

**CYZONE CY PLAY CREAMY LIP BALM HIDRATANTE EN BARRA PARA LABIOS
24H FPS 12 CORAL CREAMY- octinoxate, zinc oxide stick
CYZONE CY PLAY CREAMY LIP BALM HIDRATANTE EN BARRA PARA LABIOS
24H FPS 12 FUCHSIA CREAMY- octinoxate, zinc oxide stick
CYZONE CY PLAY CREAMY LIP BALM HIDRATANTE EN BARRA PARA LABIOS
24H FPS 12 PINK CREAMY- octinoxate, zinc oxide stick
CYZONE CY PLAY CREAMY LIP BALM HIDRATANTE EN BARRA PARA LABIOS
24H FPS 12 NUDE CREAMY- octinoxate, zinc oxide stick
CYZONE CY PLAY CREAMY LIP BALM HIDRATANTE EN BARRA PARA LABIOS
24H FPS 12 CHERRY CREAMY- octinoxate, zinc oxide stick
CYZONE CY PLAY CREAMY LIP BALM HIDRATANTE EN BARRA PARA LABIOS
24H FPS 12 BERRY CREAMY- octinoxate, zinc oxide stick
BEL STAR S A**

**CYZONE CY PLAY CREAMY LIP BALM HIDRATANTE EN BARRA PARA LABIOS
24H FPS 12**

Active Ingredients

Octinoxate 2.50%

Zinc Oxide 3.92%

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.

Other information

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

Inactive Ingredients

Octyldodecanol, ricinus communis (castor) seed oil, butyrospermum parkii (shea) butter, polyethylene, helianthus annuus (sunflower) seed wax, copernicia cerifera (carnauba) wax, glycerin, dipentaerythrityl hexacaprylate/hexacaprate, vegetable oil, oryza sativa (rice) bran oil, tridecyl trimellitate, olea europaea (olive) oil unsaponifiables, phytosteryl/behenyl/octyldodecyl lauroyl glutamate, oryza sativa (rice) bran wax, rhus succedanea fruit wax, fragrance, tridecyl stearate, disteardimonium hectorite, rhus verniciflua peel wax, shorea robusta resin, neopentyl glycol dicaprylate/dicaprate, phenoxyethanol, cetyl peg/ppg-10/1 dimethicone, polyglyceryl-4 isostearate, lauroyl lysine, hexyl laurate, punica granatum seed oil, prunus avium (sweet cherry) seed oil, pyrus malus (apple) seed oil, vaccinium macrocarpon (cranberry) seed oil, triethoxycaprylylsilane, caprylyl glycol, lecithin, chlorphenesin, water, citrus paradisi (grapefruit) fruit extract, ascorbyl palmitate, tocopherol, citronellol.

May contain:

Mica, titanium dioxide, iron oxides, synthetic fluorphlogopite, red 30 lake, red 7 lake, red 40 lake, talc, red 27 lake, yellow 5 lake, hydrogenated polyisobutene, blue 1 lake, red 21 lake, palmitic acid.

Company Information

PUERTO RICO: Dist. by Ventura Corp, Ltd., San Juan, Puerto Rico 00926. Made in Colombia.

www.cyzone.com

Product Packaging - Fuchsia Creamy

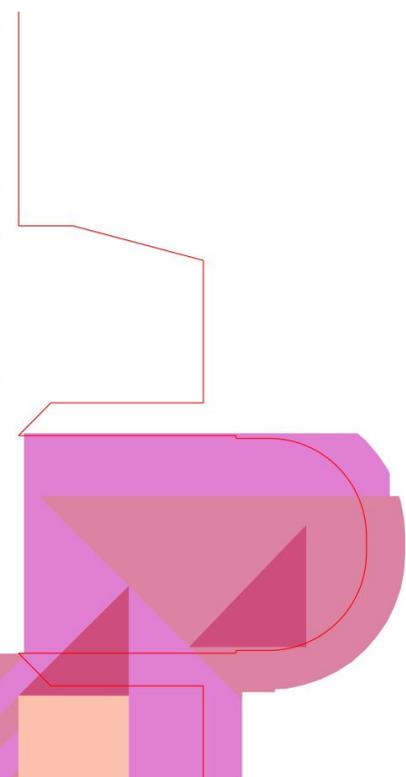
Drug Facts		Warnings ■ Skin Cancer / Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging. ■ For external use only. ■ Do not use on damaged or broken skin. ■ When 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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PUERTO RICO: Dist. by Ventura Corp, Ltd., San Juan, Puerto Rico 00926. Made in Colombia. www.cyzone.com
TONE: FUCHSIA CREAMY

