

LBEL MAXIMUM COMFORT AND LONG-LASTING FOUNDATION SPF 10 (CLAIRE 1) - BEIGE- zinc oxide liquid
LBEL MAXIMUM COMFORT AND LONG-LASTING FOUNDATION SPF 10 (CLAIRE 2) - BEIGE- zinc oxide liquid
LBEL MAXIMUM COMFORT AND LONG-LASTING FOUNDATION SPF 10 (CLAIRE 3)- BEIGE- zinc oxide liquid
LBEL MAXIMUM COMFORT AND LONG-LASTING FOUNDATION SPF 10 (CLAIRE 4) - BEIGE- zinc oxide liquid
LBEL MAXIMUM COMFORT AND LONG-LASTING FOUNDATION SPF 10 (MEDIUM 5) - BROWN- zinc oxide liquid
LBEL MAXIMUM COMFORT AND LONG-LASTING FOUNDATION SPF 10 (MEDIUM 6) - BROWN- zinc oxide liquid
LBEL MAXIMUM COMFORT AND LONG-LASTING FOUNDATION SPF 10 (MEDIUM 7) - BROWN- zinc oxide liquid
LBEL MAXIMUM COMFORT AND LONG-LASTING FOUNDATION SPF 10 (OBSCURE 8) - BROWN- zinc oxide liquid
LBEL MAXIMUM COMFORT AND LONG-LASTING FOUNDATION SPF 10 (OBSCURE 9) - BROWN- zinc oxide 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 MAXIMUM COMFORT AND LONG-LASTING FOUNDATION SPF 10

Drug Facts

Active Ingredients

Zinc oxide 1.6%

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**
- **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, trimethylsiloxysilicate, dimethicone, polymethyl methacrylate, peg/ppg-18/18 dimethicone, cyclohexasiloxane, methyl methacrylate crosspolymer, sodium chloride, bis-hydroxyethoxypropyl dimethicone, bis-peg-18 methyl ether dimethyl silane, peg/ppg-19/19 dimethicone, glycerin, oleth-5, phenyl trimethicone, hydrolyzed soy protein, propylene glycol, silica silylate, mica, methylparaben, triethoxycaprylylsilane, propylparaben, tocopheryl acetate, phenoxyethanol, fragrance, butylparaben, ethylparaben, silica, isobutylparaben.

May contain:

Titanium dioxide, iron oxides, iron oxides, iron oxides, bismuth oxychloride.

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

PRINCIPAL DISPLAY PANEL - 30 ml Tube Carton - Claire 1 - Beige

EFFET
PARFAIT

maximum comfort
and long-lasting
foundation
SPF 10

30 ml e (1 fl.oz.)

L'BEL

Drug Facts

Active Ingredients

Zinc oxide 1.6%..... 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 damage or broken skin.
- When using this product keep out of eyes. Rinse with water to remove.

Drug Facts (continued)

- 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.

Other information

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

Inactive ingredients

Water, cyclopentasiloxane, ▼

Drug Facts (continued)

trimethylsiloxysilicate, dimethicone, polymethyl methacrylate, peg/ppg-18/18 dimethicone, cyclohexasiloxane, methyl methacrylate crosspolymer, sodium chloride, bis-hydroxyethoxypropyl dimethicone, bis-peg-18 methyl ether dimethyl silane, peg/ppg-19/19 dimethicone, glycerin, oleth-5, phenyl trimethicone, hydrolyzed soy protein, propylene glycol, silica silylate, mica, methylparaben, triethoxycaprylylsilane, propylparaben, tocopheryl acetate, phenoxyethanol, fragrance, butylparaben, ethylparaben, silica, isobutylparaben. **May contain:** Titanium dioxide, iron oxides, iron oxides, iron oxides, bismuth oxychloride.



EFFET PARFAIT

maximum comfort
and long-lasting
foundation
SPF 10

30 ml e (1 fl.oz.)

L'BEL

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.

