

HYDRATING SHEER LIP BALM SPF 30 - TRIO- avobenzene, octisalate, and homosalate MDSolarSciences

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.

Hydrating Sheer Lip Balm SPF 30 - TRIO

Drug Facts

<i>Active Ingredients</i>	<i>Purpose</i>
Avobenzene 2%	Sunscreen
Octisalate 5%	Sunscreen
Homosalate 10%	Sunscreen

Uses

- Helps prevent sunburn
- If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun.

Warnings

For external use only. Do not use on damaged or broken skin. **Stop use and ask a doctor** if rash occurs. **When using this product** keep out of eyes. Rinse with water to remove.

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

Directions

- Apply liberally 15 minutes before sun exposure & again after swimming or sweating.
- Reapply at least every 2 hours.
- Children under 6 months: Ask a doctor
- Sun Protection Measures: To decrease your risk of skin cancer and early skin aging, regularly use a sunscreen of SPF15 or higher and other sun protective measures including:
- Limit time in the sun, especially from 10a.m.-2p.m.
- Wear long-sleeved shirts, pants, hats and sunglasses

Other Information

- Protect the product in this container from excessive heat and direct sunlight
- You may report serious adverse reactions to: Report Reaction, LLC. PO Box 22, Plainsboro, NJ 08536-0222

Inactive Ingredients

Persea Gratissima (Avocado) Oil, Butyrospermum Parkii (Shea) Butter, Paraffin Wax, Hydrogenated Soybean Oil, Ricinus Communis (Castor) Seed Oil, Octyldodecanol, Olea Europaea (Olive) Fruit Oil, Jojoba Esters, Hydrogenated Vegetable Oil, Microcrystalline Wax, Stearic Acid, Helianthus Annuus (Sunflower) Seed Oil, Squalane, Acacia Decurrens Flower Wax, Polyglycerin-3, Rhus Verniciflua Peel Wax, Sorbitan Oleate, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Ascorbyl Palmitate, Tocopherol. May contain: Titanium Dioxide (CI 77891), Iron Oxides (CI 77491- Red), Iron Oxides (CI

77492 - Yellow), Iron Oxides (CI 77499 - Black) CI 19140 - Yellow 5, Red 28 Lake (CI 45410)

Distributed by: MDSolarSciences Corp, Stamford, CT 06902

PRINCIPAL DISPLAY PANEL - Kit Carton

MDSolarSciences™

30

HYDRATING

SHEER

LIP BALM

TRIO

BROAD SPECTRUM SPF 30 UVA- UVB SUNSCREEN

Net Wt. 4.2 g -.15Oz

NUDE



PINK



RED



MDSolarSciences™

30

HYDRATING SHEER LIP BALM TRIO



BROAD SPECTRUM SPF 30 UVA-UVB SUNSCREEN

Net Wt. 4.2 g -.15Oz

SPF 30

SPF 30

FPO

Made in USA
Distributed by: MDSolarSciences Corp, Stamford, CT 06902

Inactive Ingredients:
Persea Gratissima (Peanut) Oil, Butyrospermum Parvum (Shea Butter), Paraffin Wax, Hydrogenated Soybean Oil, Ricinus Communis (Castor) Seed Oil, Olethoxyethanol, Oleyl Alcohol, Polybutene-1, Polyethylene Glycol, Polyethylene Glycol 3, Polyethylene Glycol 4, Polyethylene Glycol 6, Polyethylene Glycol 8, Polyethylene Glycol 10, Polyethylene Glycol 12, Polyethylene Glycol 14, Polyethylene Glycol 16, Polyethylene Glycol 18, Polyethylene Glycol 20, Polyethylene Glycol 22, Polyethylene Glycol 24, Polyethylene Glycol 26, Polyethylene Glycol 28, Polyethylene Glycol 30, Polyethylene Glycol 32, Polyethylene Glycol 34, Polyethylene Glycol 36, Polyethylene Glycol 38, Polyethylene Glycol 40, Polyethylene Glycol 42, Polyethylene Glycol 44, Polyethylene Glycol 46, Polyethylene Glycol 48, Polyethylene Glycol 50, Polyethylene Glycol 52, Polyethylene Glycol 54, Polyethylene Glycol 56, Polyethylene Glycol 58, Polyethylene Glycol 60, Polyethylene Glycol 62, Polyethylene Glycol 64, Polyethylene Glycol 66, Polyethylene Glycol 68, Polyethylene Glycol 70, Polyethylene Glycol 72, Polyethylene Glycol 74, Polyethylene Glycol 76, Polyethylene Glycol 78, Polyethylene Glycol 80, Polyethylene Glycol 82, Polyethylene Glycol 84, Polyethylene Glycol 86, Polyethylene Glycol 88, Polyethylene Glycol 90, Polyethylene Glycol 92, Polyethylene Glycol 94, Polyethylene Glycol 96, Polyethylene Glycol 98, Polyethylene Glycol 100.

