

**LBEL CLARITE CLARIFYING EFFECT FOUNDATION SPF 30 CLAIRE 1/BEIGE-
octinoxate and zinc oxide liquid**
**LBEL CLARITE CLARIFYING EFFECT FOUNDATION SPF 30 CLAIRE 2/BEIGE-
octinoxate and zinc oxide liquid**
**LBEL CLARITE CLARIFYING EFFECT FOUNDATION SPF 30 CLAIRE 3/BEIGE-
octinoxate and zinc oxide liquid**
**LBEL CLARITE CLARIFYING EFFECT FOUNDATION SPF 30 CLAIRE 4/BEIGE-
octinoxate and zinc oxide liquid**
**LBEL CLARITE CLARIFYING EFFECT FOUNDATION SPF 30 CLAIRE 5/BEIGE-
octinoxate and zinc oxide liquid**
**LBEL CLARITE CLARIFYING EFFECT FOUNDATION SPF 30 CLAIRE 6/BEIGE-
octinoxate and zinc oxide liquid**
**LBEL CLARITE CLARIFYING EFFECT FOUNDATION SPF 30 CLAIRE 7/BEIGE-
octinoxate and zinc oxide liquid**
**LBEL CLARITE CLARIFYING EFFECT FOUNDATION SPF 30 CLAIRE 8/BEIGE-
octinoxate and zinc oxide liquid**
**LBEL CLARITE CLARIFYING EFFECT FOUNDATION SPF 30 CLAIRE 9/BROWN-
octinoxate and zinc oxide liquid**
Ventura International 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.

LBEL Clarité Clarifying Effect Foundation SPF 30

Drug Facts

<i>Active Ingredients</i>	<i>Purpose</i>
OCTINOXATE 7.50 %	Sunscreen
ZINC OXIDE 7.84 %	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

Other information

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

Inactive ingredients

Dimethicone, mica, zea mays (corn) starch, ozokerite, polyethylene, silica dimethyl silylate, peg/ppg-18/18 dimethicone, copernicia cerifera (carnauba) wax, kojic dipalmitate, cetyl peg/ppg-10/1 dimethicone, polyglyceryl-4 isostearate, hexyl laurate, phenoxyethanol, triethoxycaprylylsilane, caprylyl glycol, chlorphenesin, fragante, glycyrrhiza glabra (licorice) root extract, trimethylsiloxysilicate, dimethylmethoxy chromanyl palmitato, citronellol, butylphenyl methylpropional, hydroxycitronellal, hexyl cinnamal, d-limonene, hydroxyisohexyl 3-cyclohexene carboxaldehyde, alpha-isomethyl ionone.

May Contain: titanium dioxide, iron oxides.

Dist. by Ventura Int Ltd. DBA Belcorp USA, Miami, FL 33126.

PRINCIPAL DISPLAY PANEL - 9 g Container Box - Claire 1/Beige

L'BEL

CLARITÉ

Clarifying effect foundation SPF 30

Net Wt. 0.31 oz. e (9 g)



L'BEL

CLARITÉ

Clarifying effect foundation SPF 30

Net Wt. 0.31 oz. e (9 g)

Drug Facts

Active Ingredients

Purpose

Octinoxate 7.50 % Sunscreen
Zinc oxide 7.84 % Sunscreen

Uses: ■ Helps prevent sunburn. ▼

Drug Facts (continued)

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.

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Other information: ■ Protect the product in this container from excessive heat and direct sun.

Inactive ingredients: Dimethicone, mica, zea mays (corn) starch, ozokerite, polyethylene, silica dimethyl silylate, peg/ppg-18/18 dimethicone, copernicia cerifera (carnauba) wax, kollico dipalmitate, cetyl peg/ppg-10/1 dimethicone, polyglyceryl-4 isostearate, hexyl laurate, phenoxylethanol, triethoxycaprylsilane, caprylyl glycol, chlorphenesin, fragrance, glyceryliza glabra (licorice) root extract, trimethylsilyloxydiclate, dimethylmethoxy chromanyl palmitate, citronellol, butylphenyl methylpropional, hydroxycitronellal, hexyl cinnamal, dl-limonene, hydroxyisohexyl 3-cyclohexene carboxaldehyde, alpha-isomethyl ionone. **May Contain:** titanium dioxide, iron oxides.

