

**LA ROCHE POSAY LABORATOIRE DERMATOLOGIQUE TOLERIANE DOUBLE REPAIR
MOISTURIZER UV BROAD SPECTRUM SPF 30 SUNSCREEN- avobenzone, homosalate,
octisalate and octocrylene lotion**
L'Oreal USA Products Inc

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.

Drug Facts

Active ingredients

Avobenzone 3%

Homosalate 5%

Octisalate 5%

Octocrylene 7%

Purpose

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

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

For sunscreen use:

- shake well

- apply liberally 15 minutes before sun exposure
- reapply at least every 2 hours
- use a water resistant sunscreen if swimming or sweating
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
 - limit time in the sun, especially from 10 a.m. – 2 p.m.
 - wear long-sleeved shirts, pants, hats, and sunglasses
 - 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

water, glycerin, silica, dimethicone, niacinamide, PEG-100 stearate, glyceryl stearate, stearic acid, allantoin, ceramide 3, dimethicone/vinyl dimethicone crosspolymer, sodium hydroxide, myristic acid, myristyl alcohol, palmitic acid, ammonium polyacryloyldimethyl taurate, disodium EDTA, capryloyl glycine, caprylyl glycol, citric acid, xanthan gum, t-butyl alcohol, cetyl alcohol, tocopherol

Questions or comments?

1-888-LRP-LABO 1-888-577-5226

Monday - Friday (9 a.m. - 5 p.m. EST)



LA ROCHE POSAY LABORATOIRE DERMATOLOGIQUE TOLERIANE
DOUBLE REPAIR MOISTURIZER UV BROAD SPECTRUM SPF 30 SUNSCREEN
 avobenzone, homosalate, octisalate and octocrylene lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49967-584
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 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	50 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	70 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
NIACINAMIDE (UNII: 25X51I8RD4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
ALLANTOIN (UNII: 344S277G0Z)	
CERAMIDE 3 (UNII: 4370DF050B)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
MYRISTIC ACID (UNII: 0I3V7S25AW)	
MYRISTYL ALCOHOL (UNII: V42034O9PU)	
PALMITIC ACID (UNII: 2V16EO95H1)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
CAPRYLOYL GLYCINE (UNII: 8TY5YO42NJ)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
XANTHAN GUM (UNII: TTV12P4NEE)	
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
TOCOPHEROL (UNII: R0ZB2556P8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-584-01	1 in 1 CARTON	12/21/2016	
1		75 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:49967-584-02	2 mL in 1 PACKET; Type 0: Not a Combination Product	12/21/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/21/2016	

Establishment

Name	Address	ID/FEI	Business Operations
SICOS ET CIE		276993581	manufacture(49967-584)

Establishment

Name	Address	ID/FEI	Business Operations
Cosmetique Active Products		282658798	manufacture(49967-584) , pack(49967-584)

Establishment

Name	Address	ID/FEI	Business Operations
BPS		272259304	pack(49967-584)

Establishment

Name	Address	ID/FEI	Business Operations
Socoplan		276221405	pack(49967-584)

Revised: 3/2020

L'Oreal USA Products Inc