

LBEL REPLENISHING FOUNDATION SPF 14 (CLAIRE 1) - BEIGE- octinoxate liquid
LBEL REPLENISHING FOUNDATION SPF 14 (CLAIRE 2) - BEIGE- octinoxate liquid
LBEL REPLENISHING FOUNDATION SPF 14 (CLAIRE 3) - BEIGE- octinoxate liquid
LBEL REPLENISHING FOUNDATION SPF 14 (CLAIRE 4) - BEIGE- octinoxate liquid
LBEL REPLENISHING FOUNDATION SPF 14 (MEDIUM 5) - BROWN- octinoxate liquid
LBEL REPLENISHING FOUNDATION SPF 14 (MEDIUM 6) - BROWN- octinoxate liquid
LBEL REPLENISHING FOUNDATION SPF 14 (MEDIUM 7) - BROWN- octinoxate liquid
LBEL REPLENISHING FOUNDATION SPF 14 (OBSCURE 8) - BROWN- octinoxate liquid
LBEL REPLENISHING FOUNDATION SPF 14 (OBSCURE 9) - BROWN- octinoxate liquid
Ventura Corporation 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.

L'BEL REPLENISHING FOUNDATION SPF 14

Drug Facts

Active Ingredients

Octinoxate (4.5 %)

Purpose

Sunscreen

Uses

- Helps prevent sunburn.

Warnings

- **Skin Cancer / Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, **not** skin cancer or early skin aging.
- **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 and evenly 15 minutes before sun exposure.
- Reapply at least every 2 hours
- Use a water resistant sunscreen if swimming or sweating.
- Children under 6 months of age: Ask a doctor
- Apply to the forehead, nose, chin and both cheeks.

Blend with Circular motion and spread softly without stretching the skin.

Other information

- Protect the product in this container from excessive heat and direct sun.

Inactive ingredients

Water, cyclopentasiloxane, butylene glycol, cyclohexasiloxane, phenyl trimethicone, cetyl peg/ppg-10/1 dimethicone, polyglyceryl-4 isostearate, nylon-12 fluorescent brightener 230 salt, hexyl laurate, mannitol, glycerin, ethylene/acrylic acid copolymer, glycine soja (soybean) protein, peg/ppg-18/18 dimethicone, disteardimonium hectorite, sodium chloride, dimethicone, propylene glycol, dimethicone crosspolymer, dimethicone/vinyl dimethicone crosspolymer, diazolidinyl urea, hydrolyzed keratin, dimethiconol, sucrose, methylparaben, serine, fragrance, arginine, cyclodextrin, polyvinylalcohol crosspolymer, pca, bht, macrocystis pyrifera extract, yeast extract, alanine, propylparaben, hydrolyzed wheat protein, carbomer, pvp, threonine, polysorbate 20, disodium succinate, mourera fluviatilis extract, palmitoyl pentapeptide-4.

May contain: titanium dioxide, iron oxides, iron oxides, iron oxides, methicone.

PR: Distributed by Ventura Corporation, Ltd. San Juan, Puerto Rico 00926.

PRINCIPAL DISPLAY PANEL - 30 g Bottle Box - Claire 1 - BEIGE

L'BEL

replenishing foundation SPF 14

Net Weight 1 oz. (30 g)

www.lbel.com

L'BEL

SUPRÉMACIE TEINT

replenishing foundation SPF 14

Net Weight 1 oz. (30 g)

Drug Facts

Active Ingredients	Purpose
Octinoxate (4.5 %)	Sunscreen

Uses

- Helps prevent sunburn.

Warnings

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■ **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. ▶

Drug Facts (continued)

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

Directions

- Apply liberally and evenly 15 minutes before sun exposure.
- Reapply at least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating.
- Children under 6 months of age: Ask a doctor.

Other information

- Protect the product in this container from excessive heat and direct sun.