U.S.A.: Dist. by Ventura Int. Ltd, DBA Balcorp USA, Miami, FL 33128, Made in Colombia, PUERTO RICO: Dist. by Ventura Corp. Ltd., San Juan, Puerto Rico 00926, Made in Colombia.

PRINCIPAL DISPLAY PANEL - 9 g Container Box - Claire 2/Beige

L'BEL

CLARITÉ

Clarifying effect foundation SPF 30

Net Wt. 0.31 oz. e (9 g)



L'BEL

CLARITÉ

Clarifying effect foundation SPF 30

Net Wt. 0.31 oz. e (9 g)

Drug Facts

Active Ingredients

Purpose

Octinoxate 7.50 % Sunscreen
Zinc oxide 7.84 % Sunscreen

Uses: ■ Helps prevent sunburn. ▼

Drug Facts (continued)

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.

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Other information: ■ Protect the product in this container from excessive heat and direct sun.

Inactive ingredients: Dimethicone, mica, zea mays (corn) starch, ozokerite, polyethylene, silica dimethyl silylate, peg/ppg-18/18 dimethicone, copernicia cerifera (carnauba) wax, kollico dipalmitate, cetyl peg/ppg-10/1 dimethicone, polyglyceryl-4 isostearate, hexyl laurate, phenoxylethanol, triethoxycaprylsilane, caprylyl glycol, chlorphenesin, fragrance, glyceryliza glabra (licorice) root extract, trimethylsilylosilicate, dimethylmethoxy chromanyl palmitate, citronellol, butylphenyl methylpropional, hydroxycitronellal, hexyl cinnamal, dl-limonene, hydroxyisohexyl 3-cyclohexene carboxaldehyde, alpha-isomethyl ionone. **May Contain:** titanium dioxide, iron oxides.

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PRINCIPAL DISPLAY PANEL - 9 g Container Box - Claire 3/Beige

L'BEL

CLARITÉ

Clarifying effect foundation SPF 30

Net Wt. 0.31 oz. e (9 g)



L'BEL

CLARITÉ

Clarifying effect foundation SPF 30

Net Wt. 0.31 oz. e (9 g)

Drug Facts

Active Ingredients

Purpose

Octinoxate 7.50 % Sunscreen
Zinc oxide 7.84 % Sunscreen

Uses: ■ Helps prevent sunburn. ▼

Drug Facts (continued)

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.

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Inactive ingredients: Dimethicone, mica, zea mays (corn) starch, ozokerite, polyethylene, silica dimethyl silylate, peg/ppg-18/18 dimethicone, copernicia cerifera (carnauba) wax, kollico dipalmitate, cetyl peg/ppg-10/1 dimethicone, polyglyceryl-4 isostearate, hexyl laurate, phenoxylethanol, triethoxycaprylsilane, caprylyl glycol, chlorphenesin, fragrance, glyceryliza glabra (licorice) root extract, trimethylsilyloxyoctyl dimethylmethoxy chromanyl palmitate, citronellol, butylphenyl methylpropional, hydroxycitronellal, hexyl cinnamal, dl-limonene, hydroxyisohexyl 3-cyclohexene carboxaldehyde, alpha-isomethyl ionone. **May Contain:** titanium dioxide, iron oxides.

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PRINCIPAL DISPLAY PANEL - 9 g Container Box - Claire 4/Beige

L'BEL

CLARITÉ

Clarifying effect foundation SPF 30

Net Wt. 0.31 oz. e (9 g)



L'BEL

CLARITÉ

Clarifying effect foundation SPF 30

Net Wt. 0.31 oz. e (9 g)

Drug Facts

Active Ingredients

Purpose

Octinoxate 7.50 % Sunscreen
Zinc oxide 7.84 % Sunscreen

Uses: ■ Helps prevent sunburn. ▼

Drug Facts (continued)

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.

