

CLINIQUE BROAD SPECTRUM SPF 30 SUNSCREEN BODY MIST- avobenzone, homosalate, and octisalate liquid
CLINIQUE LABORATORIES 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.

CLINIQUE BROAD SPECTRUM SPF 30 SUNSCREEN BODY MIST

Drug Facts

Active ingredients

Avobenzone 3.0%
Homosalate 10.0%
Octisalate 4.5%

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

- spray generously and spread evenly by hand 15 minutes before sun exposure
- hold 4–6 inches from the body when spraying
- reapply at least every two hours
- use a water resistant sunscreen if swimming or sweating
- do not apply in windy conditions
- use in a well-ventilated area
- **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

alcohol denat. • octyldodecyl neopentanoate • butyloctyl salicylate • polyester-8 • acrylates/octylacrylamide copolymer • ethylhexyl methoxycrylene • dimethicone • trimethylsiloxysilicate • tocopheryl acetate • ethylcellulose [iln42861]

Other information

- protect the product in this container from excessive heat and direct sun
- store in a cool, dry place

PRINCIPAL DISPLAY PANEL - 144 ml Bottle Carton

CLINIQUE

broad

spectrum

SPF 30

sunscreen

UVA UVB

advanced

protection

virtu-oil

body mist

4.9 FL.OZ.

144 ml e

broad spectrum
SPF 30
sunscreen

UVA UVB
advanced protection

C162604

**Allergy Tested,
100% Fragrance Free.**

Oil-free 'virtu-oil' sunscreen formula sprays on easily, absorbs quickly. Delivers high-level UVA/UVB protection, plus a pleasant cooling sensation on application. Sheer, lightweight formula is non-acnegenic, too. Appropriate for all skin types. See enclosure.



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Sun Protection Measures.

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Inactive ingredients

alcohol denat., octyldodecyl neopentanoate-butylolyl salicylate-polyester-8-acrylates/octylacrylamide copolymer-ethylhexyl methoxycrylene-dimethicone-trimethylsiloxysilicate-tocopheryl acetate-ethylcellulose [In42861]

Other information

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CLINIQUE

broad spectrum
SPF 30
sunscreen

UVA UVB
advanced protection

virtu-oil
body mist
4.9 FL.OZ.
144 ml e





CLINIQUE BROAD SPECTRUM SPF 30 SUNSCREEN BODY MIST

avobenzone, homosalate, and octisalate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49527-059
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.0261 g in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	0.087 g in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	0.0392 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
octyldodecyl neopentanoate (UNII: X8725R883T)	
butyloctyl salicylate (UNII: 2EH13UN8D3)	
polyester-8 (1400 mw, cyanodiphenylpropenoyl capped) (UNII: T9296U138P)	
ethylhexyl methoxycrylene (UNII: S3KFG6Q5X8)	
dimethicone (UNII: 92RU3N3Y1O)	
ethylcellulose, unspecified (UNII: 7Z8S9VYZ4B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49527-059-01	1 in 1 CARTON	06/01/2017	
1		144 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	06/01/2017	

Labeler - CLINIQUE LABORATORIES INC. (173047747)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COMPANY, THE		828534516	RELABEL(49527-059) , REPACK(49527-059)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(49527-059)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		202952982	MANUFACTURE(49527-059)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(49527-059)

Establishment

Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(49527-059)

Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC INC		943871157	RELABEL(49527-059) , REPACK(49527-059)

Establishment

Name	Address	ID/FEI	Business Operations
PADC 1		949264774	RELABEL(49527-059) , REPACK(49527-059)

Establishment

Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(49527-059)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		255175580	MANUFACTURE(49527-059)