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PRINCIPAL DISPLAY PANEL - 30 ml Tube Carton - Claire 2 - Beige

EFFET
PARFAIT

maximum comfort
and long-lasting
foundation
SPF 10

30 ml e (1 fl.oz.)

L'BEL

Drug Facts

Active Ingredients

Zinc oxide 1.6%

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 damage or broken skin.
- When using this product keep out of eyes. Rinse with water to remove.

Drug Facts (continued)

- 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.

Other information

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

Inactive ingredients Water, cyclopentasiloxane, ▼

Drug Facts (continued)

trimethylsiloxysilicate, dimethicone, polymethyl methacrylate, peg/ppg-18/18 dimethicone, cyclohexasiloxane, methyl methacrylate crosspolymer, sodium chloride, bis-hydroxyethoxypropyl dimethicone, bis-peg-18 methyl ether dimethyl silane, peg/ppg-19/19 dimethicone, glycerin, oleth-5, phenyl trimethicone, hydrolyzed soy protein, propylene glycol, silica silylate, mica, methylparaben, triethoxycaprylylsilane, propylparaben, tocopheryl acetate, phenoxyethanol, fragrance, butylparaben, ethylparaben, silica, isobutylparaben, **May contain:** Titanium dioxide, iron oxides, iron oxides, iron oxides, bismuth oxychloride.



EFFET PARFAIT

maximum comfort and long-lasting foundation
SPF 10

30 ml e (1 fl.oz.)

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PRINCIPAL DISPLAY PANEL - 30 ml Tube Carton - Claire 3 - Beige

EFFET
PARFAIT

maximum comfort
and long-lasting
foundation
SPF 10

30 ml e (1 fl.oz.)

L'BEL

Drug Facts

Active Ingredients

Zinc oxide 1.6%..... 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 damage or broken skin.
- When using this product keep out of eyes. Rinse with water to remove.

Drug Facts (continued)

- 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.

Other information

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

Inactive ingredients Water, cyclopentasiloxane, ▼

Drug Facts (continued)

trimethylsiloxysilicate, dimethicone, polymethyl methacrylate, peg/ppg-18/18 dimethicone, cyclohexasiloxane, methyl methacrylate crosspolymer, sodium chloride, bis-hydroxyethoxypropyl dimethicone, bis-peg-18 methyl ether dimethyl silane, peg/ppg-19/19 dimethicone, glycerin, oleth-5, phenyl trimethicone, hydrolyzed soy protein, propylene glycol, silica silylate, mica, methylparaben, triethoxycaprylylsilane, propylparaben, tocopheryl acetate, phenoxyethanol, fragrance, butylparaben, ethylparaben, silica, isobutylparaben, **May contain:** Titanium dioxide, iron oxides, iron oxides, iron oxides, bismuth oxychloride.



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PRINCIPAL DISPLAY PANEL - 30 ml Tube Carton - Claire 4 - Beige

EFFET
PARFAIT

maximum comfort
and long-lasting
foundation
SPF 10

30 ml e (1 fl.oz.)

L'BEL

Drug Facts

Active Ingredients

Zinc oxide 1.6%..... 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 damage or broken skin.
- When using this product keep out of eyes. Rinse with water to remove.

Drug Facts (continued)

- 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.

Other information

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

Inactive ingredients

Water, cyclopentasiloxane, ▼

Drug Facts (continued)

trimethylsiloxysilicate, dimethicone, polymethyl methacrylate, peg/ppg-18/18 dimethicone, cyclohexasiloxane, methyl methacrylate crosspolymer, sodium chloride, bis-hydroxyethoxypropyl dimethicone, bis-peg-18 methyl ether dimethyl silane, peg/ppg-19/19 dimethicone, glycerin, oleth-5, phenyl trimethicone, hydrolyzed soy protein, propylene glycol, silica silylate, mica, methylparaben, triethoxycaprylylsilane, propylparaben, tocopheryl acetate, phenoxyethanol, fragrance, butylparaben, ethylparaben, silica, isobutylparaben. **May contain:** Titanium dioxide, iron oxides, iron oxides, iron oxides, bismuth oxychloride.