Inactive Ingredients Aqua (water), cyclopentasiloxane, butylene glycol, cyclohexasiloxane, phenyl trimethicone, cetyl peg/ppg-10/1 dimethicone, polyglyceryl-4 isostearate, nylon-12 fluorescent brightener 230 salt, hexyl laurate, mannitol, glycerin, ethylene/acrylic acid copolymer, ▶

Drug Facts (continued)

glycine soja protein (glycine soja (soybean) protein), peg/ppg-18/18 dimethicone, disteardimonium hectorite, sodium chloride, dimethicone, propylene glycol, dimethicone crosspolymer, dimethicone/vinyl dimethicone crosspolymer, diazolidinyl urea, hydrolyzed keratin, dimethiconol, sucrose, methylparaben, serine, parfum (fragrance), arginine, cyclodextrin, polyvinylalcohol crosspolymer, pca, bht, macrocystis pyrifera extract, faex extract (yeast extract), alanine, propylparaben, hydrolyzed wheat protein, carbomer, pvp, threonine, polysorbate 20, disodium succinate, mourera fluvialilis extract, palmitoyl pentapeptide-4.

US: Distributed by Ventura International Ltd, DBA Belcorp USA, San Francisco, CA 94111
PUERTO RICO: Distributed by Ventura Corporation, Ltd, San Juan, Puerto Rico 00926, Made in Colombia.

PRINCIPAL DISPLAY PANEL - 30 g Bottle Box - Claire 2 - BEIGE

L'BEL

replenishing foundation SPF 14

Net Weight 1 oz. (30 g)

www.lbel.com

L'BEL

SUPRÉMACIE TEINT

replenishing foundation SPF 14

Net Weight 1 oz. (30 g)

Drug Facts

Active Ingredients	Purpose
Octinoxate (4.5 %)	Sunscreen

Uses

- Helps prevent sunburn.

Warnings

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■ **When using this product** keep out of eyes. Rinse with water to remove.

■ **Stop use and ask a doctor** if rash occurs. ▶

Drug Facts (continued)

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

Directions

- Apply liberally and evenly 15 minutes before sun exposure.
- Reapply at least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating.
- Children under 6 months of age: Ask a doctor.

Other information

- Protect the product in this container from excessive heat and direct sun.

Inactive Ingredients Aqua (water), cyclopentasiloxane, butylene glycol, cyclohexasiloxane, phenyl trimethicone, cetyl peg/ppg-10/1 dimethicone, polyglyceryl-4 isostearate, nylon-12 fluorescent brightener 230 salt, hexyl laurate, mannitol, glycerin, ethylene/acrylic acid copolymer, ▶

Drug Facts (continued)

glycine soja protein (glycine soja (soybean) protein), peg/ppg-18/18 dimethicone, disteardimonium hectorite, sodium chloride, dimethicone, propylene glycol, dimethicone crosspolymer, dimethicone/vinyl dimethicone crosspolymer, diazolidinyl urea, hydrolyzed keratin, dimethiconol, sucrose, methylparaben, serine, parfum (fragrance), arginine, cyclodextrin, polyvinylalcohol crosspolymer, pca, bht, macrocystis pyrifera extract, faex extract (yeast extract), alanine, propylparaben, hydrolyzed wheat protein, carbomer, pvp, threonine, polysorbate 20, disodium succinate, mourera fluvialis extract, palmitoyl pentapeptide-4.

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PRINCIPAL DISPLAY PANEL - 30 g Bottle Box - Claire 3 - BEIGE

L'BEL

replenishing foundation SPF 14

Net Weight 1 oz. (30 g)

www.lbel.com

L'BEL

SUPRÉMACIE TEINT

replenishing foundation SPF 14

Net Weight 1 oz. (30 g)

Drug Facts

Active Ingredients	Purpose
Octinoxate (4.5 %)	Sunscreen

Uses

- Helps prevent sunburn.

Warnings

■ **Skin Cancer / Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, **not** skin cancer or early skin aging.

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■ **When using this product** keep out of eyes. Rinse with water to remove.

■ **Stop use and ask a doctor** if rash occurs. ▶

Drug Facts (continued)

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

Directions

- Apply liberally and evenly 15 minutes before sun exposure.
- Reapply at least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating.
- Children under 6 months of age: Ask a doctor.

Other information

- Protect the product in this container from excessive heat and direct sun.

