

**KAPLAN MD PERFECT POUT LIP BALM- octinoxate, octisalate,  
octocrylene lipstick  
KAPLAN MD INC**

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**Kaplan MD Perfect Pout Lip Balm (Clear)**

**Active Ingredients**

Octinoxate 7.5%

Octisalate 5%

Octocrylene 3%

**Purpose**

Sunscreen

**Warnings**

**For external use only.**

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

**Do not use on** damaged and broken skin.

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

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

**Other Information**

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

**Directions**

- apply generously to lips 15 minutes before sun exposure
- children under 6 months of age: Ask a doctor
- reapply at least every 2 hours
- use a water-resistant sunscreen if swimming or sweating

**Inactive Ingredients**

Hydrogenated Polyisobutene, Ethylhexyl Methoxycinnamate, Ethylene/Propylene/Styrene Copolymer, Ethylhexyl Salicylate, Ethylhexyl Palmitate, Octocrylene, Octyldodecanol, Polyisobutene, Silica Silylate, Caprylyl Methicone, Helianthus Annuus (Sunflower) Seed Wax, Rebaudioside A, Sodium Hyaluronate, Palmitoyl Tripeptide-1, Euphorbia Cerifera Cera, Carthamus Tinctorius (Safflower) Oleoseomes, Beeswax, Aloe Barbadensis Leaf

Extract\*, Camellia Sinensis (Green Tea) Extract\*, Salvia Officinalis (Sage) Extract\*, Pelargonium Graveolens (Rose Geranium) Extract\*, Melissa Officinalis (Lemon Balm) Extract\*, Ginkgo Biloba Extract\*, Lavandula Intermedia (Lavender) Extract\*, Rosmarinus Officinalis (Rosemary) Extract\*, Mentha Piperita (Peppermint) Extract\*, Thymus Vulgaris (Thyme) Extract\*, Chamomilla Recutita (Matricaria) Extract\*, Trifolium Pratense (Red Clover) Extract\*, Rosa Canina (Rose Hips) Extract\*, Borago Officinalis (Borage) Extract\*, Macrocystis Pyrifera (Kelp) Extract\*, Panax Ginseng Root Extract\*, Camellia Sinensis (White Tea) Extract\*, Ilex Paraguariensis (Yerba Mate) Extract\*, Lippia Citriodora (Lemon Verbena) Extract\*, Citrus Grandis (Grapefruit) Extract\*, Sambucus Nigra (Elderflower) Extract\*, Fucus Vesiculosus (Seaweed) Extract\*, Phenoxyethanol, Tocopheryl Acetate, Butylene/Ethylene/Styrene Copolymer, Caprylyl Glycol, Tetrahexyldecyl Ascorbate, Ethylhexylglycerin, Hexylene Glycol, Tribehenin, Glyceryl Caprylate, Sorbitan Isostearate, Silica Dimethyl Silylate, BHT, Butylene Glycol, Pentylene Glycol, Glycerin, Mentha Piperita (Peppermint) Oil, Aqua.

Keep out of reach of children.

apply generously to lips 15 minutes before sun exposure

<b>Drug Facts &amp; Full Ingredient List</b>	<b>For external use only.</b> <b>Do not use</b> on damaged or broken skin. <b>When using this product</b> keep out of eyes. Rinse with water to remove. <b>Stop use and ask a doctor</b> if rash occurs. <b>Skin Cancer/Skin Aging Alert:</b> 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, <b>not</b> skin cancer or early skin aging.	<b>Directions</b> ■ apply generously to lips 15 minutes before sun exposure ■ children under 6 months of age: Ask a doctor ■ reapply at least every 2 hours ■ use a water-resistant sunscreen if swimming or sweating <b>Other information</b> ■ protect the product in this container from excessive heat and direct sun (continued on back)
<b>Active ingredients</b> Octinoxate 7.5%, Octisalate 5%, Octocrylene 3%, Sunscreen	<b>Purpose</b>	
<b>Uses</b> ■ helps prevent sunburn.		
<b>Warnings</b>		

