin, while Broad Spectrum sunscreens shield against damaging UV rays. Hydrolyzed Pearl amino acids, hydrating Hyaluronic Acid and antioxidant Walnut Seed extracts help improve skin texture and reduce the appearance of fine dehydration lines.

*Formulated without artificial fragrances, colors or parabens. Product guaranteed when professionally recommended.*

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**dermalogica**  
dermalogica.com

### Drug Facts

#### Active Ingredients

Octinoxate 4.5%,  
Zinc Oxide 9.5%

#### Purpose

Sunscreen

#### Uses

- helps prevent sunburn.
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#### Directions

- apply liberally 15 minutes before sun exposure
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  - wear long-sleeve shirts, pants, hats and sunglasses
- Children under 6 months: ask a doctor

sheer tint  
medium

sheer tint



medium

# dermalogica®

a skin care system researched and developed by The International Dermal Institute

### Drug Facts (continued)

#### Other Information

- Protect this product from excessive heat and direct sun

#### Inactive ingredients

Water/Aqua/Eau, Caprylic/Capric Triglyceride, Dimethicone, Dimethyl Isosorbide, Methyl Gluceth-20, Glycerin Stearate, PEG-100 Stearate, Stearic Acid, Cetearyl Alcohol, Hydrolyzed Pearl, Juglans Regia (Walnut) Seed Extract, Sodium Hyaluronate Crosspolymer, Silanetriol, Lavandula Spica (Lavender) Flower Oil, Lavandula Hybrid Oil, Eucalyptus Globulus Leaf Oil, Lavandula Angustifolia (Lavender) Flower/Leaf/Stem Extract, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Polyhydroxystearic Acid, Squalane, Triethoxycaprylylsilane, Polysorbate 60, Cetyl Alcohol, Silica Dimethyl Silylate, Magnesium Aluminum Silicate, Pentylene Glycol, Ethylhexylglycerin, Disodium EDTA, Silica, Phenoxethanol, Tin Oxide, Iron Oxides (CI 77491, CI 77492, CI 77499), Titanium Dioxide (CI 77891).

**Questions?**  
1-800-831-5150  
in USA

1.3 US FL OZ / 40 mL e

(D1119-01)

111127-01





**PRINCIPAL DISPLAY PANEL - 40 mL Tube Carton - Dark**

sheer

tint

spf

20

broad

spectrum

dark

1.3 US FL OZ / 40 mL e

**dermalogica**<sup>®</sup>

sheer  
tint



dark

Lightly-tinted moisturizer provides an all-day sheer wash of color. Natural, light-diffusing Iron Oxides provide translucent color for radiant skin, while Broad Spectrum sunscreens shield against damaging UV rays. Hydrolyzed Pearl amino acids, hydrating Hyaluronic Acid and antioxidant Walnut Seed extracts help improve skin texture and reduce the appearance of fine dehydration lines.

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Los Angeles, CA 90009 USA  
1-800-831-5150  
Europe: London KT22 8JB UK Made in the USA



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dermalogica.com

### Drug Facts

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  - wear long-sleeve shirts, pants, hats and sunglasses
- Children under 6 months: ask a doctor

sheer  
tint  
dark

sheer  
tint



dark

# dermalogica®

a skin care system researched and developed by The International Dermal Institute

### Drug Facts (continued)

#### Other Information

- Protect this product from excessive heat and direct sun

#### Inactive ingredients

Water/Aqua/Eau, Caprylic/Capric Triglyceride, Dimethicone, Dimethyl Isosorbide, Methyl Gluceth-20, Glycerol Stearate, PEG-100 Stearate, Stearic Acid, Cetearyl Alcohol, Hydrolyzed Pearl, Juglans Regia (Walnut) Seed Extract, Sodium Hyaluronate Crosspolymer, Silanetriol, Lavandula Spica (Lavender) Flower Oil, Lavandula Hybrid Oil, Eucalyptus Globulus Leaf Oil, Lavandula Angustifolia (Lavender) Flower/Leaf/Stem Extract, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Polyhydroxystearic Acid, Squalane, Triethoxycaprylsilane, Polysorbate 60, Cetyl Alcohol, Silica Dimethyl Silylate, Magnesium Aluminum Silicate, Pentylene Glycol, Ethylhexylglycerin, Disodium EDTA, Silica, Phenoxyethanol, Tin Oxide, Iron Oxides (CI 77491, CI 77492, CI 77499), Titanium Dioxide (CI 77891).

