**SUNSCREEN- octinoxate, octisalate, octocrylene, oxybenzone lotion**
**Humphreyline**

*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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**Drug Facts**

Octinoxate (6.5%)

Octisalate (4.0%)

Octocrylene (7.0%)

Oxybenzone (5.5%)

Sunscreen

For external use only.

Avoid contact with eyes.

Discontinue use if rash or irritation occurs.

Children under 6 months consult a doctor before use.

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For external use only.

Water, PPG-15 Stearyl Ether Benzoate, Corn Starch modified, Triethanolamine, Hypromellose, Acrylic Polymer, Propylene Glycol, Diazolidinyl Urea, Methylparaben, Propylparaben, Disodium EDTA

# SUNSCREEN

octinoxate, octisalate, octocrylene, oxybenzone lotion

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:19392-400 |
| **Route of Administration** | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **OCTINOXATE** (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 65 mg in 1 g |
| **OXYBENZONE** (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE | 55 mg in 1 g |
| **OCTISALATE** (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) | OCTISALATE | 40 mg in 1 g |
| **OCTOCRYLENE** (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE | 70 mg in 1 g |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **WATER** (UNII: 059QF0KO0R) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **TROLAMINE** (UNII: 9O3K93S3TK) | |
| **HYPROMELLOSES** (UNII: 3NXW29V3WO) | |
| **POLYQUATERNIUM-39 (31/40/29 ACRYLIC ACID/ACRYLAMIDE/DADMAC; 1500000 MW)** (UNII: 5CO59WNJ6R) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **DIAZOLIDINYL UREA** (UNII: H5RIZ3MPW4) | |
| **METHYLPARABEN** (UNII: A2I8C7HI9T) | |
| **EDETATE DISODIUM** (UNII: 7FLD91C86K) | |
| **PROPYLPARABEN** (UNII: Z8IX2SC1OH) | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:19392-400-03 | 28 g in 1 BOTTLE, PLASTIC | | |
| **2** | NDC:19392-400-04 | 44 g in 1 BOTTLE, PLASTIC | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph not final | part352 | 01/01/2010 | |

## Labeler - Humphreyline (122539042)

Revised: 8/2012 Humphreyline