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PRINCIPAL DISPLAY PANEL - 30 ml Tube Carton - Medium 5 - Brown

EFFET
PARFAIT

maximum comfort
and long-lasting
foundation
SPF 10

30 ml e (1 fl.oz.)

L'BEL

Drug Facts

Active Ingredients

Zinc oxide 1.6%..... 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 damage or broken skin.**

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

Drug Facts (continued)

- **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.

Other information

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

Inactive ingredients Water, cyclopentasiloxane, ▼

Drug Facts (continued)

trimethylsiloxysilicate, dimethicone, polymethyl methacrylate, peg/ppg-18/18 dimethicone, cyclohexasiloxane, methyl methacrylate crosspolymer, sodium chloride, bis-hydroxyethoxypropyl dimethicone, bis-peg-18 methyl ether dimethyl silane, peg/ppg-19/19 dimethicone, glycerin, oleth-5, phenyl trimethicone, hydrolyzed soy protein, propylene glycol, silica silylate, mica, methylparaben, triethoxycaprylylsilane, propylparaben, tocopheryl acetate, phenoxyethanol, fragrance, butylparaben, ethylparaben, silica, isobutylparaben, **May contain:** Titanium dioxide, iron oxides, iron oxides, iron oxides, bismuth oxychloride.



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PRINCIPAL DISPLAY PANEL - 30 ml Tube Carton - Medium 6 - Brown

EFFET
PARFAIT

maximum comfort
and long-lasting
foundation
SPF 10

30 ml e (1 fl.oz.)

L'BEL

Drug Facts

Active Ingredients

Zinc oxide 1.6%..... 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 damage or broken skin.
- When using this product keep out of eyes. Rinse with water to remove.

Drug Facts (continued)

- 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.

Other information

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

Inactive ingredients Water, cyclopentasiloxane, ▼

Drug Facts (continued)

trimethylsiloxysilicate, dimethicone, polymethyl methacrylate, peg/ppg-18/18 dimethicone, cyclohexasiloxane, methyl methacrylate crosspolymer, sodium chloride, bis-hydroxyethoxypropyl dimethicone, bis-peg-18 methyl ether dimethyl silane, peg/ppg-19/19 dimethicone, glycerin, oleth-5, phenyl trimethicone, hydrolyzed soy protein, propylene glycol, silica silylate, mica, methylparaben, triethoxycaprylylsilane, propylparaben, tocopheryl acetate, phenoxyethanol, fragrance, butylparaben, ethylparaben, silica, isobutylparaben, **May contain:** Titanium dioxide, iron oxides, iron oxides, iron oxides, bismuth oxychloride.



EFFET PARFAIT

maximum comfort
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SPF 10

30 ml e (1 fl.oz.)

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PRINCIPAL DISPLAY PANEL - 30 ml Tube Carton - Medium 7 - Brown

EFFET
PARFAIT

maximum comfort
and long-lasting
foundation
SPF 10

30 ml e (1 fl.oz.)

L'BEL

Drug Facts

Active Ingredients

Zinc oxide 1.6%..... 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 damage or broken skin.**

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

Drug Facts (continued)

- **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.

Other information

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

Inactive ingredients Water, cyclopentasiloxane, ▼

Drug Facts (continued)

trimethylsiloxysilicate, dimethicone, polymethyl methacrylate, peg/ppg-18/18 dimethicone, cyclohexasiloxane, methyl methacrylate crosspolymer, sodium chloride, bis-hydroxyethoxypropyl dimethicone, bis-peg-18 methyl ether dimethyl silane, peg/ppg-19/19 dimethicone, glycerin, oleth-5, phenyl trimethicone, hydrolyzed soy protein, propylene glycol, silica silylate, mica, methylparaben, triethoxycaprylylsilane, propylparaben, tocopheryl acetate, phenoxyethanol, fragrance, butylparaben, ethylparaben, silica, isobutylparaben, **May contain:** Titanium dioxide, iron oxides, iron oxides, iron oxides, bismuth oxychloride.



