

**RODAN AND FIELDS ESSENTIALS LIP SHIELD SPF 25 - avobenzene, homosalate, octisalate, octocrylene lipstick**

**Rodan & Fields**

*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.*

**Rodan + Fields Essentials Lip Shield SPF 25**

Active Ingredients	Purpose
Avobenzene 2.5%	Sunscreen
Homosalate 8%	Sunscreen
Octisalate 5%	Sunscreen
Octocrylene 2.2%	Sunscreen

Use Helps prevent sunburn.

Warnings Stop use if skin rash occurs.

Directions Apply liberally and evenly. Covering lips completely. For best result use daily and reapply frequently.

Other Information You may report a serious adverse reaction to Rodan + Fields. Attn: Product Development, 111 Maiden Lane, Suite 400, San Francisco, CA 94108.

Inactive Ingredients: Beeswax, Hydrogenated Avocado Oil, Butyrospermum Parkii (Shea Butter), Persea Gratissima (Avocado) Oil, Simmondsia Chinensis (Jojoba) Seed Oil, Acacia Decurrens / Jojoba / Sunflower Seed Wax / Polyglyceryl-3 Esters, Sunflower (Helianthus Annuus) Seed Oil Unsaponifiables, Dimethicone, Fragrance, Ethylhexyl Palmitate, Hydrogenated Polydecane, Dunaliella Salina Extract, Palmityl Oligopeptide, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Retinyl Palmitate, Molaleuca Alternifolia (Sea Tree) Leaf Oil, Tribehenin, Sorbitan Isostearate.

8 84164 00530 5 RODAN+FIELDS ESSENTIALS Dermatologist Developed Lip Shield SPF 25  
Contains 2 Tubes - 4.25 g/ .15 Oz. Each

<b>Drug Facts (continued)</b>
Simmondsia Chinensis (Jojoba) Seed Oil, Acacia Decurrens / Jojoba / Sunflower Seed Wax / Polyglyceryl-3 Esters, Sunflower (Helianthus Annuus) Seed Oil Unsaponifiables, Dimethicone, Fragrance, Ethylhexyl Palmitate, Hydrogenated Polydecane, Dunaliella Salina Extract, Palmityl Oligopeptide, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Retinyl Palmitate, Molaleuca Alternifolia (Sea Tree) Leaf Oil, Tribehenin, Sorbitan Isostearate



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avobenzone, homosalate, octisalate, octocrylene lipstick

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14222-425
Route of Administration	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2.5 g in 100 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	8 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2.2 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
YELLOW WAX (UNII: 2ZA36H0S2V)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
SHEA BUTTER (UNII: K49155WL9Y)	
JOJOBA OIL (UNII: 724GKU717M)	
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	
SUNFLOWER OIL (UNII: 3W1JG795Y)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
DUNALIELLA SALINA (UNII: F401DKI9A6)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
TRIBEHENIN (UNII: 8OC9U7TQZ0)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14222-425-01	2 in 1 PACKAGE		
1		4.25 g in 1 TUBE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	06/21/2011	

Labeler - Rodan & Fields (051659584)

Establishment

Name	Address	ID/FEI	Business Operations
Englewood Lab, LLC		172198223	manufacture

Revised: 6/2011

Rodan & Fields