<b>PERFECT POUT LIP BALM</b> Ultra Hydrating Treatment + Sunscreen SPF 30 <b>INGREDIENTS</b> Hydrogenated Polyisobutene, Ethylhexyl Methoxycinnamate, Ethylene/Propylene/Styrene Copolymer, Ethylhexyl Salicylate, Ethylhexyl Palmitate, Octocrylene, Octyldodecanol, Polyisobutene, Silica Silylate, Caprylyl Methicone, Helianthus Annuus (Sunflower) Seed Wax, Rebaudioside A, Sodium Hyaluronate, Palmitoyl Tripeptide-1, Euphorbia Cerifera Cera, Carthamus Tinctorius (Safflower) Oleosomes, Beeswax, Aloe Barbadosensis Leaf Extract*, Camellia Sinensis (Green Tea) Extract*, Salvia Officinalis (Sage) Extract*,	Pelargonium Graveolens (Rose Geranium) Extract*, Melissa Officinalis (Lemon Balm) Extract*, Ginkgo Biloba Extract*, Lavandula Intermedia (Lavender) Extract*, Rosmarinus Officinalis (Rosemary) Extract*, Mentha Piperita (Peppermint) Extract*, Thymus Vulgaris (Thyme) Extract*, Chamomilla Recutita (Matricaria) Extract*, Trifolium Pratense (Red Clover) Extract*, Rosa Canina (Rose Hips) Extract*, Borago Officinalis (Borage) Extract*, Macrocystis Pyrifera (Kelp) Extract*, Panax Ginseng Root Extract*, Camellia Sinensis (White Tea) Extract*, Ilex Paraguariensis (Yerba Mate) Extract*, Lippia Citriodora (Lemon Verbena) Extract*, Citrus Grandis (Grapefruit) Extract*, Sambucus Nigra (Elderflower) Extract*, Fucus Vesiculosus (Seaweed) Extract*, Phenoxyethanol, Tocopheryl	Acetate, Butylene/Ethylene/Styrene Copolymer, Caprylyl Glycol, Tetrahexyldecyl Ascorbate, Ethylhexylglycerin, Hexylene Glycol, Tribehenin, Glyceryl Caprylate, Sorbitan Isostearate, Silica Dimethyl Silylate, BHT, Butylene Glycol, Pentylene Glycol, Glycerin, Mentha Piperita (Peppermint) Oil, Aqua. <b>*Certified Organic Extracts</b> MADE IN USA = KAPLANMD.COM DISTRIBUTED BY KAPLAN MD, INC. BEVERLY HILLS, CA 90210 COSMETRADE, S.L. AVDA. SUDAFRICA 110, 11408 SPAIN
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## KAPLAN MD PERFECT POUT LIP BALM

octinoxate, octisalate, octocrylene lipstick

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:84300-001
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	3 g in 100 g
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>RED CLOVER</b> (UNII: L9153EKV2Y)	
<b>HELIANTHUS ANNUUS SEED WAX</b> (UNII: 42DG15CHXV)	

<b>HYDROGENATED POLYISOBUTENE (1300 MW)</b> (UNII: 7D1YQ9Y5EZ)
<b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)
<b>WATER</b> (UNII: 059QF0KO0R)
<b>MACROCYSTIS PYRIFERA</b> (UNII: K31S3OG5C4)
<b>FUCUS VESICULOSUS</b> (UNII: 535G2ABX9M)
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85KORA)
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)
<b>.ALPHA.-TOCOPHEROL ACETATE, DL-</b> (UNII: WR1WPI7EW8)
<b>SILICA DIMETHYL SILYLATE</b> (UNII: EU2PSP0G0W)
<b>REBAUDIOSIDE A</b> (UNII: B3FUD0528F)
<b>ROSEMARY</b> (UNII: IJ67X351P9)
<b>SAGE</b> (UNII: 065C5D077J)
<b>LEMON BALM OIL</b> (UNII: MJ76269K9S)
<b>MATRICARIA CHAMOMILLA</b> (UNII: G0R4UBI2ZZ)
<b>BORAGE</b> (UNII: PB618V0K2W)
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)
<b>WHITE TEA</b> (UNII: O0M3396E09)
<b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)
<b>CARTHAMUS TINCTORIUS (SAFFLOWER) OLEOSOMES</b> (UNII: 9S60Q72309)
<b>GRAPEFRUIT</b> (UNII: O82C39RR8C)
<b>THYME</b> (UNII: CW6570BU4N)
<b>PANAX GINSENG ROOT OIL</b> (UNII: P9T4K47OM0)
<b>TRIBEHENIN</b> (UNII: 8OC9U7TQZ0)
<b>SORBITAN ISOSTEARATE</b> (UNII: 01S2G2C1E4)
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)
<b>PEPPERMINT</b> (UNII: V95R5KMY2B)
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)
<b>HEXYLENE GLYCOL</b> (UNII: KEH0A3F75J)
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)
<b>GLYCERYL CAPRATE</b> (UNII: 197M6VFC1W)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84300-001-10	10 g in 1 TUBE, WTH APPLICATOR; Type 0: Not a Combination Product	05/08/2024	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	05/08/2024	

**Labeler** - KAPLAN MD INC (782764638)

**Registrant** - KDC/ONE SOCIAL LABORATORIES, LLC (118384240)

**Establishment**

Name	Address	ID/FEI	Business Operations
KDC/ONE SOCIAL LABORATORIES, LLC		118384240	manufacture(84300-001)

Revised: 5/2024

KAPLAN MD INC