Inactive Ingredients Aqua (water), cyclopentasiloxane, butylene glycol, cyclohexasiloxane, phenyl trimethicone, cetyl peg/ppg-10/1 dimethicone, polyglyceryl-4 isostearate, nylon-12 fluorescent brightener 230 salt, hexyl laurate, mannitol, glycerin, ethylene/acrylic acid copolymer, ▶

Drug Facts (continued)

glycine soja protein (glycine soja (soybean) protein), peg/ppg-18/18 dimethicone, disteardimonium hectorite, sodium chloride, dimethicone, propylene glycol, dimethicone crosspolymer, dimethicone/vinyl dimethicone crosspolymer, diazolidinyl urea, hydrolyzed keratin, dimethiconol, sucrose, methylparaben, serine, parfum (fragrance), arginine, cyclodextrin, polyvinylalcohol crosspolymer, pca, bht, macrocystis pyrifera extract, faex extract (yeast extract), alanine, propylparaben, hydrolyzed wheat protein, carbomer, pvp, threonine, polysorbate 20, disodium succinate, mourera fluvialis extract, palmitoyl pentapeptide-4.

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PRINCIPAL DISPLAY PANEL - 30 g Bottle Box - Claire 4 - BEIGE

L'BEL

replenishing foundation SPF 14

Net Weight 1 oz. (30 g)

www.lbel.com

L'BEL

SUPRÉMACIE TEINT

replenishing foundation SPF 14

Net Weight 1 oz. (30 g)

Drug Facts

Active Ingredients	Purpose
Octinoxate (4.5 %)	Sunscreen

Uses

- Helps prevent sunburn.

Warnings

■ **Skin Cancer / Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, **not** skin cancer or early skin aging.

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■ **Stop use and ask a doctor** if rash occurs. ▶

Drug Facts (continued)

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

Directions

- Apply liberally and evenly 15 minutes before sun exposure.
- Reapply at least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating.
- Children under 6 months of age: Ask a doctor.

Other information

- Protect the product in this container from excessive heat and direct sun.

Inactive Ingredients Aqua (water), cyclopentasiloxane, butylene glycol, cyclohexasiloxane, phenyl trimethicone, cetyl ppg-10/1 dimethicone, polyglyceryl-4 isostearate, nylon-12 fluorescent brightener 230 salt, hexyl laurate, mannitol, glycerin, ethylene/acrylic acid copolymer, ▶

Drug Facts (continued)

glycine soja protein (glycine soja (soybean) protein), peg/ppg-18/18 dimethicone, disteardimonium hectorite, sodium chloride, dimethicone, propylene glycol, dimethicone crosspolymer, dimethicone/vinyl dimethicone crosspolymer, diazolidinyl urea, hydrolyzed keratin, dimethiconol, sucrose, methylparaben, serine, parfum (fragrance), arginine, cyclodextrin, polyvinylalcohol crosspolymer, pca, bht, macrocystis pyrifera extract, faex extract (yeast extract), alanine, propylparaben, hydrolyzed wheat protein, carbomer, pvp, threonine, polysorbate 20, disodium succinate, mourera fluvialilis extract, palmitoyl pentapeptide-4.

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PRINCIPAL DISPLAY PANEL - 30 g Bottle Box - Medium 5 - BROWN

L'BEL

replenishing foundation SPF 14

Net Weight 1 oz. (30 g)

www.lbel.com

L'BEL

SUPRÉMACIE TEINT

replenishing foundation SPF 14

Net Weight 1 oz. (30 g)

Drug Facts

Active Ingredients	Purpose
Octinoxate (4.5 %)	Sunscreen

Uses

- Helps prevent sunburn.

Warnings

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Drug Facts (continued)

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

Directions

- Apply liberally and evenly 15 minutes before sun exposure.
- Reapply at least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating.
- Children under 6 months of age: Ask a doctor.

Other information

- Protect the product in this container from excessive heat and direct sun.

Inactive Ingredients Aqua (water), cyclopentasiloxane, butylene glycol, cyclohexasiloxane, phenyl trimethicone, cetyl peg/ppg-10/1 dimethicone, polyglyceryl-4 isostearate, nylon-12 fluorescent brightener 230 salt, hexyl laurate, mannitol, glycerin, ethylene/acrylic acid copolymer, ▶

Drug Facts (continued)

glycine soja protein (glycine soja (soybean) protein), peg/ppg-18/18 dimethicone, disteardimonium hectorite, sodium chloride, dimethicone, propylene glycol, dimethicone crosspolymer, dimethicone/vinyl dimethicone crosspolymer, diazolidinyl urea, hydrolyzed keratin, dimethiconol, sucrose, methylparaben, serine, parfum (fragrance), arginine, cyclodextrin, polyvinylalcohol crosspolymer, pca, bht, macrocystis pyrifera extract, faex extract (yeast extract), alanine, propylparaben, hydrolyzed wheat protein, carbomer, pvp, threonine, polysorbate 20, disodium succinate, mourera fluvialilis extract, palmitoyl pentapeptide-4.