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Other information: ■ Protect the product in this container from excessive heat and direct sun.

Inactive ingredients: Dimethicone, mica, zea mays (corn) starch, ozokerite, polyethylene, silica dimethyl silylate, peg/ppg-18/18 dimethicone, copernicia cerifera (carnauba) wax, kollico dipalmitate, cetyl peg/ppg-10/1 dimethicone, polyglyceryl-4 isostearate, hexyl laurate, phenoxylethanol, triethoxycaprylsilane, caprylyl glycol, chlorphenesin, fragrance, glyceryliza glabra (licorice) root extract, trimethylsilyloxydiclate, dimethylmethoxy chromanyl palmitate, citronellol, butylphenyl methylpropional, hydroxycitronellal, hexyl cinnamal, d-limonene, hydroxyisohexyl 3-cyclohexene carboxaldehyde, alpha-isomethyl ionone. **May Contain:** titanium dioxide, iron oxides.

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PRINCIPAL DISPLAY PANEL - 9 g Container Box - Claire 5/Beige

L'BEL

CLARITÉ

Clarifying effect foundation SPF 30

Net Wt. 0.31 oz. e (9 g)



L'BEL

CLARITÉ

Clarifying effect foundation SPF 30

Net Wt. 0.31 oz. e (9 g)

Drug Facts

Active Ingredients

Purpose

Octinoxate 7.50 % Sunscreen
Zinc oxide 7.84 % Sunscreen

Uses: ■ Helps prevent sunburn. ▼

Drug Facts (continued)

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.

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PRINCIPAL DISPLAY PANEL - 9 g Container Box - Claire 6/Beige

L'BEL

CLARITÉ

Clarifying effect foundation SPF 30

Net Wt. 0.31 oz. e (9 g)



L'BEL

CLARITÉ

Clarifying effect foundation SPF 30

Net Wt. 0.31 oz. e (9 g)

Drug Facts

Active Ingredients

Purpose

Octinoxate 7.50 % Sunscreen
Zinc oxide 7.84 % Sunscreen

Uses: ■ Helps prevent sunburn. ▼

Drug Facts (continued)

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.

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Inactive ingredients: Dimethicone, mica, zea mays (corn) starch, ozokerite, polyethylene, silica dimethyl silylate, peg/ppg-18/18 dimethicone, copernicia cerifera (carnauba) wax, kollico dipalmitate, cetyl peg/ppg-10/1 dimethicone, polyglyceryl-4 isostearate, hexyl laurate, phenoxylethanol, triethoxycaprylsilane, caprylyl glycol, chlorphenesin, fragrance, glyceryliza glabra (licorice) root extract, trimethylsilyloxyoctyl dimethylmethoxy chromanyl palmitate, citronellol, butylphenyl methylpropional, hydroxycitronellal, hexyl cinnamal, dl-limonene, hydroxyisohexyl 3-cyclohexene carboxaldehyde, alpha-isomethyl ionone. **May Contain:** titanium dioxide, iron oxides.

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PRINCIPAL DISPLAY PANEL - 9 g Container Box - Claire 7/Beige

L'BEL

CLARITÉ

Clarifying effect foundation SPF 30

Net Wt. 0.31 oz. e (9 g)



L'BEL

CLARITÉ

Clarifying effect foundation SPF 30

Net Wt. 0.31 oz. e (9 g)

Drug Facts

Active Ingredients

Purpose

Octinoxate 7.50 % Sunscreen
Zinc oxide 7.84 % Sunscreen

Uses: ■ Helps prevent sunburn. ▼

Drug Facts (continued)

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.