Questions?  
1-800-831-5150  
in USA

1.3 US FL OZ / 40 mL e

(D1123-01)

11128-01



# SHEER TINT SPF20 - LIGHT

zinc oxide and octinoxate lotion

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68479-201
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Zinc Oxide</b> (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	95 mg in 1 mL
<b>Octinoxate</b> (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	45 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>Water</b> (UNII: 059QF0KO0R)	
<b>Medium-Chain Triglycerides</b> (UNII: C9H2L21V7U)	
<b>Dimethicone</b> (UNII: 92RU3N3Y1O)	
<b>Dimethyl Isosorbide</b> (UNII: SA6A6V432S)	
<b>Methyl Gluceth-20</b> (UNII: J3QD0LD11P)	
<b>Glyceryl Monostearate</b> (UNII: 230OU9XXE4)	
<b>PEG-100 Stearate</b> (UNII: YD01N1999R)	
<b>Stearic Acid</b> (UNII: 4ELV7Z65AP)	
<b>Cetostearyl Alcohol</b> (UNII: 2DMT128M1S)	
<b>Calcium Carbonate</b> (UNII: H0G9379FGK)	
<b>English Walnut</b> (UNII: 1V3SHR7QB7)	
<b>PEG-9 Diglycidyl Ether/Sodium Hyaluronate Crosspolymer</b> (UNII: 788QAG3W8A)	
<b>Silanetriol</b> (UNII: E52D0J3TS5)	
<b>Lavender Oil</b> (UNII: ZBP1YXW0H8)	
<b>Lavandin Oil</b> (UNII: 9RES347CKG)	
<b>Eucalyptus Oil</b> (UNII: 2R04ONI662)	
<b>LAVANDULA ANGUSTIFOLIA SUBSP. ANGUSTIFOLIA FLOWERING TOP</b> (UNII: 9YT4B71U8P)	
<b>Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer (100000 MPA.S at 1.5%)</b> (UNII: 86FQE96TZ4)	
<b>Polyhydroxystearic Acid (2300 MW)</b> (UNII: YXH47AOU0F)	
<b>Squalane</b> (UNII: GW89575KF9)	
<b>Triethoxycaprylsilane</b> (UNII: LDC331P08E)	
<b>Polysorbate 60</b> (UNII: CAL22UVI4M)	
<b>Cetyl Alcohol</b> (UNII: 936JST6JCN)	
<b>Silica Dimethyl Silylate</b> (UNII: EU2PSP0G0W)	
<b>Magnesium Aluminum Silicate</b> (UNII: 6M3P64V0NC)	
<b>Pentylene Glycol</b> (UNII: 50C1307PZG)	



Ethylhexylglycerin (UNII: 147D247K3P)	
Edetate Disodium (UNII: 7FLD91C86K)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Stannic Oxide (UNII: KM7N50LOS6)	
Ferric Oxide Red (UNII: 1K09F3G675)	
Ferric Oxide Yellow (UNII: EX438O2MRT)	
Ferrosoferric Oxide (UNII: XM0M87F357)	
Titanium Dioxide (UNII: 15FIX9V2JP)	

**Product Characteristics**

Color	BROWN (Skin Tone Light)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68479-201-02	1 in 1 CARTON	01/22/2015	
1		40 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:68479-201-00	2 mL in 1 POUCH; Type 0: Not a Combination Product	01/22/2015	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/22/2015	

**SHEER TINT SPF20 - MEDIUM**

zinc oxide and octinoxate lotion

**Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68479-901
Route of Administration	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	95 mg in 1 mL
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	45 mg in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
-----------------	----------

<b>Water</b> (UNII: 059QF0KO0R)
<b>Medium-Chain Triglycerides</b> (UNII: C9H2L21V7U)
<b>Dimethicone</b> (UNII: 92RU3N3Y1O)
<b>Dimethyl Isosorbide</b> (UNII: SA6A6V432S)
<b>Methyl Gluceth-20</b> (UNII: J3QD0LD11P)
<b>Glyceryl Monostearate</b> (UNII: 230OU9XXE4)
<b>PEG-100 Stearate</b> (UNII: YD01N1999R)
<b>Stearic Acid</b> (UNII: 4ELV7Z65AP)
<b>Cetostearyl Alcohol</b> (UNII: 2DMT128M1S)
<b>Calcium Carbonate</b> (UNII: H0G9379FGK)
<b>English Walnut</b> (UNII: 1V3SHR7QB7)
<b>PEG-9 Diglycidyl Ether/Sodium Hyaluronate Crosspolymer</b> (UNII: 788QAG3W8A)
<b>Silanetriol</b> (UNII: E52D0J3TS5)
<b>Lavender Oil</b> (UNII: ZBP1YXW0H8)
<b>Lavandin Oil</b> (UNII: 9RES347CKG)
<b>Eucalyptus Oil</b> (UNII: 2R04ONI662)
<b>LAVANDULA ANGUSTIFOLIA SUBSP. ANGUSTIFOLIA FLOWERING TOP</b> (UNII: 9YT4B71U8P)
<b>Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer (100000 MPA.S at 1.5%)</b> (UNII: 86FQE96TZ4)
<b>Polyhydroxystearic Acid (2300 MW)</b> (UNII: YXH47AOU0F)
<b>Squalane</b> (UNII: GW89575KF9)
<b>Triethoxycaprylsilane</b> (UNII: LDC331P08E)
<b>Polysorbate 60</b> (UNII: CAL22UVI4M)
<b>Cetyl Alcohol</b> (UNII: 936JST6JCN)
<b>Silica Dimethyl Silylate</b> (UNII: EU2PSP0G0W)
<b>Magnesium Aluminum Silicate</b> (UNII: 6M3P64V0NC)
<b>Pentylene Glycol</b> (UNII: 50C1307PZG)
<b>Ethylhexylglycerin</b> (UNII: 147D247K3P)
<b>Edetate Disodium</b> (UNII: 7FLD91C86K)
<b>Silicon Dioxide</b> (UNII: ETJ7Z6XBU4)
<b>Phenoxyethanol</b> (UNII: HIE492ZZ3T)
<b>Stannic Oxide</b> (UNII: KM7N50LOS6)
<b>Ferric Oxide Red</b> (UNII: 1K09F3G675)
<b>Ferric Oxide Yellow</b> (UNII: EX438O2MRT)
<b>Ferrosoferric Oxide</b> (UNII: XM0M87F357)
<b>Titanium Dioxide</b> (UNII: 15FIX9V2JP)