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PRINCIPAL DISPLAY PANEL - 30 g Bottle Box - Medium 6 - BROWN

L'BEL

replenishing foundation SPF 14

Net Weight 1 oz. (30 g)

www.lbel.com

L'BEL

SUPRÉMACIE TEINT

replenishing foundation SPF 14

Net Weight 1 oz. (30 g)

Drug Facts

Active Ingredients	Purpose
Octinoxate (4.5 %)	Sunscreen

Uses

- Helps prevent sunburn.

Warnings

■ **Skin Cancer / Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, **not** skin cancer or early skin aging.

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■ **Stop use and ask a doctor** if rash occurs. ▶

Drug Facts (continued)

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

Directions

- Apply liberally and evenly 15 minutes before sun exposure.
- Reapply at least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating.
- Children under 6 months of age: Ask a doctor.

Other information

- Protect the product in this container from excessive heat and direct sun.

Inactive Ingredients Aqua (water), cyclopentasiloxane, butylene glycol, cyclohexasiloxane, phenyl trimethicone, cetyl peg/ppg-10/1 dimethicone, polyglyceryl-4 isostearate, nylon-12 fluorescent brightener 230 salt, hexyl laurate, mannitol, glycerin, ethylene/acrylic acid copolymer, ▶

Drug Facts (continued)

glycine soja protein (glycine soja (soybean) protein), peg/ppg-18/18 dimethicone, disteardimonium hectorite, sodium chloride, dimethicone, propylene glycol, dimethicone crosspolymer, dimethicone/vinyl dimethicone crosspolymer, diazolidinyl urea, hydrolyzed keratin, dimethiconol, sucrose, methylparaben, serine, parfum (fragrance), arginine, cyclodextrin, polyvinylalcohol crosspolymer, pca, bht, macrocystis pyrifera extract, faex extract (yeast extract), alanine, propylparaben, hydrolyzed wheat protein, carbomer, pvp, threonine, polysorbate 20, disodium succinate, mourera fluviatilis extract, palmitoyl pentapeptide-4.

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PRINCIPAL DISPLAY PANEL - 30 g Bottle Box - Medium 7 - BROWN

L'BEL

replenishing foundation SPF 14

Net Weight 1 oz. (30 g)

www.lbel.com

L'BEL

SUPRÉMACIE TEINT
replenishing foundation SPF 14
Net Weight 1 oz. (30 g)

Drug Facts

Active Ingredients	Purpose
Octinoxate (4.5 %)	Sunscreen

Uses

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Warnings

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Drug Facts (continued)

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Directions

- Apply liberally and evenly 15 minutes before sun exposure.
- Reapply at least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating.
- Children under 6 months of age: Ask a doctor.

Other information

- Protect the product in this container from excessive heat and direct sun.

Inactive Ingredients Aqua (water), cyclopentasiloxane, butylene glycol, cyclohexasiloxane, phenyl trimethicone, cetyl ppg-10/1 dimethicone, polyglyceryl-4 isostearate, nylon-12 fluorescent brightener 230 salt, hexyl laurate, mannitol, glycerin, ethylene/acrylic acid copolymer, ▶

Drug Facts (continued)

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PRINCIPAL DISPLAY PANEL - 30 g Bottle Box - Obscure 8 - BROWN

L'BEL

replenishing foundation SPF 14

Net Weight 1 oz. (30 g)

www.lbel.com

L'BEL

SUPRÉMACIE TEINT

replenishing foundation SPF 14

Net Weight 1 oz. (30 g)

Drug Facts

Active Ingredients	Purpose
Octinoxate (4.5 %)	Sunscreen

Uses

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Drug Facts (continued)

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Directions

- Apply liberally and evenly 15 minutes before sun exposure.
- Reapply at least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating.
- Children under 6 months of age: Ask a doctor.

Other information

- Protect the product in this container from excessive heat and direct sun.

