

**AGE DEFENSE BB BROAD SPECTRUM SPF 30 ALL SKIN TYPES- octinoxate, octisalate, titanium dioxide, and zinc oxide cream**  
**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.*

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**AGE DEFENSE BB BROAD SPECTRUM SPF 30 ALL SKIN TYPES**

***Drug Facts***

**Active ingredients**

Octinoxate 7.5%  
Octisalate 4.4%  
Titanium dioxide 3.5%  
Zinc oxide 2.2%

**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**

water\aquaeau • octyldodecyl neopentanoate • butylene glycol • dimethicone • propanediol • glyceryl stearate • behenyl alcohol • peg-40 stearate • polyglyceryl-10 pentastearate • phenyl trimethicone • polymethylsilsesquioxane • hordeum vulgare (barley) extract/extrait d'orge • triticum vulgare (wheat) germ extract • laminaria saccharina extract • linoleic acid • oryzanol • squalane • caffeine • hydrogenated lecithin • sucrose • glycerin • polyquaternium-51 • lecithin • sodium stearoyl lactylate • polyglyceryl-6 polyricinoleate • sodium pca • isopropyl titanium triisostearate • trehalose • urea • tocopheryl acetate • sodium hyaluronate • ammonium acryloyldimethyltaurate/vp copolymer • xanthan gum • glycyrrhetic acid • stearic acid • alumina • silica • pentaerythrityl tetra-di-t-butyl hydroxyhydrocinnamate • disodium edta • chlorphenesin • sodium dehydroacetate • phenoxyethanol • [+/- titanium dioxide (ci 77891) • iron oxides (ci 77491, ci 77492, ci 77499) • mica] [iln39837]

### **Other information**

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

### **PRINCIPAL DISPLAY PANEL - 40 ml Tube Carton**

**C**  
**CLINIQUE**

age defense

**BB**  
**cream**

broad spectrum

SPF 30

ALL SKIN TYPES

1.4 FL.OZ.LIQ./40 ml e

1, 2, 3, 4

ALL SKIN TYPES

0789

TP 031

1

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

Perfecting cream conceals, helps prevent premature signs of aging with UVA/UVB protection. Unique complex of optics instantly reduces the appearance of lines and wrinkles. Antioxidants help defend against environmental aggressors. Anti-irritants instantly soothe. Long-wearing, oil-control formula works beautifully under foundation, or alone. Skin feels soft, smooth. Looks brighter, perfected. See enclosure.



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**Drug Facts (cont'd)**

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NEW YORK, N.Y. 10022  
LONDON W1K 3BQ • PARIS  
MADE IN BELGIUM  
7KYL



clinique.com



CLINIQUE

age defense

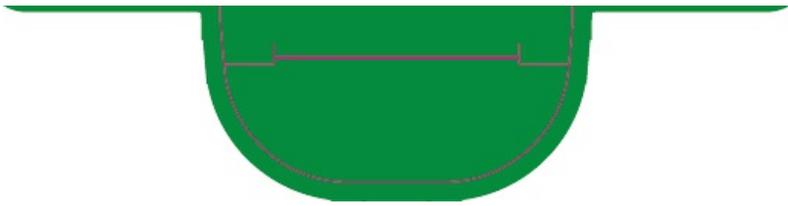
BB  
cream

broad spectrum  
SPF 30

ALL SKIN TYPES

1.4 FL.OZ.LIQ./40 ml e

7KYL-01-1113



## AGE DEFENSE BB BROAD SPECTRUM SPF 30 ALL SKIN TYPES

octinoxate, octisalate, titanium dioxide, and zinc oxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49527-030
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.084375 g in 100 mL
<b>OCTISALATE</b> (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	0.0495 g in 100 mL
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	0.039375 g in 100 mL
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.02475 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>water</b> (UNII: 059QF0K00R)	
<b>octyldodecyl neopentanoate</b> (UNII: X8725R883T)	
<b>butylene glycol</b> (UNII: 3XUS85K0RA)	
<b>dimethicone</b> (UNII: 92RU3N3Y1O)	
<b>propanediol</b> (UNII: 5965N8W85T)	
<b>glyceryl monostearate</b> (UNII: 230OU9XXE4)	
<b>docosanol</b> (UNII: 9G1OE216XY)	
<b>peg-40 stearate</b> (UNII: ECU18C66Q7)	
<b>phenyl trimethicone</b> (UNII: DR0K5NOJ4R)	
<b>wheat germ</b> (UNII: YR3G369F5A)	
<b>saccharina latissima</b> (UNII: 68CMP2MB55)	
<b>linoleic acid</b> (UNII: 9KJL21T0QJ)	
<b>oryzanol</b> (UNII: SST9XCL51M)	
<b>squalane</b> (UNII: GW89575KF9)	
<b>caffeine</b> (UNII: 3G6A5W338E)	
<b>sucrose</b> (UNII: C151H8M554)	
<b>glycerin</b> (UNII: PDC6A3C0OX)	
<b>sodium stearoyl lactylate</b> (UNII: IN99IT31LN)	
<b>sodium pyrrolidone carboxylate</b> (UNII: 469OTG57A2)	
<b>isopropyl titanium triisostearate</b> (UNII: 949E3KBJ1I)	
<b>trehalose</b> (UNII: B8WCK70T7I)	
<b>urea</b> (UNII: 8W8T17847W)	
<b>.alpha.-tocopherol acetate</b> (UNII: 9E8X80D2L0)	
<b>hyaluronate sodium</b> (UNII: YSE9PPT4TH)	

<b>ammonium acryloyldimethyltaurate/vp copolymer</b> (UNII: W59H9296ZG)
<b>xanthan gum</b> (UNII: TTV12P4NEE)
<b>enoxolone</b> (UNII: P540XA09DR)
<b>stearic acid</b> (UNII: 4ELV7Z65AP)
<b>aluminum oxide</b> (UNII: LM26O6933)
<b>silicon dioxide</b> (UNII: ETJ7Z6XBU4)
<b>pentaerythritol tetrakis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate)</b> (UNII: 255PIF62MS)
<b>edetate disodium</b> (UNII: 7FLD91C86K)
<b>chlorphenesin</b> (UNII: I670DAL4SZ)
<b>sodium dehydroacetate</b> (UNII: 8W46YN971G)
<b>phenoxyethanol</b> (UNII: HIE492ZZ3T)
<b>ferric oxide red</b> (UNII: 1K09F3G675)
<b>ferric oxide yellow</b> (UNII: EX438O2MRT)
<b>ferrosoferric oxide</b> (UNII: XM0M87F357)
<b>mica</b> (UNII: V8A1AW0880)

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49527-030-01	1 in 1 CARTON	05/01/2013	
1		40 mL in 1 TUBE; Type 0: Not a Combination Product		

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	05/01/2013	

**Labeler** - CLINIQUE LABORATORIES LLC (044475127)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COMPANY, THE		828534516	RELABEL(49527-030) , REPACK(49527-030)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(49527-030)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		202952982	MANUFACTURE(49527-030)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(49527-030)

## Establishment

Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(49527-030)

## Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC INC		943871157	RELABEL(49527-030) , REPACK(49527-030)

## Establishment

Name	Address	ID/FEI	Business Operations
PADC 1		949264774	RELABEL(49527-030) , REPACK(49527-030)

## Establishment

Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(49527-030)

## Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		255175580	MANUFACTURE(49527-030)

Revised: 11/2019

CLINIQUE LABORATORIES LLC