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Inactive ingredients: Dimethicone, mica, zea mays (corn) starch, ozokerite, polyethylene, silica dimethyl silylate, peg/ppg-18/18 dimethicone, copernicia cerifera (carnauba) wax, kollico dipalmitate, cetyl peg/ppg-10/1 dimethicone, polyglyceryl-4 isostearate, hexyl laurate, phenoxylethanol, triethoxycaprylsilane, caprylyl glycol, chlorphenesin, fragrance, glyceryliza glabra (licorice) root extract, trimethylsilyloxydiclate, dimethylmethoxy chromanyl palmitate, citronellol, butylphenyl methylpropional, hydroxycitronellal, hexyl cinnamal, dl-limonene, hydroxyisohexyl 3-cyclohexene carboxaldehyde, alpha-isomethyl ionone. **May Contain:** titanium dioxide, iron oxides.

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PRINCIPAL DISPLAY PANEL - 9 g Container Box - Claire 8/Beige

L'BEL

CLARITÉ

Clarifying effect foundation SPF 30

Net Wt. 0.31 oz. e (9 g)



L'BEL

CLARITÉ

Clarifying effect foundation SPF 30

Net Wt. 0.31 oz. e (9 g)

Drug Facts

Active Ingredients

Purpose

Octinoxate 7.50% Sunscreen
Zinc oxide 7.84% Sunscreen

Uses: ■ Helps prevent sunburn. ▼

Drug Facts (continued)

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.

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PRINCIPAL DISPLAY PANEL - 9 g Container Box - Claire 9/Brown

L'BEL

CLARITÉ

Clarifying effect foundation SPF 30

Net Wt. 0.31 oz. e (9 g)



L'BEL

CLARITÉ

Clarifying effect foundation SPF 30

Net Wt. 0.31 oz. e (9 g)



LBL CLARITE CLARIFYING EFFECT FOUNDATION SPF 30 CLAIRE 1/BEIGE

octinoxate and zinc oxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-213
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.075 g in 1g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.0784 g in 1g

Inactive Ingredients

Ingredient Name	Strength
Dimethicone (UNII: 92RU3N3Y1O)	
mica (UNII: V8A1AW0880)	
starch, corn (UNII: O8232NY3SJ)	
high density polyethylene (UNII: UG00KM4WR7)	
silica dimethyl silylate (UNII: EU2PSP0G0W)	
peg/ppg-18/18 dimethicone (UNII: 9H0AO7T794)	
carnauba wax (UNII: R12CBM0EIZ)	
kojic dipalmitate (UNII: 13N249RWTM)	
polyglyceryl-4 isostearate (UNII: 820DPX33S7)	
hexyl laurate (UNII: 4CG9F9W01Q)	
phenoxyethanol (UNII: HIE492ZZ3T)	
triethoxycaprylsilane (UNII: LDC331P08E)	
caprylyl glycol (UNII: 00YIU5438U)	
chlorphenesin (UNII: I670DAL4SZ)	
licorice (UNII: 61ZBX54883)	
dimethylmethoxy chromanyl palmitate (UNII: 5G222ZDK7U)	
.beta.-citronellool, (R)- (UNII: P01OUT964K)	
butylphenyl methylpropional (UNII: T7540GJV69)	
hydroxycitronellal (UNII: 8SQ0VA4YUR)	
.alpha.-hexylcinnamaldehyde (UNII: 7X6O37OK2I)	
limonene, (+)- (UNII: GFD7C86Q1W)	
hydroxyisohexyl 3-cyclohexene carboxaldehyde (UNII: QUE43B9Z2Q)	
isomethyl-.alpha.-ionone (UNII: 9XP4LC555B)	
titanium dioxide (UNII: 15FIX9V2JP)	
ferric oxide red (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-213-02	1 in 1 BOX	12/26/2018	
1	NDC:14783-213-01	9 g in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	12/26/2018	

