PRESIDENTS CHOICE - octinoxate, homosalate, oxybenzone, avobenzone lotion Fruit of the Earth, 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.

Principal Display Panel

Enter section text here

President's Choice SPF/FPS 30 Sunblock Lotion

Broadspectrum UVA/UVB Protection

Non-comedogenic Dermatologist tested

Waterproof 220 mL

Recognized by the Canadian Dermatology Association

DIN # 02263068

Directions

Enter section text here

Apply liberally 15 to 30 minutes before sun exposure. Reapply after swimming, excessive perspiration or washing.

The sun may cause sunburn, premature aging of the skin and skin cancer. Avoiding the sun, wearing protective clothing and regular use of sunscreens over the years may reduce the chance of these harmful effects.

CAUTION

Enter section text here

CAUTION: FOR EXTERNAL USE ONLY. DISCONTINUE USE IF SIGNS OF RASH OR IRRITATION DEVELOP. AVOID CONTACT WITH EYES. FOR USE ON CHILDREN UNDER 6 MONTHS OF AGE, CONSULT YOUR DOCTOR. MINIMIZE YOUR CHILD'S EXPOSURE TO THE SUN; DRESS BABIES AND YOUNG CHILDREN IN APPROPRIATE PROTECTIVE CLOTHING. **KEEP OUT OF THE REACH OF CHILDREN.**

Medicinal Ingredients

Enter section text here

MEDICINAL INGREDIENTS: OCTINOXATE (7.5%), HOMOSALATE (5%), OXYBENZONE (4%), AVOBENZONE (2%)



PRESIDENTS CHOICE

octinoxate, homosalate, oxybenzone, avobenzone lotion

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:62217-152 |
| Route of Administration | TOPICAL | | |

| Active Ingredient/Active Moiety | | | | |
|--|-------------------|----------------|--|--|
| Ingredient Name | Basis of Strength | Strength | | |
| Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51) | Octinoxate | 7.5 g in 100 g | | |
| Homosalate (UNII: V06SV4M95S) (Homosalate - UNII:V06SV4M95S) | Ho mo salate | 5 g in 100 g | | |
| Oxybenzone (UNII: 9500S7VE0Y) (Oxybenzone - UNII:950OS7VE0Y) | Oxybenzone | 4 g in 100 g | | |
| Avobenzone (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX) | Avobenzone | 2 g in 100 g | | |
| | | | | |

| Packaging | | | | | | | |
|-----------|------------------|---------------------|----------------------|--------------------|--|--|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | | | |
| 1 | NDC:62217-152-23 | 220 g in 1 TUBE | | | | | |

| Marketing Information | | | | | |
|-------------------------|--|----------------------|--------------------|--|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | | |
| OTC monograph not final | part352 | 03/30/2005 | | | |
| | | | | | |

$\boldsymbol{Labeler} \text{ - Fruit of the Earth, Inc. } (039336490)$

Revised: 4/2010 Fruit of the Earth, Inc.