

REPAIRWEAR LIFT SPF 15 FIRMING DAY COMBO TO OILY SKIN- 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.

active ingredients: octinoxate 7.50% [] titanium dioxide 1.40%

ingredients: water [] cetyl ethylhexanoate [] butylene glycol [] glyceryl stearate [] peg-100 stearate [] octyldodecyl neopentanoate [] hydrogenated lecithin [] pentylene glycol [] coleus barbatus extract [] prunus amygdalus dulcis (sweet almond) seed extract [] olea europaea (olive) fruit extract [] triticum vulgare (wheat bran) extract [] sigesbeckia orientalis extract [] cholesterol/potassium sulfate [] persea gratissima (avocado) oil [] cucumis melo (melon) fruit extract [] betula alba (birch) bark extract [] decarboxy carnosine hcl [] polygonum cuspidatum root extract [] coffea robusta seed extract [] saccharomyces lysate extract [] isomerized linoleic acid [] whey protein [] glycerin [] creatine [] algae extract [] thermus thermophilus ferment [] linoleic acid [] cholesterol [] adenosine phosphate [] sodium dna [] polyethylene [] caffeine [] glycine soja (soybean) sterols [] lecithin [] astrocaryum murumuru seed butter [] trehalose [] acetyl hexapeptide-8 [] sodium rna [] sorbitol [] aminopropyl ascorbyl phosphate [] propylene glycol dicaprylate [] ethylhexyl palmitate [] sodium hyaluronate [] silica [] ethylhexyl stearate [] behenyl alcohol [] caprylyl glycol [] phytosphingosine [] hexylene glycol [] propylene glycol dicaprate [] ethylhexylglycerin [] xanthan gum [] carbomer [] potassium carbomer [] aluminum stearate [] potassium stearate [] disodium edta [] sodium dehydroacetate [] phenoxyethanol

warning: keep out of eyes. stop use if irritation occurs

keep out of reach of children

PRINCIPAL DISPLAY PANEL

CLINIQUE

REPAIRWEAR LIFT SPF 15

FIRMING CREAM

OILY/COMB SKIN

NT WT 1.7 OZ./50 ML

clinique laboratories distr.

new york, ny 10022



REPAIRWEAR LIFT SPF 15 FIRMING DAY COMBO TO OILY SKIN

octinoxate, titanium dioxide cream

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:49527-009 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|------------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 7.5 mL in 100 mL |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE | 1.4 mL in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| WATER (UNII: 059QF0K00R) | |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| PROPYLENE GLYCOL MONOSTEARATE (UNII: F76354LMGR) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N) | |
| PENTYLENE GLYCOL (UNII: 50C1307PZG) | |
| OLIVE OIL (UNII: 6UYK2W1W1E) | |
| POTASSIUM SULFATE (UNII: 1K573LC5TV) | |
| CHOLESTEROL (UNII: 97C5T2UQ7J) | |
| AVOCADO OIL (UNII: 6VNO72PFC1) | |
| CUCUMBER JUICE (UNII: 61845009SP) | |
| POLYGONUM CUSPIDATUM ROOT (UNII: 7TRV45YZF7) | |
| SACCHAROMYCES LYSATE (UNII: R85W246Z1C) | |

| |
|---|
| CREATINE (UNII: MU728 12GK0) |
| ADENOSINE PHOSPHATE (UNII: 415SHH325A) |
| CAFFEINE (UNII: 3G6A5W338E) |
| LECITHIN, SOYBEAN (UNII: 1DI56QDM62) |
| ASTROCARYUM MURUMURU SEED BUTTER (UNII: 12V64UPU6R) |
| TREHALOSE (UNII: B8WCK70T7I) |
| SORBITOL (UNII: 506T60A25R) |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) |
| HEXYLENE GLYCOL (UNII: KEH0A3F75J) |
| XANTHAN GUM (UNII: TTV12P4NEE) |
| CARBOMER HOMO POLYMER TYPE C (UNII: 4Q93RCW27E) |
| EDETATE DISODIUM (UNII: 7FLD91C86K) |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:49527-009-01 | 1 in 1 CARTON | | |
| 1 | NDC:49527-009-02 | 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 | 12/01/2010 | |

Labeler - CLINIQUE LABORATORIES INC (173047747)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------------|---------|-----------|---------------------|
| ESTEE LAUDER COSMETICS, LTD | | 205952385 | manufacture |

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 |
|---|---------|-----------|------------------------------|
| Estee Lauder Pennsylvania Distribution Center 2 | | 828534516 | 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 | repack, 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 |