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Drug Facts (continued)

glycine soja protein (glycine soja (soybean) protein), peg/ppg-18/18 dimethicone, disteardimonium hectorite, sodium chloride, dimethicone, propylene glycol, dimethicone crosspolymer, dimethicone/vinyl dimethicone crosspolymer, diazolidinyl urea, hydrolyzed keratin, dimethiconol, sucrose, methylparaben, serine, parfum (fragrance), arginine, cyclodextrin, polyvinylalcohol crosspolymer, pca, bht, macrocystis pyrifera extract, faex extract (yeast extract), alanine, propylparaben, hydrolyzed wheat protein, carbomer, pvp, threonine, polysorbate 20, disodium succinate, mourera fluviatilis extract, palmitoyl pentapeptide-4.

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PRINCIPAL DISPLAY PANEL - 30 g Bottle Box - Obscure 9 - BROWN

L'BEL

replenishing foundation SPF 14

Net Weight 1 oz. (30 g)

www.lbel.com

L'BEL

SUPRÉMACIE TEINT

replenishing foundation SPF 14

Net Weight 1 oz. (30 g)

Drug Facts

Active Ingredients	Purpose
Octinoxate (4.5 %)	Sunscreen

Uses

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Warnings

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■ **Stop use and ask a doctor** if rash occurs. ▶

Drug Facts (continued)

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Directions

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- Reapply at least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating.
- Children under 6 months of age: Ask a doctor.

Other information

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Drug Facts (continued)

glycine soja protein (glycine soja (soybean) protein), peg/ppg-18/18 dimethicone, disteardimonium hectorite, sodium chloride, dimethicone, propylene glycol, dimethicone crosspolymer, dimethicone/vinyl dimethicone crosspolymer, diazolidinyl urea, hydrolyzed keratin, dimethiconol, sucrose, methylparaben, serine, parfum (fragrance), arginine, cyclodextrin, polyvinylalcohol crosspolymer, pca, bht, macrocystis pyrifera extract, faex extract (yeast extract), alanine, propylparaben, hydrolyzed wheat protein, carbomer, pvp, threonine, polysorbate 20, disodium succinate, mourera fluvialis extract, palmitoyl pentapeptide-4.

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LBEL REPLENISHING FOUNDATION SPF 14 (CLAIRE 1) - BEIGE

octinoxate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-257
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.045 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

CYCLOMETHICONE 5 (UNII: 0THT5PC10R)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
CYCLOMETHICONE 6 (UNII: XHK3U310BA)
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
HEXYL LAURATE (UNII: 4CG9F9W01Q)
MANNITOL (UNII: 3OWL53L36A)
GLYCERIN (UNII: PDC6A3C0OX)
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
DIMETHICONE (UNII: 92RU3N3Y1O)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)
SUCROSE (UNII: C151H8M554)
METHYL PARABEN (UNII: A2I8C7HI9T)
SERINE (UNII: 452VLY9402)
ARGININE (UNII: 94ZLA3W45F)
PIDOLIC ACID (UNII: SZB83O1W42)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
MACROCYSTIS PYRIFERA (UNII: K31S3OG5C4)
YEAST (UNII: 3NY3SM6B8U)
ALANINE (UNII: OF5P57N2ZX)
PROPYL PARABEN (UNII: Z8IX2SC1OH)
THREONINE (UNII: 2ZD004190S)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
SODIUM SUCCINATE ANHYDROUS (UNII: V8ZGC8ISR3)
PALMITOYL PENTAPEPTIDE-4 (UNII: KK181SM5JG)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-257-02	1 in 1 BOX		
1	NDC:13537-257-01	30 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	12/16/2013	

LBEL REPLENISHING FOUNDATION SPF 14 (CLAIRE 2) - BEIGE

octinoxate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-258
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Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.045 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
MANNITOL (UNII: 3OWL53L36A)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
SUCROSE (UNII: C151H8M554)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
SERINE (UNII: 452VLY9402)	
ARGININE (UNII: 94ZLA3W45F)	
PIDOLIC ACID (UNII: SZB8301W42)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
MACROCYSTIS PYRIFERA (UNII: K31S3OG5C4)	
YEAST (UNII: 3NY3SM6B8U)	
ALANINE (UNII: OF5P57N2ZX)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
THREONINE (UNII: 2ZD004190S)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM SUCCINATE ANHYDROUS (UNII: V8ZGC8ISR3)	
PALMITOYL PENTAPEPTIDE-4 (UNII: KK181SM5JG)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-258-04	1 in 1 BOX		
1	NDC:13537-258-03	30 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	12/16/2013	