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CREAMY LIP BALM
Hidratante en barra para labios 24H **FPS 12**
3 g | Net Wt. 0.10 oz.



Product Packaging - Pink Creamy

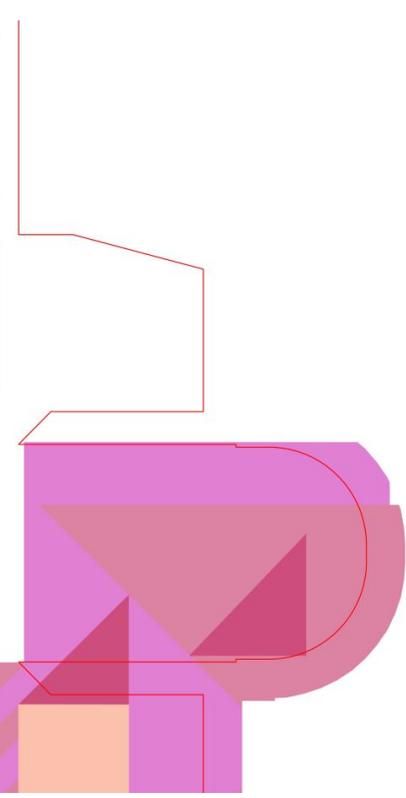
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TONE: PINK CREAMY

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CREAMY LIP BALM
Hidratante en barra para labios 24H **FPS 12**
3 g | Net Wt. 0.10 oz.



Product Packaging - Nude Creamy

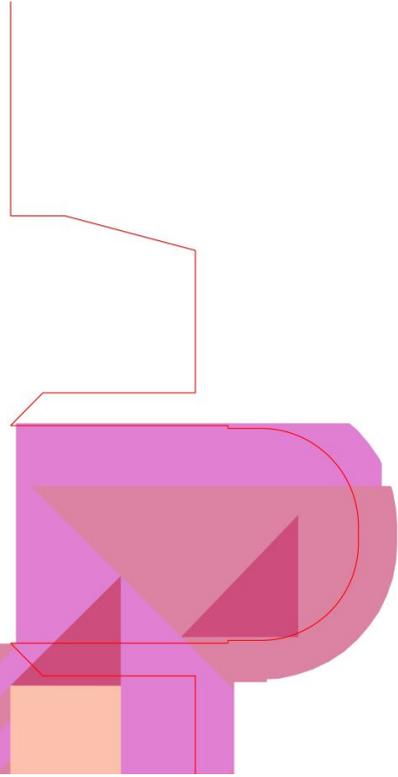
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TONE: NUDE CREAMY

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CREAMY LIP BALM
Hidratante en barra para labios 24H **FPS 12**
3 g | Net Wt. 0.10 oz.



Product Packaging - Coral Creamy

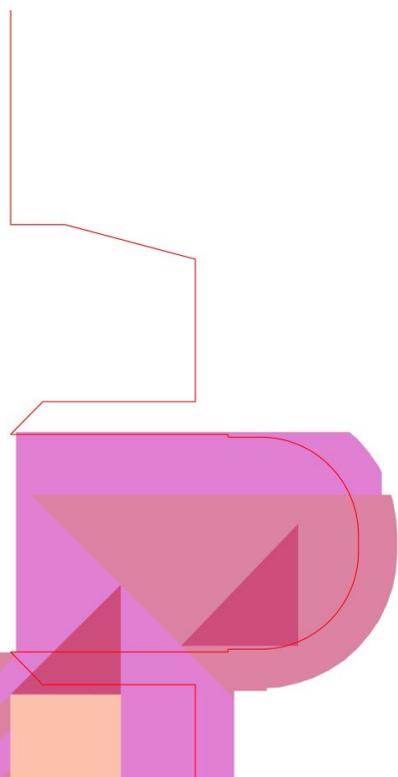
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CREAMY LIP BALM
Hidratante en barra para labios 24H **FPS 12**
3 g | Net Wt. 0.10 oz.



