GENERAL PROTECTION- avobenzone, homos alate, octis alate, octinoxate, octocrylene aeros ol, spray

Cross-Brands Manufacturing 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.

Sea & Ski Cspray 50

SPF 50 Cspray

Comfort Trigger Spray



SEA*SKI® Dri-Mist SPF 50

Drug Facts

Active ingredients

Avobenzone 3.0%, Homosalate 10.0%, Octinoxate 7.5%, Octisalate 5.0%, Octocrylene 5.0%

Purpose

Sunscreen

Uses • helps prevent sunburn • if used as directed with other sun protection measures (see *Directions*), decreases the risk of skin cancer and early skin aging caused by the sun

harmful or fatal.

• For external use only • Do not use on damaged or broken skin
• When using this product = keep away from face to avoid breathing it
• 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. •
Cautien: Flammable. Contents under pressure. Do not use near fire, heat or while smoking. Do not puncture or incinerate. Store at temperature below 122 F (50 °C). Use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be

Directions • spray liberally and spread evenly by hand 15 minutes before sun exposure • hold container 4-6 inches from the skin to apply. Rub in. • do not spray directly into face. Spray on hands and then apply to face. Rub in. • do not apply in windy conditions • use in a well-ventilated area • reapply: ■ after 80 minutes of swimming or sweating ■ immediately after towel drying ■ at least every 2 hours • Sum Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including: ■ limit time in the higher and other sun protection measures including: I limit time in the sun, especially from 10 a.m. – 2 p.m. I wear long- sleeved shirts, pants, hats and sunglasses I Children under 6 months: Ask a doctor.

Other information • protect this product from excessive heat and direct sun • may stain some fabrics, wood, plastics, vinyl • for use on skin only.

Inactive ingredients
acrylates/octylacrylamide copolymer, alcohol denatured, aloe barbadensis leaf juice, argania spinosa, ascorbic acid, cholecalciferol, fragrance, neopentyl glycol diheptanoate, octyldodecanol, PEG-16 macadamia glycerides, propylene glycol, pyridoxine HCl, retinyl palmitate, silica, sodium propoxyhydroxypropyl thiosulfate silica, tocopheryl acetate, zea mays (corn) oil

Questions or comments? Call 855-sea-n-ski (855-732-6754) or visit www.seanski.com.

www.seanski.com Made in U.S.A.



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GENERAL PROTECTION

avobenzone, homosalate, octisalate, octinoxate, octocrylene aerosol, spray

| Product Information | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:71153-2007 |
| Route of Administration | TOPICAL | | |

| Active Ingredient/Active Moiety | | | | |
|--|-------------------|--------------|--|--|
| Ingredient Name | Basis of Strength | Strength | | |
| OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W) | OCTISALATE | 5 g in 1 g | | |
| HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S) | HOMOSALATE | 10 g in 1 g | | |
| OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE | 5 g in 1 g | | |
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 7.5 g in 1 g | | |
| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | AVOBENZONE | 3 g in 1 g | | |

| Inactive Ingredients | | |
|--------------------------------------|--------------|--|
| Ingredient Name | Strength | |
| ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X) | 0.1 g in 1 g | |

| Packaging | | | | |
|---------------------------------|--|-----------------------------|--------------------|--|
| # Item Code Package Description | | Marketing Start Date | Marketing End Date | |
| ı | 1 NDC:71153-2007-1 170 g in 1 CAN; Type 0: Not a Combination Product | | 0 1/0 4/20 17 | |

| Marketing Information | | | | |
|-----------------------|--|----------------------|--------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph final | part352 | 0 1/0 4/20 17 | | |
| | | | | |

Labeler - Cross-Brands Manufacturing LLC (080319350)

| Establishment | | | | |
|--------------------------------|---------|-----------|--|--|
| Name | Address | ID/FEI | Business Operations | |
| Cross-Brands Manufacturing LLC | | 080319350 | manufacture(71153-2007), label(71153-2007) | |

Revised: 1/2019 Cross-Brands Manufacturing LLC