

SUNSCREEN WATER RESISTANT- homosalate oxybenzone octisalate avobenzone octylcrylene aerosol, spray
220 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.

SPF-30 Artwork

Active Ingredients	Purpose
Butyl Methoxydibenzoylmethane 3.0%.....	Sunscreen
Homosalate 15.0%.....	Sunscreen
Benzophenone-3 5.0%.....	Sunscreen
Octocrylene 2.0%.....	Sunscreen
Ethylhexyl Salicylate 5.0%.....	Sunscreen

When Using this product

- Keep out of reach of children
- Keep out of eyes. Rinse with water to remove.
- Do not use if allergic to any ingredient.
- If swallowed, get medical help or contact Poison Control Center immediately.

Warnings

- For external use only
- Do not spray directly into face
- Use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.

Stop use and ask doctor if

- Rash or irritation develops.

Flammable

- Do not use near heat, open flame or while smoking.
- Do not puncture or incinerate. Contents under pressure.
- Do not store at temperature about 120°F (49°C).
- Avoid long term storage about 104°F (40°C).

Directions

- Apply generously and evenly to all areas 15 minutes before sun exposure.
- Spray on hands and apply to face.
- Use in well-ventilated area.
- Reapply to dry skin as needed.
- Ask doctor before use on children under six months of age.

Other Information

Sun Alert: Limiting sun exposure, wearing protective clothing and using sunscreens may reduce the risk of skin aging, skin cancer and other harmful effects of the sun.

Other Ingredients

Butane, Alcohol Denat., Taploca Starch, **Zinc Oxide**, Retinyl Palmitate, Zea Mays (Corn) oil,

Cholecalciferol, Tocopheryl Acetate, Panthenol, Tetrahexyldecyl Ascorbate, Ascorbyl Palmitate, Acrylates/Octylacrylamide Copolymer, Fragrance (Parfum)

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Zinka Clear continuous sunscreen spray

Mega mist water resistant

Broad spectrum

UVA/UVB Protection

Non-greasy, no slip grip

Fast and even application



----- Acceptable margins for texts and logos

General Specifications

Date	January 8th, 2009
Customer	220 Labs
Condensa Code	54 035 45140 002
Customer Code	XZIN-18-9005
Dimensions	ø 45 x 140 mm.
Shoulder	Ogived
Mouth	1 Inch

Decoration Specifications

Base Coat	White	External Laquer	PENDING
Color 1	PMS Process Yellow C plane	Color 2	PMS Process Yellow C gradient
Color 3	PMS 172 C	Color 4	Black
Color 5	-----	Color 6	-----

Included Data in the Decoration

Sanitary Register	Not included	Ozone Logo	Not included
Precautions	Included	Bar Code N°	0 77550 00031 6

Remarks:

PLEASE: Review carefully the texts, graphics, layout and specifications, since any change after approval will result in additional costs. **NOTE:** This file is for texts, spelling, layout and specifications approval only, not for color and gradients effects. The approval to this electronic file does not replace an approval at our facilities or an approval to a pre-production sample can.

SUNSCREEN WATER RESISTANT

homosalate oxybenzone octisalate avobenzone octylcrylene aerosol, spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57367-029
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	150 mg in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	50 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	20 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
STARCH, TAPIOCA (UNII: 24SC3U704I)	
ZINC OXIDE (UNII: SOI2LOH54Z)	
COUMARIN (UNII: A4VZ22K1WT)	
BENZYL SALICYLATE (UNII: WAO5MNK9TU)	
PANTHENOL (UNII: WV9CM0O67Z)	
BENZYL BENZOATE (UNII: N863NB338G)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
CORN OIL (UNII: 8470G57WFM)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57367-029-05	106 g in 1 CAN		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	05/10/2010	

Registrant - 220 Laboratories Inc (783247950)

Establishment

Name	Address	ID/FEI	Business Operations
220 Laboratories Inc		783247950	manufacture

Revised: 5/2010

220 Laboratories Inc