Product Packaging - Berry Creamy

Drug Facts		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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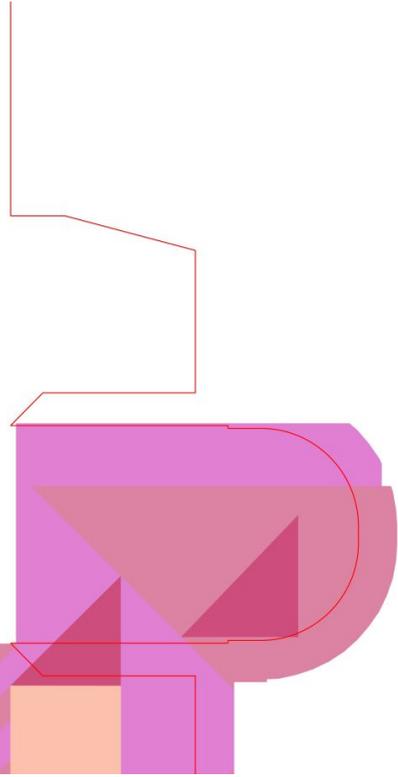
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STONE: BERRY CREAMY

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CREAMY LIP BALM
Hidratante en barra para labios 24H **FPS 12**
3 g | Net Wt. 0.10 oz.



Product Packaging - Cherry Creamy

Drug Facts		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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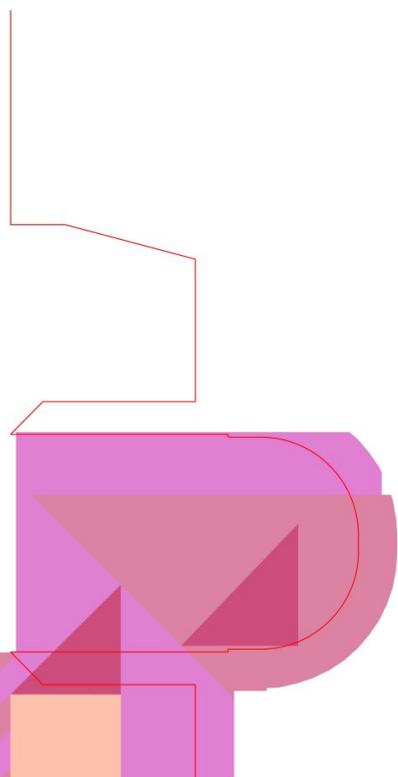
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STONE: CHERRY CREAMY

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CREAMY LIP BALM
Hidratante en barra para labios 24H **FPS 12**
3 g | Net Wt. 0.10 oz.



CYZONE CY PLAY CREAMY LIP BALM HIDRATANTE EN BARRA PARA LABIOS 24H FPS 12 CORAL CREAMY
octinoxate, zinc oxide stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14141-309
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	39.2 mg in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	25 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SHOREA ROBUSTA RESIN (UNII: XUK1106UBO)	
LAUROYL LYSINE (UNII: 113171Q70B)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
GRAPEFRUIT (UNII: O82C39RR8C)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
TOCOPHEROL (UNII: R0ZB2556P8)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CORN OIL (UNII: 8470G57WFM)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
SWEET CHERRY SEED OIL (UNII: 9X3RP3RJFH)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
WATER (UNII: 059QF0KO0R)	
LECITHIN, SUNFLOWER (UNII: 834K0W0S5G)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
GLYCERIN (UNII: PDC6A3C0OX)	
RICE BRAN OIL (UNII: LZ06K1506A)	
OLEA EUROPAEA (OLIVE) OIL UNSAPONIFIABLES (UNII: XO45V955LT)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
PALMITIC ACID (UNII: 2V16EO95H1)	
TALC (UNII: 7SEV7J4R1U)	
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
CRANBERRY SEED OIL (UNII: 73KDS3BW5E)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MAGNESIUM POTASSIUM ALUMINOSILICATE FLUORIDE (UNII: YK3DC63Y5M)	
RICE BRAN (UNII: R60QEP13IC)	