EFFET PARFAIT

maximum comfort
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foundation
SPF 10

30 ml e (1 fl.oz.)

L'BEL

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PRINCIPAL DISPLAY PANEL - 30 ml Tube Carton - Obscure 8 - Brown

EFFET
PARFAIT

maximum comfort
and long-lasting
foundation
SPF 10

30 ml e (1 fl.oz.)

L'BEL

Drug Facts

Active Ingredients

Zinc oxide 1.6%..... 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 damage or broken skin.
- When using this product keep out of eyes. Rinse with water to remove.

Drug Facts (continued)

- 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.

Other information

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

Inactive ingredients

Water, cyclopentasiloxane, ▼

Drug Facts (continued)

trimethylsiloxysilicate, dimethicone, polymethyl methacrylate, peg/ppg-18/18 dimethicone, cyclohexasiloxane, methyl methacrylate crosspolymer, sodium chloride, bis-hydroxyethoxypropyl dimethicone, bis-peg-18 methyl ether dimethyl silane, peg/ppg-19/19 dimethicone, glycerin, oleth-5, phenyl trimethicone, hydrolyzed soy protein, propylene glycol, silica silylate, mica, methylparaben, triethoxycaprylylsilane, propylparaben, tocopheryl acetate, phenoxyethanol, fragrance, butylparaben, ethylparaben, silica, isobutylparaben. **May contain:** Titanium dioxide, iron oxides, iron oxides, iron oxides, bismuth oxychloride.



EFFET PARFAIT

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SPF 10

30 ml e (1 fl.oz.)

L'BEL

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PRINCIPAL DISPLAY PANEL - 30 ml Tube Carton - Obscure 9 - Brown

EFFET
PARFAIT

maximum comfort
and long-lasting
foundation
SPF 10

30 ml e (1 fl.oz.)

L'BEL



EFFET PARFAIT

maximum comfort
and long-lasting
foundation
SPF 10

30 ml e (1 fl.oz.)

L'BEL

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Drug Facts

Active Ingredients

Zinc oxide 1.6%..... 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 damage or broken skin.
- When using this product keep out of eyes. Rinse with water to remove.

Drug Facts (continued)

- 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.

Other information

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

Inactive ingredients

Water, cyclopentasiloxane, ▼

Drug Facts (continued)

trimethylsiloxysilicate, dimethicone, polymethyl methacrylate, peg/ppg-18/18 dimethicone, cyclohexasiloxane, methyl methacrylate crosspolymer, sodium chloride, bis-hydroxyethoxypropyl dimethicone, bis-peg-18 methyl ether dimethyl silane, peg/ppg-19/19 dimethicone, glycerin, oleth-5, phenyl trimethicone, hydrolyzed soy protein, propylene glycol, silica silylate, mica, methylparaben, triethoxycaprylylsilane, propylparaben, tocopheryl acetate, phenoxyethanol, fragrance, butylparaben, ethylparaben, silica, isobutylparaben, **May contain:** Titanium dioxide, iron oxides, iron oxides, iron oxides, bismuth oxychloride.