Other Information:
• Protect the product in this container from excessive heat and direct sunlight.
• You may report serious adverse reactions to Report Reaction, LLC, PO Box 22, Plainville, NJ 08536-0222.

Directions:
Apply liberally 15 minutes before sun exposure and again after swimming or sweating.
• Reapply at least every 2 hours.
• Use often under a doctor's supervision to decrease your risk of skin cancer and early skin aging, regularly use a sunscreen of SPF 15 or higher and other sun protective measures including:
• Limit time in the sun, especially from 10am-2pm.
• Wear long-sleeved shirts, pants, hats and sunglasses.

Warnings:
For external use only. Do not use on damaged or broken skin. Stop use and ask a doctor if rash occurs. When using this product keep out of eyes. Rinse with water to remove. Keep out of children's reach if swallowed. Get medical help or contact a Poison Control Center right away.

Drug Facts:
Uses:
• Helps prevent sunburn
• Helps prevent skin aging caused by the sun.
Active Ingredients:
Sunscreen 2%
Sunscreen 5%
Sunscreen 10%
Purpose:
Sunscreen
Sunscreen
Sunscreen
Sunscreen



Drink Of Color
Supple, sensual, and sun-ready. This Hydrating Lip Balm Trio envelops your lips in a sheer wash of color while delivering a luxurious, creamy formula that leaves lips hydrated. As if that wasn't enough, each lip balm provides broad spectrum SPF protection, so you have every reason to smile in the sunshine. A color for every mood: red, pink and nude. Add this trio to your lip wardrobe today!
Reapply when you want to pack more punch with your pucker! #optoutside, #sunnysmiles



HYDRATING SHEER LIP BALM SPF 30 - TRIO

avobenzone, octisalate, and homosalate kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49358-567
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49358-567-01	1 in 1 CARTON	10/01/2019	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 APPLICATOR	4.2 g
Part 2	1 APPLICATOR	4.2 g
Part 3	1 APPLICATOR	4.2 g

Part 1 of 3

HYDRATING SHEER LIP BALM SPF 30 - RED BROAD SPECTRUM SPF 30 UVA-UVB SUNSCREEN

avobenzone, octisalate, and homosalate lipstick

Product Information

Item Code (Source) NDC:49358-564

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Avobenzone (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX)	Avobenzone	30 mg in 1 g
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	50 mg in 1 g
Homosalate (UNII: V06SV4M95S) (Homosalate - UNII:V06SV4M95S)	Homosalate	100 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
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Avocado Oil (UNII: 6VNO72PFC1)
Shea Butter (UNII: K49155WL9Y)
PARAFFIN (UNII: I9O0E3H2ZE)
HYDROGENATED SOYBEAN OIL (UNII: A2M91M918C)
Castor Oil (UNII: D5340Y2I9G)
OCTYLDODECANOL (UNII: 461N1O614Y)
OLIVE OIL (UNII: 6UYK2W1W1E)
HYDROGENATED JOJOBA OIL, RANDOMIZED (UNII: Q47ST02F58)
CORN OIL (UNII: 8470G57WFM)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
STEARIC ACID (UNII: 4ELV7Z65AP)
SUNFLOWER OIL (UNII: 3W1JG795YI)
SQUALANE (UNII: GW89575KF9)
ACACIA DECURRENS FLOWER WAX (UNII: AU6XZE9IY9)
POLYGLYCERIN-3 (UNII: 4A0NCJ6RD6)
TOXICODENDRON VERNICIFLUUM FRUIT RIND WAX (UNII: 6RG2461FCH)
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
ASCORBYL PALMITATE (UNII: QN83US2B0N)
TOCOPHEROL (UNII: R0ZB2556P8)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 28 (UNII: 767IP0Y5NH)