LBEL CLARITE CLARIFYING EFFECT FOUNDATION SPF 30 CLAIRE 2/BEIGE

octinoxate and zinc oxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-214
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Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.075 g in 1 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.0784 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
Dimethicone (UNII: 92RU3N3Y1O)	
mica (UNII: V8A1AW0880)	
starch, corn (UNII: O8232NY3SJ)	
high density polyethylene (UNII: UG00KM4WR7)	
silica dimethyl silylate (UNII: EU2PSP0G0W)	
peg/ppg-18/18 dimethicone (UNII: 9H0AO7T794)	
carnauba wax (UNII: R12CBM0EIZ)	
kojic dipalmitate (UNII: 13N249RWTM)	
polyglyceryl-4 isostearate (UNII: 820DPX33S7)	
hexyl laurate (UNII: 4CG9F9W01Q)	
phenoxyethanol (UNII: HIE492ZZ3T)	
triethoxycaprylylsilane (UNII: LDC331P08E)	
caprylyl glycol (UNII: 00YIU5438U)	
chlorphenesin (UNII: I670DAL4SZ)	
licorice (UNII: 61ZBX54883)	
dimethylmethoxy chromanyl palmitate (UNII: 5G222ZDK7U)	
.beta.-citronellool, (R)- (UNII: P01OUT964K)	
butylphenyl methylpropional (UNII: T7540GJV69)	
hydroxycitronellal (UNII: 8SQ0VA4YUR)	
.alpha.-hexylcinnamaldehyde (UNII: 7X6O37OK2I)	
limonene, (+)- (UNII: GFD7C86Q1W)	
hydroxyisohexyl 3-cyclohexene carboxaldehyde (UNII: QUE43B9Z2Q)	
isomethyl-.alpha.-ionone (UNII: 9XP4LC555B)	
titanium dioxide (UNII: 15FIX9V2JP)	
ferric oxide red (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-214-02	1 in 1 BOX	12/26/2018	
1	NDC:14783-214-01	9 g in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	12/26/2018	

LBEL CLARITE CLARIFYING EFFECT FOUNDATION SPF 30 CLAIRE 3/BEIGE

octinoxate and zinc oxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-215
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.075 g in 1 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.0784 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
Dimethicone (UNII: 92RU3N3Y1O)	
mica (UNII: V8A1AW0880)	
starch, corn (UNII: O8232NY3SJ)	
high density polyethylene (UNII: UG00KM4WR7)	
silica dimethyl silylate (UNII: EU2PSP0G0W)	
peg/ppg-18/18 dimethicone (UNII: 9H0AO7T794)	
carnauba wax (UNII: R12CBM0EIZ)	
kojic dipalmitate (UNII: 13N249RWTM)	
polyglyceryl-4 isostearate (UNII: 820DPX33S7)	
hexyl laurate (UNII: 4CG9F9W01Q)	
phenoxyethanol (UNII: HIE492ZZ3T)	
triethoxycaprylylsilane (UNII: LDC331P08E)	
caprylyl glycol (UNII: 00YIU5438U)	
chlorphenesin (UNII: I670DAL4SZ)	
licorice (UNII: 61ZBX54883)	
dimethylmethoxy chromanyl palmitate (UNII: 5G222ZDK7U)	
.beta.-citronellol, (R)- (UNII: P01OUT964K)	
butylphenyl methylpropional (UNII: T7540GJV69)	
hydroxycitronellal (UNII: 8SQ0VA4YUR)	
.alpha.-hexylcinnamaldehyde (UNII: 7X6O37OK2I)	
limonene, (+)- (UNII: GFD7C86Q1W)	
hydroxyisohexyl 3-cyclohexene carboxaldehyde (UNII: QUE43B9Z2Q)	
isomethyl-.alpha.-ionone (UNII: 9XP4LC555B)	
titanium dioxide (UNII: 15FIX9V2JP)	
ferric oxide red (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:14783-215-02	1 in 1 BOX	12/26/2018	
1	NDC:14783-215-01	9 g in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	12/26/2018	