PHENOXYETHANOL (UNII: HIE492ZZ3T)
APPLE SEED OIL (UNII: 9ACA4K9013)
TOXICODENDRON SUCCEDANEUM FRUIT WAX (UNII: 684PA7HRMI)
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)
TOXICODENDRON VERNICIFLUUM FRUIT RIND WAX (UNII: 6RG2461FCH)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
TRIDECYL STEARATE (UNII: A8OE252M6L)
PUNICA GRANATUM SEED OIL (UNII: 0UI45XV0T6)
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)
OCTYLDODECANOL (UNII: 461N1O614Y)
CASTOR OIL (UNII: D5340Y2I9G)
SHEA BUTTER (UNII: K49155WL9Y)
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)
HEXYL LAURATE (UNII: 4CG9F9W01Q)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 ALUMINUM LAKE (UNII: 2M7H5Y5MJP)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14141-309-01	1 in 1 CARTON	10/07/2022	
1		3 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	10/07/2022	

CYZONE CY PLAY CREAMY LIP BALM HIDRATANTE EN BARRA PARA LABIOS 24H FPS 12 FUCHSIA CREAMY

octinoxate, zinc oxide stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14141-306
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	25 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	39.2 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
D&C RED NO. 21 ALUMINUM LAKE (UNII: 2M7H5Y5MJP)	
SHOREA ROBUSTA RESIN (UNII: XUK1106UBO)	
LAUROYL LYSINE (UNII: 113171Q70B)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
GRAPEFRUIT (UNII: O82C39RR8C)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
TOCOPHEROL (UNII: ROZB2556P8)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CORN OIL (UNII: 8470G57WFM)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
SWEET CHERRY SEED OIL (UNII: 9X3RP3RJFH)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
WATER (UNII: 059QF0KO0R)	
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)	
OLEA EUROPAEA (OLIVE) OIL UNSAPONIFIABLES (UNII: XO45V955LT)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
GLYCERIN (UNII: PDC6A3C0OX)	
RICE BRAN OIL (UNII: LZ06K1506A)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
PALMITIC ACID (UNII: 2V16EO95H1)	
TALC (UNII: 7SEV7J4R1U)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
CRANBERRY SEED OIL (UNII: 73KDS3BW5E)	
MAGNESIUM POTASSIUM ALUMINOSILICATE FLUORIDE (UNII: YK3DC63Y5M)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
RICE BRAN (UNII: R60QEP13IC)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
APPLE SEED OIL (UNII: 9ACA4K9013)	
TOXICODENDRON SUCCEDANEUM FRUIT WAX (UNII: 684PA7HRMI)	
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TOXICODENDRON VERNICIFLUUM FRUIT RIND WAX (UNII: 6RG2461FCH)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
PUNICA GRANATUM SEED OIL (UNII: 0UI45XV0T6)	
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)	

CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
CASTOR OIL (UNII: D5340Y2I9G)	
SHEA BUTTER (UNII: K49155WL9Y)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14141-306-01	1 in 1 CARTON	10/07/2022	
1		3 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	10/07/2022	

CYZONE CY PLAY CREAMY LIP BALM HIDRATANTE EN BARRA PARA LABIOS 24H FPS 12 PINK CREAMY

octinoxate, zinc oxide stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14141-307
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	39.2 mg in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	25 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SHOREA ROBUSTA RESIN (UNII: XUK1106UBO)	
LAUROYL LYSINE (UNII: 113171Q70B)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
GRAPEFRUIT (UNII: O82C39RR8C)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
TOCOPHEROL (UNII: R0ZB2556P8)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	

MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CORN OIL (UNII: 8470G57WFM)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
SWEET CHERRY SEED OIL (UNII: 9X3RP3RJFH)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
WATER (UNII: 059QF0KO0R)	
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
GLYCERIN (UNII: PDC6A3C0OX)	
RICE BRAN OIL (UNII: LZ06K1506A)	
OLEA EUROPAEA (OLIVE) OIL UNSAPONIFIABLES (UNII: XO45V955LT)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
PALMITIC ACID (UNII: 2V16EO95H1)	
TALC (UNII: 7SEV7J4R1U)	
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
CRANBERRY SEED OIL (UNII: 73KDS3BW5E)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MAGNESIUM POTASSIUM ALUMINOSILICATE FLUORIDE (UNII: YK3DC63Y5M)	
RICE BRAN (UNII: R60QEP13IC)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
APPLE SEED OIL (UNII: 9ACA4K9013)	
TOXICODENDRON SUCCEDANEUM FRUIT WAX (UNII: 684PA7HRMI)	
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
TOXICODENDRON VERNICIFLUUM FRUIT RIND WAX (UNII: 6RG2461FCH)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
PUNICA GRANATUM SEED OIL (UNII: 0UI45XV0T6)	
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
CASTOR OIL (UNII: D5340Y2I9G)	
SHEA BUTTER (UNII: K49155WL9Y)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 ALUMINUM LAKE (UNII: 2M7H5Y5MJP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:14141-307-01	1 in 1 CARTON	10/07/2022
1		3 g in 1 TUBE; Type 0: Not a Combination Product	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	10/07/2022	

CYZONE CY PLAY CREAMY LIP BALM HIDRATANTE EN BARRA PARA LABIOS 24H FPS 12 NUDE CREAMY

octinoxate, zinc oxide stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14141-308
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	39.2 mg in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	25 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CASTOR OIL (UNII: D5340Y2I9G)	
SHEA BUTTER (UNII: K49155WL9Y)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
D&C RED NO. 21 ALUMINUM LAKE (UNII: 2M7H5Y5MJP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
SHOREA ROBUSTA RESIN (UNII: XUK1106UBO)	
LAUROYL LYSINE (UNII: 113171Q70B)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
GRAPEFRUIT (UNII: O82C39RR8C)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
TOCOPHEROL (UNII: R0ZB2556P8)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CORN OIL (UNII: 8470G57WFM)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	

FERROSFERRIC OXIDE (UNII: XM0M87F357)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
SWEET CHERRY SEED OIL (UNII: 9X3RP3RJFH)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLV429K27K)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
WATER (UNII: 059QF0KO0R)	
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
GLYCERIN (UNII: PDC6A3C0OX)	
RICE BRAN OIL (UNII: LZ06K1506A)	
OLEA EUROPAEA (OLIVE) OIL UNSAPONIFIABLES (UNII: XO45V955LT)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
PALMITIC ACID (UNII: 2V16EO95H1)	
TALC (UNII: 7SEV7J4R1U)	
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
CRANBERRY SEED OIL (UNII: 73KDS3BW5E)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MAGNESIUM POTASSIUM ALUMINOSILICATE FLUORIDE (UNII: YK3DC63Y5M)	
RICE BRAN (UNII: R60QEP13IC)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
APPLE SEED OIL (UNII: 9ACA4K9013)	
TOXICODENDRON SUCCEDANEUM FRUIT WAX (UNII: 684PA7HRMI)	
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
TOXICODENDRON VERNICIFLUUM FRUIT RIND WAX (UNII: 6RG2461FCH)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
PUNICA GRANATUM SEED OIL (UNII: 0UI45XV0T6)	
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)	
OCTYLDODECANOL (UNII: 461N1O614Y)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14141-308-01	1 in 1 CARTON	10/07/2022	
1		3 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	10/07/2022	

CYZONE CY PLAY CREAMY LIP BALM HIDRATANTE EN BARRA PARA LABIOS 24H FPS 12 CHERRY CREAMY

octinoxate, zinc oxide stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14141-349
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	39.2 mg in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	25 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SHOREA ROBUSTA RESIN (UNII: XUK1106UBO)	
LAUROYL LYSINE (UNII: 113171Q70B)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
GRAPEFRUIT (UNII: O82C39RR8C)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
TOCOPHEROL (UNII: R0ZB2556P8)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CORN OIL (UNII: 8470G57WFM)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
SWEET CHERRY SEED OIL (UNII: 9X3RP3RJFH)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
WATER (UNII: 059QF0KO0R)	
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
GLYCERIN (UNII: PDC6A3C0OX)	
RICE BRAN OIL (UNII: LZ06K1506A)	
OLEA EUROPAEA (OLIVE) OIL UNSAPONIFIABLES (UNII: XO45V955LT)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
PALMITIC ACID (UNII: 2V16EO95H1)	
TALC (UNII: 7SEV7J4R1U)	

HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
CRANBERRY SEED OIL (UNII: 73KDS3BW5E)
FD&C RED NO. 40 (UNII: WZB9127XOA)
MAGNESIUM POTASSIUM ALUMINOSILICATE FLUORIDE (UNII: YK3DC63Y5M)
RICE BRAN (UNII: R60QEP13IC)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
APPLE SEED OIL (UNII: 9ACA4K9013)
TOXICODENDRON SUCCEDANEUM FRUIT WAX (UNII: 684PA7HRMI)
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)
TOXICODENDRON VERNICIFLUUM FRUIT RIND WAX (UNII: 6RG2461FCH)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
TRIDECYL STEARATE (UNII: A8OE252M6L)
PUNICA GRANATUM SEED OIL (UNII: 0UI45XV0T6)
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)
OCTYLDODECANOL (UNII: 461N1O614Y)
CASTOR OIL (UNII: D5340Y2I9G)
SHEA BUTTER (UNII: K49155WL9Y)
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)
HEXYL LAURATE (UNII: 4CG9F9W01Q)
D&C RED NO. 21 ALUMINUM LAKE (UNII: 2M7H5Y5MJP)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14141-349-01	1 in 1 CARTON	09/12/2024	
1		3 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	09/12/2024	

CYZONE CY PLAY CREAMY LIP BALM HIDRATANTE EN BARRA PARA LABIOS 24H FPS 12 BERRY CREAMY

octinoxate, zinc oxide stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14141-348
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	39.2 mg in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	25 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SHOREA ROBUSTA RESIN (UNII: XUK1106UBO)	
LAUROYL LYSINE (UNII: 113171Q70B)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
GRAPEFRUIT (UNII: O82C39RR8C)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
TOCOPHEROL (UNII: R0ZB2556P8)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CORN OIL (UNII: 8470G57WFM)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
SWEET CHERRY SEED OIL (UNII: 9X3RP3RJFH)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLVW429K27K)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
WATER (UNII: 059QF0KO0R)	
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
GLYCERIN (UNII: PDC6A3C0OX)	
RICE BRAN OIL (UNII: LZ06K1506A)	
OLEA EUROPAEA (OLIVE) OIL UNSAPONIFIABLES (UNII: XO45V955LT)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
PALMITIC ACID (UNII: 2V16EO95H1)	
TALC (UNII: 7SEV7J4R1U)	
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
CRANBERRY SEED OIL (UNII: 73KDS3BW5E)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MAGNESIUM POTASSIUM ALUMINOSILICATE FLUORIDE (UNII: YK3DC63Y5M)	
RICE BRAN (UNII: R60QEP13IC)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
APPLE SEED OIL (UNII: 9ACA4K9013)	
TOXICODENDRON SUCCEDANEUM FRUIT WAX (UNII: 684PA7HRMI)	
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWWW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	

TOXICODENDRON VERNICIFLUUM FRUIT RIND WAX (UNII: 6RG2461FCH)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
TRIDECYL STEARATE (UNII: A8OE252M6L)
PUNICA GRANATUM SEED OIL (UNII: 0UI45XV0T6)
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)
OCTYLDODECANOL (UNII: 461N1O614Y)
CASTOR OIL (UNII: D5340Y2I9G)
SHEA BUTTER (UNII: K49155WL9Y)
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)
HEXYL LAURATE (UNII: 4CG9F9W01Q)
D&C RED NO. 21 ALUMINUM LAKE (UNII: 2M7H5Y5MJP)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14141-348-01	1 in 1 CARTON	09/12/2024	
1		3 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	09/12/2024	

Labeler - BEL STAR S A (880160197)