LBEL REPLENISHING FOUNDATION SPF 14 (CLAIRE 3) - BEIGE

octinoxate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-259
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.045 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
MANNITOL (UNII: 3OWL53L36A)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
SUCROSE (UNII: C151H8M554)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
SERINE (UNII: 452VLY9402)	
ARGININE (UNII: 94ZLA3W45F)	
PIDOLIC ACID (UNII: SZB8301W42)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
MACROCYSTIS PYRIFERA (UNII: K31S3OG5C4)	
YEAST (UNII: 3NY3SM6B8U)	
ALANINE (UNII: OF5P57N2ZX)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
THREONINE (UNII: 2ZD004190S)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	

SODIUM SUCCINATE ANHYDROUS (UNII: V8ZGC8ISR3)

PALMITOYL PENTAPEPTIDE-4 (UNII: KK181SM5JG)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

FERRIC OXIDE RED (UNII: 1K09F3G675)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-259-06	1 in 1 BOX		
1	NDC:13537-259-05	30 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	12/16/2013	

LBEL REPLENISHING FOUNDATION SPF 14 (CLAIRE 4) - BEIGE

octinoxate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-260
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.045 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
MANNITOL (UNII: 3OWL53L36A)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	

SUCROSE (UNII: C151H8M554)
METHYL PARABEN (UNII: A2I8C7H9T)
SERINE (UNII: 452VLY9402)
ARGININE (UNII: 94ZLA3W45F)
PIDOLIC ACID (UNII: SZB83O1W42)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
MACROCYSTIS PYRIFERA (UNII: K31S3OG5C4)
YEAST (UNII: 3NY3SM6B8U)
ALANINE (UNII: OF5P57N2ZX)
PROPYL PARABEN (UNII: Z8IX2SC1OH)
THREONINE (UNII: 2ZD004190S)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
SODIUM SUCCINATE ANHYDROUS (UNII: V8ZGC8ISR3)
PALMITOYL PENTAPEPTIDE-4 (UNII: KK181SM5JG)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-260-08	1 in 1 BOX		
1	NDC:13537-260-07	30 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	12/16/2013	

LBEL REPLENISHING FOUNDATION SPF 14 (MEDIUM 5) - BROWN

octinoxate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-298
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.045 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THF5PCI0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	

CYCLOMETHICONE 6 (UNII: XHK3U310BA)
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
HEXYL LAURATE (UNII: 4CG9F9W01Q)
MANNITOL (UNII: 3OWL53L36A)
GLYCERIN (UNII: PDC6A3C0OX)
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
DIMETHICONE (UNII: 92RU3N3Y1O)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)
SUCROSE (UNII: C151H8M554)
METHYL PARABEN (UNII: A2I8C7HI9T)
SERINE (UNII: 452VLY9402)
ARGININE (UNII: 94ZLA3W45F)
PIDOLIC ACID (UNII: SZB83O1W42)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
MACROCYSTIS PYRIFERA (UNII: K31S3OG5C4)
YEAST (UNII: 3NY3SM6B8U)
ALANINE (UNII: OF5P57N2ZX)
PROPYL PARABEN (UNII: Z8IX2SC1OH)
THREONINE (UNII: 2ZD004190S)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
SODIUM SUCCINATE ANHYDROUS (UNII: V8ZGC8ISR3)
PALMITOYL PENTAPEPTIDE-4 (UNII: KK181SM5JG)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-298-10	1 in 1 BOX		
1	NDC:13537-298-09	30 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	12/16/2013	

LBEL REPLENISHING FOUNDATION SPF 14 (MEDIUM 6) - BROWN

octinoxate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-262
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.045 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THF5PCI0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
MANNITOL (UNII: 3OWL53L36A)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
SUCROSE (UNII: C151H8M554)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
SERINE (UNII: 452VLY9402)	
ARGININE (UNII: 94ZLA3W45F)	
PIDOLIC ACID (UNII: SZB83O1W42)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
MACROCYSTIS PYRIFERA (UNII: K31S3OG5C4)	
YEAST (UNII: 3NY3SM6B8U)	
ALANINE (UNII: OF5P57N2ZX)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
THREONINE (UNII: 2ZD004190S)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM SUCCINATE ANHYDROUS (UNII: V8ZGC8ISR3)	
PALMITOYL PENTAPEPTIDE-4 (UNII: KK181SM5JG)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-262-12	1 in 1 BOX		
1	NDC:13537-262-11	30 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	12/16/2013	