LBEL MAXIMUM COMFORT AND LONG-LASTING FOUNDATION SPF 10 (CLAIRE 1) - BEIGE

zinc oxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-266
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.016 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
cyclomethicone 5 (UNII: 0THT5PCI0R)	
dimethicone (UNII: 92RU3N3Y1O)	
peg/ppg-18/18 dimethicone (UNII: 9H0AO7T794)	
cyclomethicone 6 (UNII: XHK3U310BA)	
sodium chloride (UNII: 451W47IQ8X)	
bis-peg-18 methyl ether dimethyl silane (UNII: OEB4R3WW9C)	
peg/ppg-19/19 dimethicone (UNII: EHH90CO7TL)	
glycerin (UNII: PDC6A3C0OX)	
oleth-5 (UNII: 1GH33785AY)	
phenyl trimethicone (UNII: DR0K5NOJ4R)	
propylene glycol (UNII: 6DC9Q167V3)	
mica (UNII: V8A1AW0880)	
methylparaben (UNII: A2I8C7HI9T)	
triethoxycaprylylsilane (UNII: LDC331P08E)	
propylparaben (UNII: Z8IX2SC1OH)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	
phenoxyethanol (UNII: HIE492ZZ3T)	
butylparaben (UNII: 3QPII03FV8)	
ethylparaben (UNII: 14255EXE39)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
isobutylparaben (UNII: 0QQJ25X58G)	
titanium dioxide (UNII: 15FIX9V2JP)	
ferric oxide red (UNII: 1K09F3G675)	
bismuth oxychloride (UNII: 4ZR792I587)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-266-02	1 in 1 BOX		
1	NDC:13537-266-01	30 mL in 1 BOTTLE, PLASTIC		
2	NDC:13537-266-04	1 in 1 BOX		

2	NDC:13537-266-03	3 mL in 1 TUBE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part352	12/16/2013		

LBEL MAXIMUM COMFORT AND LONG-LASTING FOUNDATION SPF 10 (CLAIRE 2) - BEIGE
zinc oxide liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-267
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.016 g in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
cyclomethicone 5 (UNII: 0THT5PCI0R)	
dimethicone (UNII: 92RU3N3Y1O)	
peg/ppg-18/18 dimethicone (UNII: 9H0AO7T794)	
cyclomethicone 6 (UNII: XHK3U310BA)	
sodium chloride (UNII: 451W47IQ8X)	
bis-peg-18 methyl ether dimethyl silane (UNII: OEB4R3WW9C)	
peg/ppg-19/19 dimethicone (UNII: EHH90CO7TL)	
glycerin (UNII: PDC6A3C0OX)	
oleth-5 (UNII: 1GH33785AY)	
phenyl trimethicone (UNII: DR0K5NOJ4R)	
propylene glycol (UNII: 6DC9Q167V3)	
mica (UNII: V8A1AW0880)	
methylparaben (UNII: A2I8C7HI9T)	
triethoxycaprylylsilane (UNII: LDC331P08E)	
propylparaben (UNII: Z8IX2SC1OH)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	
phenoxyethanol (UNII: HIE492ZZ3T)	
butylparaben (UNII: 3QPIU3FV8)	
ethylparaben (UNII: 14255EXE39)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
isobutylparaben (UNII: 0QQJ25X58G)	
titanium dioxide (UNII: 15FIX9V2JP)	

ferric oxide red (UNII: 1K09F3G675)

bismuth oxychloride (UNII: 4ZR792I587)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-267-06	1 in 1 BOX		
1	NDC:13537-267-05	30 mL in 1 BOTTLE, PLASTIC		
2	NDC:13537-267-08	1 in 1 BOX		
2	NDC:13537-267-07	3 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	12/16/2013	

LBEL MAXIMUM COMFORT AND LONG-LASTING FOUNDATION SPF 10 (CLAIRE 3)- BEIGE

zinc oxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-268
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.016 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
cyclomethicone 5 (UNII: 0THT5PCI0R)	
dimethicone (UNII: 92RU3N3Y1O)	
peg/ppg-18/18 dimethicone (UNII: 9H0AO7T794)	
cyclomethicone 6 (UNII: XHK3U310BA)	
sodium chloride (UNII: 451W47IQ8X)	
bis-peg-18 methyl ether dimethyl silane (UNII: OEB4R3WW9C)	
peg/ppg-19/19 dimethicone (UNII: EHH90CO7TL)	
glycerin (UNII: PDC6A3C0OX)	
oleth-5 (UNII: 1GH33785AY)	
phenyl trimethicone (UNII: DR0K5NOJ4R)	
propylene glycol (UNII: 6DC9Q167V3)	
mica (UNII: V8A1AW0880)	
methylparaben (UNII: A2I8C7HI9T)	

