

**HIGH IMPACT LIP COLOUR SPF 15- octinoxate, titanium dioxide cream**  
**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.*

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ACTIVE INGREDIENTS: OCTINOXATE 7.50% [ ] ZINC OXIDE 2.10%

**WARNING: STOP USE IF IRRITATION OCCURS**

PRINCIPAL DISPLAY PANEL:

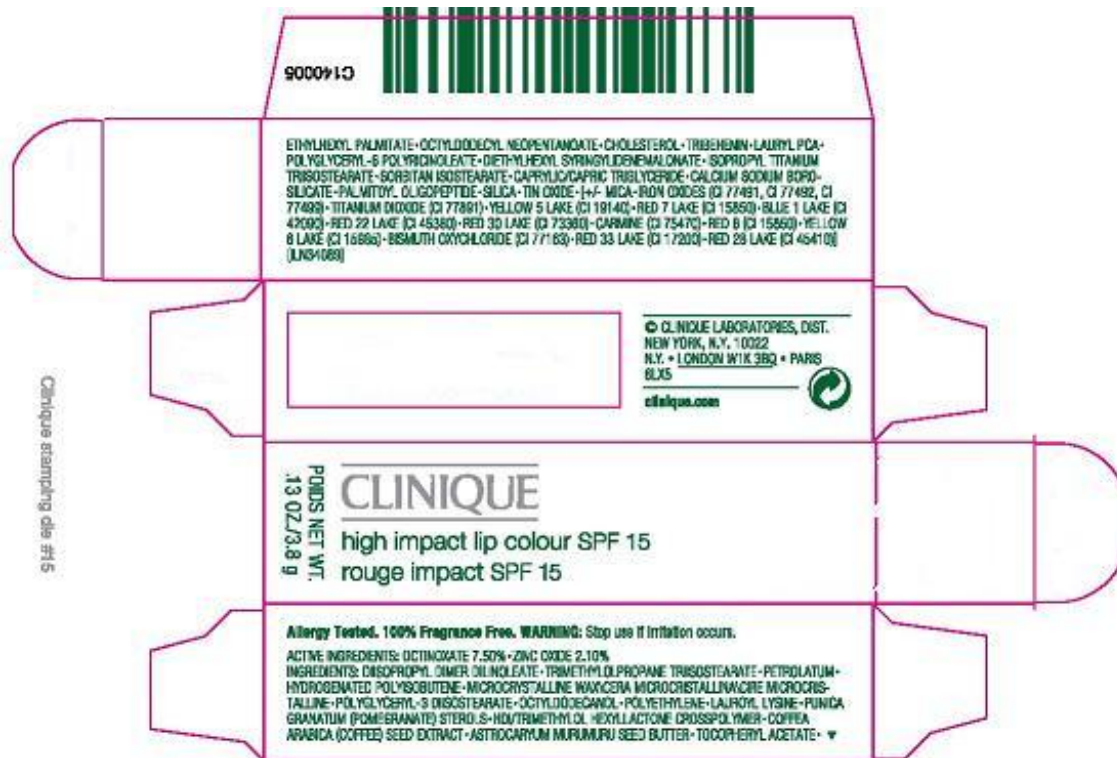
CLINIQUE

HIGH IMPACT LIP COLOUR SPF 15

NET WT.

0.13 OZ / 3.8 G

CLINIQUE LABORATORIES, DIST.  
NEW YORK, NY 10022



**HIGH IMPACT LIP COLOUR SPF 15**

octinoxate, titanium dioxide cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49527-727
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	2.1 g in 100 g

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:49527-727-01	1 in 1 CARTON		
1	NDC:49527-727-02	3.8 g in 1 VIAL, PLASTIC		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part352	02/01/2007	

**Labeler** - CLINIQUE LABORATORIES INC (173047747)**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
ESTEE LAUDER COSMETICS, LTD		205952385	manufacture

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
ESTEE LAUDER N.V.		370151326	manufacture

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Len-Ron Manufacturing Division of Aramis Inc.		809771152	manufacture

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Aramis Inc.		042918826	manufacture

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Northtec Bristol		949264774	manufacture, relabel, repack

**Establishment**

Name	Address	ID/FEI	Business Operations
Northtec Keystone		6 18 10 7429	manufacture, relabel, repack

## Establishment

Name	Address	ID/FEI	Business Operations
PADC 1		110 48 2184	manufacture, relabel, repack

## Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Pennsylvania Distribution Center 2		8 28 534516	manufacture, relabel, repack

## Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Cosmetics, Ltd.		255175580	manufacture

## Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Cosmetics, Ltd.		253616536	manufacture

## Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Cosmetics Distribution Center		208579636	manufacture, label, relabel

## Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Kabushiki Kaisha		712808195	relabel, repack

## Establishment

Name	Address	ID/FEI	Business Operations
Whitman Laboratories Ltd.		216866277	manufacture

## Establishment

Name	Address	ID/FEI	Business Operations
Aveda Corporation		071352058	manufacture