# MOISTURE THERAPY INTENSIVE HEALING AND REPAIR LIP- octinoxate, oxybenzone ointment New Avon 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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### **Active Ingredients**

Octinoxate 7.5%, Oxybenzone 3.0%.....

## **Purpose**

...... Sunscreen

#### Uses

■ helps prevent sunburn

#### **WARNINGS**

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging.

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 swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions**

- apply liberally 15 minutes before sun exposure
- children under 6 months of age: ask a doctor
- reapply at least every 2 hours
- use a water-resistant sunscreen if swimming or sweating

#### Other Information

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

Inactive ingredients: PETROLATUM, ORYZA SATIVA (RICE) BRAN OIL, PARAFFIN, SIMMONDSIA CHINENSIS (JOJOBA) SEED OIL, HYDROGENATED POLYISOBUTENE, GLYCINE SOJA (SOYBEAN) STEROLS, LECITHIN, GLYCINE SOJA (SOYBEAN) OIL, BENZYL ALCOHOL, BHT.

Questions? 1-800-FOR-AVON



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Inactive Ingredients: Petrolatum, Oryza Sativa (Rice) Bran Oil, Paraffin, Simmondsia Chinensis (Jojoba) Seed Oil, Hydrogenated Polyisobutene, Glycine Soja (Soybean) Sterols, Lecithin, Glycine Soja (Soybean) Oil, Benzyl Alcohol, Bht.

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| Product Information     |                |                    |                |
|-------------------------|----------------|--------------------|----------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:10096-0103 |
| Route of Administration | TOPICAL        |                    |                |

| Active Ingredient/Active Moiety                              |                   |               |  |
|--|-------------------|---------------|--|
| Ingredient Name  | Basis of Strength | Strength      |  |
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 75 mg in 1 mL |  |
| OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y) | OXYBENZONE        | 30 mg in 1 mL |  |

| l | Packaging              |   |                         |                       |  |
|---|------------------------|---|-------------------------|-----------------------|--|
|   | # Item Code            | Package Description   | Marketing Start<br>Date | Marketing End<br>Date |  |
|   | 1 NDC:10096-<br>0103-1 | 15 mL in 1 TUBE, WITH APPLICATOR; Type 0: Not a Combination Product |                         |                       |  |

|   | <b>Marketing Inform</b> | nation                                   |                      |                    |
|---|-------------------------|--|----------------------|--------------------|
| ı | Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |

| OTC monograph not final | part352 | 05/22/2012 |  |
|-------------------------|---------|------------|--|
|                         |         |            |  |

# Labeler - New Avon LLC (080143520)

| Establishment       |         |           |                         |  |
|---------------------|---------|-----------|-------------------------|--|
| Name                | Address | ID/FEI    | Business Operations     |  |
| Avon Products, Inc. |         | 005149471 | manufacture(10096-0103) |  |

Revised: 2/2016 New Avon LLC