LBEL CLARITE CLARIFYING EFFECT FOUNDATION SPF 30 CLAIRE 4/BEIGE

octinoxate and zinc oxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-217
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.075 g in 1 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.0784 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
Dimethicone (UNII: 92RU3N3Y1O)	
mica (UNII: V8A1AW0880)	
starch, corn (UNII: O8232NY3SJ)	
high density polyethylene (UNII: UG00KM4WR7)	
silica dimethyl silylate (UNII: EU2PSP0G0W)	
peg/ppg-18/18 dimethicone (UNII: 9H0AO7T794)	
carnauba wax (UNII: R12CBM0EIZ)	
kojic dipalmitate (UNII: 13N249RWTM)	
polyglyceryl-4 isostearate (UNII: 820DPX33S7)	
hexyl laurate (UNII: 4CG9F9W01Q)	
phenoxyethanol (UNII: HIE492ZZ3T)	
triethoxycaprylylsilane (UNII: LDC331P08E)	
caprylyl glycol (UNII: 00YIU5438U)	
chlorphenesin (UNII: I670DAL4SZ)	
licorice (UNII: 61ZBX54883)	
dimethylmethoxy chromanyl palmitate (UNII: 5G222ZDK7U)	
.beta.-citronellol, (R)- (UNII: P01OUT964K)	
butylphenyl methylpropional (UNII: T7540GJV69)	
hydroxycitronellal (UNII: 8SQ0VA4YUR)	
.alpha.-hexylcinnamaldehyde (UNII: 7X6O37OK2I)	
limonene, (+)- (UNII: GFD7C86Q1W)	

hydroxyisohexyl 3-cyclohexene carboxaldehyde (UNII: QUE43B9Z2Q)	
isomethyl-.alpha.-ionone (UNII: 9XP4LC555B)	
titanium dioxide (UNII: 15FIX9V2JP)	
ferric oxide red (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-217-02	1 in 1 BOX	12/26/2018	
1	NDC:14783-217-01	9 g in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	12/26/2018	

LBEL CLARITE CLARIFYING EFFECT FOUNDATION SPF 30 CLAIRE 5/BEIGE

octinoxate and zinc oxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-218
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.075 g in 1 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.0784 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
Dimethicone (UNII: 92RU3N3Y1O)	
mica (UNII: V8A1AW0880)	
starch, corn (UNII: O8232NY3SJ)	
high density polyethylene (UNII: UG00KM4WR7)	
silica dimethyl silylate (UNII: EU2PSP0G0W)	
peg/ppg-18/18 dimethicone (UNII: 9H0AO7T794)	
carnauba wax (UNII: R12CBM0EIZ)	
kojic dipalmitate (UNII: 13N249RWTM)	
polyglyceryl-4 isostearate (UNII: 820DPX33S7)	
hexyl laurate (UNII: 4CG9F9W01Q)	
phenoxyethanol (UNII: HIE492ZZ3T)	
triethoxycaprylylsilane (UNII: LDC331P08E)	
caprylyl glycol (UNII: 00YIU5438U)	

chlorphenesin (UNII: I670DAL4SZ)
licorice (UNII: 61ZBX54883)
dimethylmethoxy chromanyl palmitate (UNII: 5G222ZDK7U)
.beta.-citronellol, (R)- (UNII: P01OUT964K)
butylphenyl methylpropional (UNII: T7540GJV69)
hydroxycitronellal (UNII: 8SQ0VA4YUR)
.alpha.-hexylcinnamaldehyde (UNII: 7X6O37OK2I)
limonene, (+)- (UNII: GFD7C86Q1W)
hydroxyisohexyl 3-cyclohexene carboxaldehyde (UNII: QUE43B9Z2Q)
isomethyl-.alpha.-ionone (UNII: 9XP4LC555B)
titanium dioxide (UNII: 15FIX9V2JP)
ferric oxide red (UNII: 1K09F3G675)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-218-02	1 in 1 BOX	12/26/2018	
1	NDC:14783-218-01	9 g in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	12/26/2018	