triethoxycaprylylsilane (UNII: LDC331P08E)	
propylparaben (UNII: Z8IX2SC1OH)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	
phenoxyethanol (UNII: HIE492ZZ3T)	
butylparaben (UNII: 3QPIU3FV8)	
ethylparaben (UNII: 14255EXE39)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
isobutylparaben (UNII: 0QQJ25X58G)	
titanium dioxide (UNII: 15FIX9V2JP)	
ferric oxide red (UNII: 1K09F3G675)	
bismuth oxychloride (UNII: 4ZR792I587)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-268-10	1 in 1 BOX		
1	NDC:13537-268-09	30 mL in 1 BOTTLE, PLASTIC		
2	NDC:13537-268-12	1 in 1 BOX		
2	NDC:13537-268-11	3 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	12/16/2013	

LBEL MAXIMUM COMFORT AND LONG-LASTING FOUNDATION SPF 10 (CLAIRE 4) - BEIGE

zinc oxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-269
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.016 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
cyclomethicone 5 (UNII: 0THT5PCI0R)	
dimethicone (UNII: 92RU3N3Y1O)	
peg/ppg-18/18 dimethicone (UNII: 9H0AO7T794)	

cyclomethicone 6 (UNII: XHK3U310BA)
sodium chloride (UNII: 451W47IQ8X)
bis-peg-18 methyl ether dimethyl silane (UNII: OEB4R3WW9C)
peg/ppg-19/19 dimethicone (UNII: EHH90CO7TL)
glycerin (UNII: PDC6A3C0OX)
oleth-5 (UNII: 1GH33785AY)
phenyl trimethicone (UNII: DR0K5NOJ4R)
propylene glycol (UNII: 6DC9Q167V3)
mica (UNII: V8A1AW0880)
methylparaben (UNII: A2I8C7HI9T)
triethoxycaprylylsilane (UNII: LDC331P08E)
propylparaben (UNII: Z8IX2SC1OH)
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)
phenoxyethanol (UNII: HIE492ZZ3T)
butylparaben (UNII: 3QPIU3FV8)
ethylparaben (UNII: 14255EXE39)
silicon dioxide (UNII: ETJ7Z6XBU4)
isobutylparaben (UNII: 0QQJ25X58G)
titanium dioxide (UNII: 15FIX9V2JP)
ferric oxide red (UNII: 1K09F3G675)
bismuth oxychloride (UNII: 4ZR792I587)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-269-14	1 in 1 BOX		
1	NDC:13537-269-13	30 mL in 1 BOTTLE, PLASTIC		
2	NDC:13537-269-16	1 in 1 BOX		
2	NDC:13537-269-15	3 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	12/16/2013	

LBEL MAXIMUM COMFORT AND LONG-LASTING FOUNDATION SPF 10 (MEDIUM 5) - BROWN

zinc oxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-270
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength

Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.016 g in 1 mL
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Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
cyclomethicone 5 (UNII: 0THT5PCI0R)	
dimethicone (UNII: 92RU3N3Y1O)	
peg/ppg-18/18 dimethicone (UNII: 9H0AO7T794)	
cyclomethicone 6 (UNII: XHK3U310BA)	
sodium chloride (UNII: 451W47IQ8X)	
bis-peg-18 methyl ether dimethyl silane (UNII: OEB4R3WW9C)	
peg/ppg-19/19 dimethicone (UNII: EHH90CO7TL)	
glycerin (UNII: PDC6A3C0OX)	
oleth-5 (UNII: 1GH33785AY)	
phenyl trimethicone (UNII: DR0K5NOJ4R)	
propylene glycol (UNII: 6DC9Q167V3)	
mica (UNII: V8A1AW0880)	
methylparaben (UNII: A2I8C7HI9T)	
triethoxycaprylsilane (UNII: LDC331P08E)	
propylparaben (UNII: Z8IX2SC1OH)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	
phenoxyethanol (UNII: HIE492ZZ3T)	
butylparaben (UNII: 3QPII1U3FV8)	
ethylparaben (UNII: 14255EXE39)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
isobutylparaben (UNII: 0QQJ25X58G)	
titanium dioxide (UNII: 15FIX9V2JP)	
ferric oxide red (UNII: 1K09F3G675)	
bismuth oxychloride (UNII: 4ZR792I587)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-270-18	1 in 1 BOX		
1	NDC:13537-270-17	30 mL in 1 BOTTLE, PLASTIC		
2	NDC:13537-270-20	1 in 1 BOX		
2	NDC:13537-270-19	3 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	12/16/2013	

