

**YOUTH SURGE SPF 15 AGE DECELERATING MOISTURIZER DRY COMBINATION  
SKIN- octinoxate octisalate 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 7.5%, OCTISALATE 3.5%, TITANIUM DIOXIDE, 1.2%

**WARNING:** KEEP OUT OF EYES. STOP USE IF IRRITATION OCCURS. KEEP OUT OF REACH OF CHILDREN.

**PRINCIPLE DISPLAY PANEL 1.7 OZ CARTON**

CLINIQUE

YOUTH SURGE SPF 15  
AGE DECELERATING MOISTURIZER  
DRY COMBINATION

NET WT. 1.7 OZ/ 50 ML

CLINIQUE LABORATORIES DISTR.

NEW YORK, NY 10022

6NFC

CLINIQUE.COM



## YOUTH SURGE SPF 15 AGE DECELERATING MOISTURIZER DRY COMBINATION SKIN

octinoxate octisalate titanium dioxide cream

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:49527-730 |
| Route of Administration | TOPICAL        |                    |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength          |
|--|-------------------|-------------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)             | OCTINOXATE        | 7.50 mL in 100 mL |
| OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)             | OCTISALATE        | 3.5 mL in 100 mL  |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE  | 1.2 mL in 100 mL  |

**Packaging**

| # | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:49527-730-01 | 1 in 1 CARTON       |                      |                    |
| 1 | NDC:49527-730-02 | 50 mL in 1 JAR      |                      |                    |

**Marketing Information**

| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part352                                  | 01/01/2009           |                    |

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

| Name              | Address | ID/FEI    | Business Operations |
|-------------------|---------|-----------|---------------------|
| ESTEE LAUDER N.V. |         | 370151326 | manufacture         |

**Establishment**

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

**Establishment**

| Name        | Address | ID/FEI    | Business Operations |
|-------------|---------|-----------|---------------------|
| Aramis Inc. |         | 042918826 | manufacture         |

**Establishment**

| Name             | Address | ID/FEI    | Business Operations          |
|------------------|---------|-----------|------------------------------|
| Northtec Bristol |         | 949264774 | manufacture, relabel, repack |

**Establishment**

| Name              | Address | ID/FEI    | Business Operations          |
|-------------------|---------|-----------|------------------------------|
| Northtec Keystone |         | 618107429 | manufacture, relabel, repack |

**Establishment**

| Name   | Address | ID/FEI    | Business Operations          |
|--------|---------|-----------|------------------------------|
| PADC 1 |         | 110482184 | manufacture, relabel, repack |

**Establishment**

| Name  | Address | ID/FEI    | Business Operations          |
|---|---------|-----------|------------------------------|
| Estee Lauder Pennsylvania Distribution Center 2 |         | 828534516 | manufacture, relabel, repack |

**Establishment**

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

**Establishment**

| <b>Name</b>                 | <b>Address</b> | <b>ID/FEI</b> | <b>Business Operations</b> |
|-----------------------------|----------------|---------------|----------------------------|
| Estee Lauder Cosmetics, Ltd |                | 253616536     | manufacture                |

### **Establishment**

| <b>Name</b>                                | <b>Address</b> | <b>ID/FEI</b> | <b>Business Operations</b>  |
|--|----------------|---------------|-----------------------------|
| Estee Lauder Cosmetics Distribution Center |                | 208579636     | manufacture, label, relabel |

### **Establishment**

| <b>Name</b>                   | <b>Address</b> | <b>ID/FEI</b> | <b>Business Operations</b> |
|-------------------------------|----------------|---------------|----------------------------|
| Estee Lauder Kabushiki Kaisha |                | 712808195     | relabel, repack            |

### **Establishment**

| <b>Name</b>               | <b>Address</b> | <b>ID/FEI</b> | <b>Business Operations</b> |
|---------------------------|----------------|---------------|----------------------------|
| Whitman Laboratories Ltd. |                | 216866277     | manufacture                |

### **Establishment**

| <b>Name</b>       | <b>Address</b> | <b>ID/FEI</b> | <b>Business Operations</b> |
|-------------------|----------------|---------------|----------------------------|
| Aveda Corporation |                | 071352058     | manufacture                |

Revised: 4/2010

CLINIQUE LABORATORIES INC