

CLINIQUE SUPERBALANCED SILK MAKEUP BROAD SPECTRUM SPF 15- octinoxate, octisalate, titanium dioxide, and zinc oxide liquid
CLINIQUE LABORATORIES LLC

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.

CLINIQUE SUPERBALANCED SILK MAKEUP BROAD SPECTRUM SPF 15

Drug Facts

Active ingredients

Octinoxate 7.0%
Octisalate 4.5%
Titanium Dioxide 7.8%
Zinc Oxide 1.9%

Purpose

Sunscreen

Use

helps prevent sunburn

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 product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

For sunscreen use:

- apply liberally 15 minutes before sun exposure
- reapply at least every two 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

Inactive ingredients

dimethicone•water/aqua/eau•vinyl dimethicone/methicone silsesquioxane crosspolymer•peg-10 dimethicone•butylene glycol•phenyl trimethicone•isododecane•isodecyl isononanoate•alcohol denat. •lauryl peg-9 polydimethylsiloxyethyl dimethicone•dimethicone silylate•laminaria saccharina extract•silk powder/serica/poudre de soie•sodium hyaluronate•triethoxycaprylylsilane•sorbitan sesquioleate•tocopheryl acetate•propylene carbonate•polysilicone-11•lecithin•laureth-7•disteardimonium hectorite•silica•dimethicone/peg-10/15 crosspolymer•sodium chloride•xanthan gum•tetrasodium edta•phenoxyethanol•[+/- mica•titanium dioxide (ci 77891)•iron oxides (ci 77491)•iron oxides (ci 77492)•iron oxides (ci 77499)] [iln42344]

Other information

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

PRINCIPAL DISPLAY PANEL - 30 ml Bottle Carton

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CLINIQUE

superbalanced

silk makeup

broad spectrum

SPF 15

1 FL.OZ.LIQ./30 ml e

<p>Drug Facts</p> <table border="1"> <thead> <tr> <th>Active ingredients</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Octinoxate 7.0%</td> <td rowspan="4">Sunscreen</td> </tr> <tr> <td>Octisalate 4.5%</td> </tr> <tr> <td>Titanium Dioxide 7.8%</td> </tr> <tr> <td>Zinc Oxide 1.9%</td> </tr> </tbody> </table> <p>Use helps prevent sunburn</p> <p>Warnings For external use only</p> <p>Do not use on damaged or broken skin</p> <p>When using this product keep out of eyes. Rinse with water to remove.</p> <p>Stop use and ask a doctor if rash occurs</p> <p>Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions For sunscreen use: • apply liberally 15 minutes before sun exposure • reapply at least every two 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.▶</p>	Active ingredients	Purpose	Octinoxate 7.0%	Sunscreen	Octisalate 4.5%	Titanium Dioxide 7.8%	Zinc Oxide 1.9%	<p>Drug Facts (cont'd)</p> <p>■ wear long-sleeved shirts, pants, hats and sunglasses • children under 6 months of age: ask a doctor</p> <p>Inactive ingredients dimethicone•water/aqua/eau•vinyl dimethicone/methicone silsesquioxane crosspolymer•peg-10 dimethicone•butylene glycol•phenyl trimethicone•isododecane•isodecyl isononanoate•alcohol denat. •lauryl peg-9 polydimethylsiloxyethyl dimethicone•dimethicone silylate•laminaria saccharina extract•silk powder/serica/poudre de soie•sodium hyaluronate•triethoxycaprylylsilane•sorbitan sesquioleate•tocopheryl acetate•propylene carbonate•polysilicone-11•lecithin•laureth-7•disteardimonium hectorite•silica•dimethicone/peg-10/15 crosspolymer•sodium chloride•xanthan gum•tetrasodium edta•phenoxyethanol•[+/- mica•titanium dioxide (ci 77891)•iron oxides (ci 77491)•iron oxides (ci 77492)•iron oxides (ci 77499)] [iln42344]</p> <p>Other information protect the product in this container from excessive heat and direct sun</p>	 <p>CLINIQUE</p> <p>superbalanced silk makeup broad spectrum SPF 15</p> <p>1 FL.OZ.LIQ./30 ml e</p>	<p>Allergy Tested. 100% Fragrance Free. Moderate coverage. Natural matte finish.</p> <p>Silky, ultra-fluid formula slips on, blends seamlessly. Absorbs oil, moisturizes where needed. Protects with SPF. Soft-focus finish lasts all day. Oil-free. Shake well before using.</p> <p>© CLINIQUE LABORATORIES, DIST. NEW YORK, N.Y. 10022 W.B.LTD. GU32 3DD, UK N.Y. • LONDON • PARIS ZGH4</p>  <p>clinique.com</p>
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CLINIQUE SUPERBALANCED SILK MAKEUP BROAD SPECTRUM SPF 15			
octinoxate, octisalate, titanium dioxide, and zinc oxide liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49527-052

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.077 g in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	0.05 g in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	0.085 g in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.021 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
dimethicone (UNII: 92RU3N3Y1O)	
water (UNII: 059QF0K00R)	
peg-10 dimethicone (600 cst) (UNII: 8PR7V1SVM0)	
butylene glycol (UNII: 3XUS85K0RA)	
phenyl trimethicone (UNII: DR0K5NOJ4R)	
isododecane (UNII: A8289P68Y2)	
isodecyl isononanoate (UNII: 4X46Q4U00Z)	
alcohol (UNII: 3K9958V90M)	
lauryl peg-9 polydimethylsiloxyethyl dimethicone (UNII: 25G622K2RA)	
saccharina latissima (UNII: 68CMP2MB55)	
hyaluronate sodium (UNII: YSE9PPT4TH)	
triethoxycaprylylsilane (UNII: LDC331P08E)	
sorbitan sesquioleate (UNII: 0W8RRI5W5A)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	
propylene carbonate (UNII: 8D08K3S51E)	
dimethicone/vinyl dimethicone crosspolymer (soft particle) (UNII: 9E4CO0W6C5)	
laureth-7 (UNII: Z95S6G8201)	
disteardimonium hectorite (UNII: X687XDK09L)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
sodium chloride (UNII: 451W47IQ8X)	
xanthan gum (UNII: TTV12P4NEE)	
edetate sodium (UNII: MP1J8420LU)	
phenoxyethanol (UNII: HIE492ZZ3T)	
mica (UNII: V8A1AW0880)	
ferric oxide red (UNII: 1K09F3G675)	
ferric oxide yellow (UNII: EX438O2MRT)	
ferrosoferric oxide (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49527-052-01	1 in 1 CARTON	07/15/2016	
1		30 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	07/15/2016	

Labeler - CLINIQUE LABORATORIES LLC (044475127)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COMPANY, THE		828534516	RELABEL(49527-052) , REPACK(49527-052)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(49527-052)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		202952982	MANUFACTURE(49527-052)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(49527-052)

Establishment

Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(49527-052)

Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC INC		943871157	RELABEL(49527-052) , REPACK(49527-052)

Establishment

Name	Address	ID/FEI	Business Operations
PADC 1		949264774	RELABEL(49527-052) , REPACK(49527-052)

Establishment

Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(49527-052)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		255175580	MANUFACTURE(49527-052)