LBEL REPLENISHING FOUNDATION SPF 14 (MEDIUM 7) - BROWN

octinoxate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-263
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.045 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
MANNITOL (UNII: 3OWL53L36A)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
SUCROSE (UNII: C151H8M554)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
SERINE (UNII: 452VLY9402)	
ARGININE (UNII: 94ZLA3W45F)	
PIDOLIC ACID (UNII: SZB83O1W42)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
MACROCYSTIS PYRIFERA (UNII: K31S3OG5C4)	
YEAST (UNII: 3NY3SM6B8U)	
ALANINE (UNII: OF5P57N2ZX)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
THREONINE (UNII: 2ZD004190S)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM SUCCINATE ANHYDROUS (UNII: V8ZGC8ISR3)	

PALMITOYL PENTAPEPTIDE-4 (UNII: KK181SM5JG)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
FERRIC OXIDE RED (UNII: 1K09F3G675)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-263-14	1 in 1 BOX		
1	NDC:13537-263-13	30 g in 1 BOTTLE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH NOT FINAL	part352	12/16/2013		

LBEL REPLENISHING FOUNDATION SPF 14 (OBSCURE 8) - BROWN				
octinoxate liquid				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-264	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.045 g in 1 g		
Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
CYCLOMETHICONE 5 (UNII: 0TH5PCI0R)				
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)				
CYCLOMETHICONE 6 (UNII: XHK3U310BA)				
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)				
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)				
HEXYL LAURATE (UNII: 4CG9F9W01Q)				
MANNITOL (UNII: 3OWL53L36A)				
GLYCERIN (UNII: PDC6A3C0OX)				
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)				
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
DIMETHICONE (UNII: 92RU3N3Y1O)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)				
SUCROSE (UNII: C151H8M554)				

METHYLPARABEN (UNII: A2I8C7HI9T)
SERINE (UNII: 452VLY9402)
ARGININE (UNII: 94ZLA3W45F)
PIDOLIC ACID (UNII: SZB83O1W42)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
MACROCYSTIS PYRIFERA (UNII: K31S3OG5C4)
YEAST (UNII: 3NY3SM6B8U)
ALANINE (UNII: OF5P57N2ZX)
PROPYLPARABEN (UNII: Z8IX2SC1OH)
THREONINE (UNII: 2ZD004190S)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
SODIUM SUCCINATE ANHYDROUS (UNII: V8ZGC8ISR3)
PALMITOYL PENTAPEPTIDE-4 (UNII: KK181SM5JG)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-264-16	1 in 1 BOX		
1	NDC:13537-264-15	30 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	12/16/2013	

LBEL REPLENISHING FOUNDATION SPF 14 (OBSCURE 9) - BROWN

octinoxate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-265
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.045 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	

CYCLOMETHICONE 6 (UNII: XHK3U310BA)
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
HEXYL LAURATE (UNII: 4CG9F9W01Q)
MANNITOL (UNII: 3OWL53L36A)
GLYCERIN (UNII: PDC6A3C0OX)
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
DIMETHICONE (UNII: 92RU3N3Y1O)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)
SUCROSE (UNII: C151H8M554)
METHYL PARABEN (UNII: A2I8C7HI9T)
SERINE (UNII: 452VLY9402)
ARGININE (UNII: 94ZLA3W45F)
PIDOLIC ACID (UNII: SZB83O1W42)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
MACROCYSTIS PYRIFERA (UNII: K31S3OG5C4)
YEAST (UNII: 3NY3SM6B8U)
ALANINE (UNII: OF5P57N2ZX)
PROPYL PARABEN (UNII: Z8IX2SC1OH)
THREONINE (UNII: 2ZD004190S)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
SODIUM SUCCINATE ANHYDROUS (UNII: V8ZGC8ISR3)
PALMITOYL PENTAPEPTIDE-4 (UNII: KK181SM5JG)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-265-18	1 in 1 BOX		
1	NDC:13537-265-17	30 g in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	12/16/2013	

Labeler - Ventura Corporation LTD (602751344)

Establishment			
Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(13537-257, 13537-258, 13537-259, 13537-260, 13537-298, 13537-262, 13537-263, 13537-264, 13537-265)