### Product Characteristics

<b>Color</b>	BROWN (Skin Tone Medium)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68479-901-02	1 in 1 CARTON	01/22/2015	

1		40 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:68479-901-04	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/22/2015	
3	NDC:68479-901-00	2 mL in 1 POUCH; Type 0: Not a Combination Product	01/22/2015	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/22/2015	

## SHEER TINT SPF20 - DARK

zinc oxide and octinoxate lotion

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68479-301
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	95 mg in 1 mL
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	45 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Medium-Chain Triglycerides (UNII: C9H2L21V7U)	
Dimethicone (UNII: 92RU3N3Y1O)	
Dimethyl Isosorbide (UNII: SA6A6V432S)	
Methyl Gluceth-20 (UNII: J3QD0LD11P)	
Glyceryl Monostearate (UNII: 230OU9XXE4)	
PEG-100 Stearate (UNII: YD01N1999R)	
Stearic Acid (UNII: 4ELV7Z65AP)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	
Calcium Carbonate (UNII: H0G9379FGK)	
English Walnut (UNII: 1V3SHR7QB7)	
PEG-9 Diglycidyl Ether/Sodium Hyaluronate Crosspolymer (UNII: 788QAG3W8A)	
Silanetriol (UNII: E52D0J3TS5)	
Lavender Oil (UNII: ZBP1YXW0H8)	
Lavandin Oil (UNII: 9RES347CKG)	
Eucalyptus Oil (UNII: 2R04ONI662)	
LAVANDULA ANGUSTIFOLIA SUBSP. ANGUSTIFOLIA FLOWERING TOP (UNII: 9YT4B71U8P)	
Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer (10000 MPA.S at 1.5%) (UNII: 86FQE96TZ4)	
Polyhydroxystearic Acid (2300 MW) (UNII: YXH47AOU0F)	

<b>Squalane</b> (UNII: GW89575KF9)
<b>Triethoxycaprylylsilane</b> (UNII: LDC331P08E)
<b>Polysorbate 60</b> (UNII: CAL22UVI4M)
<b>Cetyl Alcohol</b> (UNII: 936JST6JCN)
<b>Silica Dimethyl Silylate</b> (UNII: EU2PSP0G0W)
<b>Magnesium Aluminum Silicate</b> (UNII: 6M3P64V0NC)
<b>Pentylene Glycol</b> (UNII: 50C1307PZG)
<b>Ethylhexylglycerin</b> (UNII: 147D247K3P)
<b>Edetate Disodium</b> (UNII: 7FLD91C86K)
<b>Silicon Dioxide</b> (UNII: ETJ7Z6XBU4)
<b>Phenoxyethanol</b> (UNII: HIE492ZZ3T)
<b>Stannic Oxide</b> (UNII: KM7N50LOS6)
<b>Ferric Oxide Red</b> (UNII: 1K09F3G675)
<b>Ferric Oxide Yellow</b> (UNII: EX438O2MRT)
<b>Ferrosoferric Oxide</b> (UNII: XM0M87F357)
<b>Titanium Dioxide</b> (UNII: 15FIX9V2JP)

### Product Characteristics

<b>Color</b>	BROWN (Skin Tone Dark)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68479-301-02	1 in 1 CARTON	01/22/2015	
1		40 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:68479-301-00	2 mL in 1 POUCH; Type 0: Not a Combination Product	01/22/2015	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/22/2015	

**Labeler** - Dermalogica, Inc. (177698560)

### Establishment

Name	Address	ID/FEI	Business Operations
Cosway		620899877	MANUFACTURE(68479-201, 68479-901, 68479-301)

### Establishment

Name	Address	ID/FEI	Business Operations
Diamond Wipes		161104729	MANUFACTURE(68479-201, 68479-901, 68479-301)