LBEL CLARITE CLARIFYING EFFECT FOUNDATION SPF 30 CLAIRE 6/BEIGE

octinoxate and zinc oxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-219
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.075 g in 1 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.0784 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
Dimethicone (UNII: 92RU3N3Y1O)	
mica (UNII: V8A1AW0880)	
starch, corn (UNII: O8232NY3SJ)	
high density polyethylene (UNII: UG00KM4WR7)	

silica dimethyl silylate (UNII: EU2PSP0G0W)
peg/ppg-18/18 dimethicone (UNII: 9H0AO7T794)
carnauba wax (UNII: R12CBM0EIZ)
kojic dipalmitate (UNII: 13N249RWTM)
polyglyceryl-4 isostearate (UNII: 820DPX33S7)
hexyl laurate (UNII: 4CG9F9W01Q)
phenoxyethanol (UNII: HIE492ZZ3T)
triethoxycaprylylsilane (UNII: LDC331P08E)
caprylyl glycol (UNII: 00YIU5438U)
chlorphenesin (UNII: I670DAL4SZ)
licorice (UNII: 61ZBX54883)
dimethylmethoxy chromanyl palmitate (UNII: 5G222ZDK7U)
.beta.-citronellol, (R)- (UNII: P01OUT964K)
butylphenyl methylpropional (UNII: T7540GJV69)
hydroxycitronellal (UNII: 8SQ0VA4YUR)
.alpha.-hexylcinnamaldehyde (UNII: 7X6O37OK2I)
limonene, (+)- (UNII: GFD7C86Q1W)
hydroxyisohexyl 3-cyclohexene carboxaldehyde (UNII: QUE43B9Z2Q)
isomethyl-.alpha.-ionone (UNII: 9XP4LC555B)
titanium dioxide (UNII: 15FIX9V2JP)
ferric oxide red (UNII: 1K09F3G675)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-219-02	1 in 1 BOX	12/26/2018	
1	NDC:14783-219-01	9 g in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	12/26/2018	

LBEL CLARITE CLARIFYING EFFECT FOUNDATION SPF 30 CLAIRE 7/BEIGE

octinoxate and zinc oxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-220
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.075 g in 1 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.0784 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
Dimethicone (UNII: 92RU3N3Y1O)	
mica (UNII: V8A1AW0880)	
starch, corn (UNII: O8232NY3SJ)	
high density polyethylene (UNII: UG00KM4WR7)	
silica dimethyl silylate (UNII: EU2PSP0G0W)	
peg/ppg-18/18 dimethicone (UNII: 9H0AO7T794)	
carnauba wax (UNII: R12CBM0EIZ)	
kojic dipalmitate (UNII: 13N249RWTM)	
polyglyceryl-4 isostearate (UNII: 820DPX33S7)	
hexyl laurate (UNII: 4CG9F9W01Q)	
phenoxyethanol (UNII: HIE492ZZ3T)	
triethoxycaprylylsilane (UNII: LDC331P08E)	
caprylyl glycol (UNII: 00YIU5438U)	
chlorphenesin (UNII: I670DAL4SZ)	
licorice (UNII: 61ZBX54883)	
dimethylmethoxy chromanyl palmitate (UNII: 5G222ZDK7U)	
.beta.-citronellol, (R)- (UNII: P01OUT964K)	
butylphenyl methylpropional (UNII: T7540GJV69)	
hydroxycitronellal (UNII: 8SQ0VA4YUR)	
.alpha.-hexylcinnamaldehyde (UNII: 7X6O37OK2I)	
limonene, (+)- (UNII: GFD7C86Q1W)	
hydroxyisohexyl 3-cyclohexene carboxaldehyde (UNII: QUE43B9Z2Q)	
isomethyl-.alpha.-ionone (UNII: 9XP4LC555B)	
titanium dioxide (UNII: 15FIX9V2JP)	
ferric oxide red (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-220-02	1 in 1 BOX	12/26/2018	
1	NDC:14783-220-01	9 g in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	12/26/2018	