LBEL MAXIMUM COMFORT AND LONG-LASTING FOUNDATION SPF 10 (MEDIUM 6) - BROWN

zinc oxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-271
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.016 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
cyclomethicone 5 (UNII: 0THT5PCI0R)	
dimethicone (UNII: 92RU3N3Y1O)	
peg/ppg-18/18 dimethicone (UNII: 9H0AO7T794)	
cyclomethicone 6 (UNII: XHK3U310BA)	
sodium chloride (UNII: 451W47IQ8X)	
bis-peg-18 methyl ether dimethyl silane (UNII: OEB4R3WW9C)	
peg/ppg-19/19 dimethicone (UNII: EHH90CO7TL)	
glycerin (UNII: PDC6A3C0OX)	
oleth-5 (UNII: 1GH33785AY)	
phenyl trimethicone (UNII: DR0K5NOJ4R)	
propylene glycol (UNII: 6DC9Q167V3)	
mica (UNII: V8A1AW0880)	
methylparaben (UNII: A2B8C7HI9T)	
triethoxycaprylsilane (UNII: LDC331P08E)	
propylparaben (UNII: Z8IX2SC1OH)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	
phenoxyethanol (UNII: HIE492ZZ3T)	
butylparaben (UNII: 3QPIU3FV8)	
ethylparaben (UNII: 14255EXE39)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
isobutylparaben (UNII: 0QQJ25X58G)	
titanium dioxide (UNII: 15FIX9V2JP)	
ferric oxide red (UNII: 1K09F3G675)	
bismuth oxychloride (UNII: 4ZR792I587)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-271-22	1 in 1 BOX		
1	NDC:13537-271-21	30 mL in 1 BOTTLE, PLASTIC		
2	NDC:13537-271-24	1 in 1 BOX		
2	NDC:13537-271-23	3 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	12/16/2013	

LBEL MAXIMUM COMFORT AND LONG-LASTING FOUNDATION SPF 10 (MEDIUM 7) - BROWN

zinc oxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-272
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.016 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
cyclomethicone 5 (UNII: 0THT5PCI0R)	
dimethicone (UNII: 92RU3N3Y1O)	
peg/ppg-18/18 dimethicone (UNII: 9H0AO7T794)	
cyclomethicone 6 (UNII: XHK3U310BA)	
sodium chloride (UNII: 451W47IQ8X)	
bis-peg-18 methyl ether dimethyl silane (UNII: OEB4R3WW9C)	
peg/ppg-19/19 dimethicone (UNII: EHH90CO7TL)	
glycerin (UNII: PDC6A3C0OX)	
oleth-5 (UNII: 1GH33785AY)	
phenyl trimethicone (UNII: DR0K5NOJ4R)	
propylene glycol (UNII: 6DC9Q167V3)	
mica (UNII: V8A1AW0880)	
methylparaben (UNII: A2I8C7HI9T)	
triethoxycaprylylsilane (UNII: LDC331P08E)	
propylparaben (UNII: Z8IX2SC1OH)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	
phenoxyethanol (UNII: HIE492ZZ3T)	
butylparaben (UNII: 3QPII1U3FV8)	
ethylparaben (UNII: 14255EXE39)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
isobutylparaben (UNII: 0QQJ25X58G)	
titanium dioxide (UNII: 15FIX9V2JP)	
ferric oxide red (UNII: 1K09F3G675)	
bismuth oxychloride (UNII: 4ZR792I587)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-272-26	1 in 1 BOX		
1	NDC:13537-272-25	30 mL in 1 BOTTLE, PLASTIC		
2	NDC:13537-272-28	1 in 1 BOX		
2	NDC:13537-272-27	3 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	12/16/2013	