Product Characteristics			
Color	RED	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49358-564-01	4.2 g in 1 APPLICATOR; Type 1: Convenience Kit of Co-Package		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	10/01/2019	

Part 2 of 3

HYDRATING SHEER LIP BALM SPF 30 - PINK BROAD SPECTRUM SPF 30 UVA-UVB SUNSCREEN

avobenzene, octisalate, and homosalate lipstick

Product Information

Item Code (Source)	NDC:49358-565
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Avobenzene (UNII: G63QQF2NOX) (Avobenzene - UNII:G63QQF2NOX)	Avobenzene	30 mg in 1 g
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	50 mg in 1 g
Homosalate (UNII: V06SV4M95S) (Homosalate - UNII:V06SV4M95S)	Homosalate	100 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Avocado Oil (UNII: 6VNO72PFC1)	
Shea Butter (UNII: K49155WL9Y)	
PARAFFIN (UNII: I9O0E3H2ZE)	
HYDROGENATED SOYBEAN OIL (UNII: A2M91M918C)	
Castor Oil (UNII: D5340Y2I9G)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
HYDROGENATED JOJOBA OIL, RANDOMIZED (UNII: Q47ST02F58)	
CORN OIL (UNII: 8470G57WFM)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
SQUALANE (UNII: GW89575KF9)	
ACACIA DECURRENS FLOWER WAX (UNII: AU6XZE9IY9)	
POLYGLYCERIN-3 (UNII: 4A0NCJ6RD6)	
TOXICODENDRON VERNICIFLUUM FRUIT RIND WAX (UNII: 6RG2461FCH)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
TOCOPHEROL (UNII: R0ZB2556P8)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	

Product Characteristics

Color	PINK	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49358-565-01	4.2 g in 1 APPLICATOR; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	10/01/2019	

Part 3 of 3

HYDRATING SHEER LIP BALM SPF 30 - NUDE BROAD SPECTRUM SPF 30 UVA-UVB SUNSCREEN

avobenzone, octisalate, and homosalate lipstick

Product Information

Item Code (Source)	NDC:49358-566
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Avobenzone (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX)	Avobenzone	30 mg in 1 g
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	50 mg in 1 g
Homosalate (UNII: V06SV4M95S) (Homosalate - UNII:V06SV4M95S)	Homosalate	100 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Avocado Oil (UNII: 6VNO72PFC1)	
Shea Butter (UNII: K49155WL9Y)	
PARAFFIN (UNII: I9O0E3H2ZE)	
HYDROGENATED SOYBEAN OIL (UNII: A2M91M918C)	
Castor Oil (UNII: D5340Y2I9G)	

OCTYLDODECANOL (UNII: 461N1O614Y)
OLIVE OIL (UNII: 6UYK2W1W1E)
HYDROGENATED JOJOBA OIL, RANDOMIZED (UNII: Q47ST02F58)
CORN OIL (UNII: 8470G57WFM)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
STEARIC ACID (UNII: 4ELV7Z65AP)
SUNFLOWER OIL (UNII: 3W1JG795YI)
SQUALANE (UNII: GW89575KF9)
ACACIA DECURRENS FLOWER WAX (UNII: AU6XZE9IY9)
POLYGLYCERIN-3 (UNII: 4A0NCJ6RD6)
TOXICODENDRON VERNICIFLUUM FRUIT RIND WAX (UNII: 6RG2461FCH)
SORBITAN MONOLEATE (UNII: 06XEA2VD56)
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
ASCORBYL PALMITATE (UNII: QN83US2B0N)
TOCOPHEROL (UNII: R0ZB2556P8)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 28 (UNII: 767IP0Y5NH)

Product Characteristics			
Color	BROWN	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49358-566-01	4.2 g in 1 APPLICATOR; Type 1: Convenience Kit of Co-Package		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	10/01/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	10/01/2019	