LBEL CLARITE CLARIFYING EFFECT FOUNDATION SPF 30 CLAIRE 8/BEIGE

octinoxate and zinc oxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-221
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.075 g in 1 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.0784 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
Dimethicone (UNII: 92RU3N3Y1O)	
mica (UNII: V8A1AW0880)	
starch, corn (UNII: O8232NY3SJ)	
high density polyethylene (UNII: UG00KM4WR7)	
silica dimethyl silylate (UNII: EU2PSP0G0W)	
peg/ppg-18/18 dimethicone (UNII: 9H0AO7T794)	
carnauba wax (UNII: R12CBM0EIZ)	
kojic dipalmitate (UNII: 13N249RWTM)	
polyglyceryl-4 isostearate (UNII: 820DPX33S7)	
hexyl laurate (UNII: 4CG9F9W01Q)	
phenoxyethanol (UNII: HIE492ZZ3T)	
triethoxycaprylylsilane (UNII: LDC331P08E)	
caprylyl glycol (UNII: 00YIU5438U)	
chlorphenesin (UNII: I670DAL4SZ)	
licorice (UNII: 61ZBX54883)	
dimethylmethoxy chromanyl palmitate (UNII: 5G222ZDK7U)	
.beta.-citronellol, (R)- (UNII: P01OUT964K)	
butylphenyl methylpropional (UNII: T7540GJV69)	
hydroxycitronellal (UNII: 8SQ0VA4YUR)	
.alpha.-hexylcinnamaldehyde (UNII: 7X6O37OK2I)	
limonene, (+)- (UNII: GFD7C86Q1W)	
hydroxyisohexyl 3-cyclohexene carboxaldehyde (UNII: QUE43B9Z2Q)	
isomethyl-.alpha.-ionone (UNII: 9XP4LC555B)	
titanium dioxide (UNII: 15FIX9V2JP)	
ferric oxide red (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-221-02	1 in 1 BOX	12/26/2018	
1	NDC:14783-221-01	9 g in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	12/26/2018	

LBEL CLARITE CLARIFYING EFFECT FOUNDATION SPF 30 CLAIRE 9/BROWN

octinoxate and zinc oxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-216
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.075 g in 1 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.0784 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
Dimethicone (UNII: 92RU3N3Y1O)	
mica (UNII: V8A1AW0880)	
starch, corn (UNII: O8232NY3SJ)	
high density polyethylene (UNII: UG00KM4WR7)	
silica dimethyl silylate (UNII: EU2PSP0G0W)	
peg/ppg-18/18 dimethicone (UNII: 9H0AO7T794)	
carnauba wax (UNII: R12CBM0EIZ)	
kojic dipalmitate (UNII: 13N249RWTM)	
polyglyceryl-4 isostearate (UNII: 820DPX33S7)	
hexyl laurate (UNII: 4CG9F9W01Q)	
phenoxyethanol (UNII: HIE492ZZ3T)	
triethoxycaprylylsilane (UNII: LDC331P08E)	
caprylyl glycol (UNII: 00YIU5438U)	
chlorphenesin (UNII: I670DAL4SZ)	
licorice (UNII: 61ZBX54883)	
dimethylmethoxy chromanyl palmitate (UNII: 5G222ZDK7U)	
.beta.-citronellol, (R)- (UNII: P01OUT964K)	
butylphenyl methylpropional (UNII: T7540GJV69)	
hydroxycitronellal (UNII: 8SQ0VA4YUR)	
.alpha.-hexylcinnamaldehyde (UNII: 7X6O37OK2I)	
limonene, (+)- (UNII: GFD7C86Q1W)	
hydroxyisohexyl 3-cyclohexene carboxaldehyde (UNII: QUE43B9Z2Q)	
isomethyl-.alpha.-ionone (UNII: 9XP4LC555B)	
titanium dioxide (UNII: 15FIX9V2JP)	
ferric oxide red (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-216-02	1 in 1 BOX	12/26/2018	
1	NDC:14783-216-01	9 g in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	12/26/2018	

Labeler - Ventura International LTD (603192787)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(14783-213, 14783-214, 14783-215, 14783-217, 14783-218, 14783-219, 14783-220, 14783-221, 14783-216)

Revised: 12/2018

Ventura International LTD