LBEL MAXIMUM COMFORT AND LONG-LASTING FOUNDATION SPF 10 (OBSCURE 8) - BROWN

zinc oxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-273
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.016 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
cyclomethicone 5 (UNII: 0THT5PCI0R)	
dimethicone (UNII: 92RU3N3Y1O)	
peg/ppg-18/18 dimethicone (UNII: 9H0AO7T794)	
cyclomethicone 6 (UNII: XHK3U310BA)	
sodium chloride (UNII: 451W47IQ8X)	
bis-peg-18 methyl ether dimethyl silane (UNII: OEB4R3WW9C)	
peg/ppg-19/19 dimethicone (UNII: EHH90CO7TL)	
glycerin (UNII: PDC6A3C0OX)	
oleth-5 (UNII: 1GH33785AY)	
phenyl trimethicone (UNII: DR0K5NOJ4R)	
propylene glycol (UNII: 6DC9Q167V3)	
mica (UNII: V8A1AW0880)	
methylparaben (UNII: A2I8C7HI9T)	
triethoxycaprylsilane (UNII: LDC331P08E)	
propylparaben (UNII: Z8IX2SC1OH)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	

phenoxyethanol (UNII: HIE492ZZ3T)	
butylparaben (UNII: 3QPHU3FV8)	
ethylparaben (UNII: 14255EXE39)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
isobutylparaben (UNII: 0QQJ25X58G)	
titanium dioxide (UNII: 15FIX9V2JP)	
ferric oxide red (UNII: 1K09F3G675)	
bismuth oxychloride (UNII: 4ZR792I587)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-273-30	1 in 1 BOX		
1	NDC:13537-273-29	30 mL in 1 BOTTLE, PLASTIC		
2	NDC:13537-273-32	1 in 1 BOX		
2	NDC:13537-273-31	3 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	12/16/2013	

LBEL MAXIMUM COMFORT AND LONG-LASTING FOUNDATION SPF 10 (OBSCURE 9) - BROWN

zinc oxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-274
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.016 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
cyclomethicone 5 (UNII: 0THT5PCI0R)	
dimethicone (UNII: 92RU3N3Y1O)	
peg/ppg-18/18 dimethicone (UNII: 9H0AO7T794)	
cyclomethicone 6 (UNII: XHK3U310BA)	
sodium chloride (UNII: 451W47IQ8X)	
bis-peg-18 methyl ether dimethyl silane (UNII: OEB4R3WW9C)	
peg/ppg-19/19 dimethicone (UNII: EHH90CO7TL)	

glycerin (UNII: PDC6A3C0OX)
oleth-5 (UNII: 1GH33785AY)
phenyl trimethicone (UNII: DR0K5NOJ4R)
propylene glycol (UNII: 6DC9Q167V3)
mica (UNII: V8A1AW0880)
methylparaben (UNII: A2I8C7HI9T)
triethoxycaprylylsilane (UNII: LDC331P08E)
propylparaben (UNII: Z8IX2SC1OH)
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)
phenoxyethanol (UNII: HIE492ZZ3T)
butylparaben (UNII: 3QPIIU3FV8)
ethylparaben (UNII: 14255EXE39)
silicon dioxide (UNII: ETJ7Z6XBU4)
isobutylparaben (UNII: 0QQJ25X58G)
titanium dioxide (UNII: 15FIX9V2JP)
ferric oxide red (UNII: 1K09F3G675)
bismuth oxychloride (UNII: 4ZR792I587)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-274-34	1 in 1 BOX		
1	NDC:13537-274-33	30 mL in 1 BOTTLE, PLASTIC		
2	NDC:13537-274-36	1 in 1 BOX		
2	NDC:13537-274-35	3 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	12/16/2013	

Labeler - Ventura Corporation LTD (602751344)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(13537-266, 13537-267, 13537-268, 13537-269, 13537-270, 13537-271, 13537-272, 13537-273, 13537-274)