DYNAMIC BROAD SPECTRUM SUNSCREEN SPF 55- octinoxate and zinc oxide cream
National Hair Loss 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.

Dynamic Broad Spectrum Sunscreen SPF 55

DRUG FACTS

ACTIVE INGREDIENTS

Octinoxate 7.5%

Zinc Oxide 4.8%

PURPOSE

Sunscreen

USES

Help prevent sunburn.

WARNINGS

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 or irritation occurs.

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

DIRECTIONS

Apply liberally and evenly 15 minutes before sun exposure. [1]Reapply:

At least 80 minutes after swimming or sweating, immediately after towel drying, at least every 2 hours.

- Sun 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 of 15 or higher and other sun protection measures including:
- limit time in the sun, especially from 10 a.m. – 2 p.m.
- wear long-sleeve shirts, pants, hats, and sunglasses.

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[1] For children under 6 months of age: Ask a doctor.

INACTIVE INGREDIENTS

Water, Hydrogenated Polybutene, Octyl Stearate, Polyglyceryl-4-Isostearate, Aloe Barbadensis Leaf Extract, Isopropyl Palmitate, Cyclomethicone, Sunflower Oil, Hydrogenated Microcrystalline Wax, Cetyl Dimethicone Copolyol, Cetyl Dimethicone, Hydrogenated Castor Oil, Sodium Chloride,
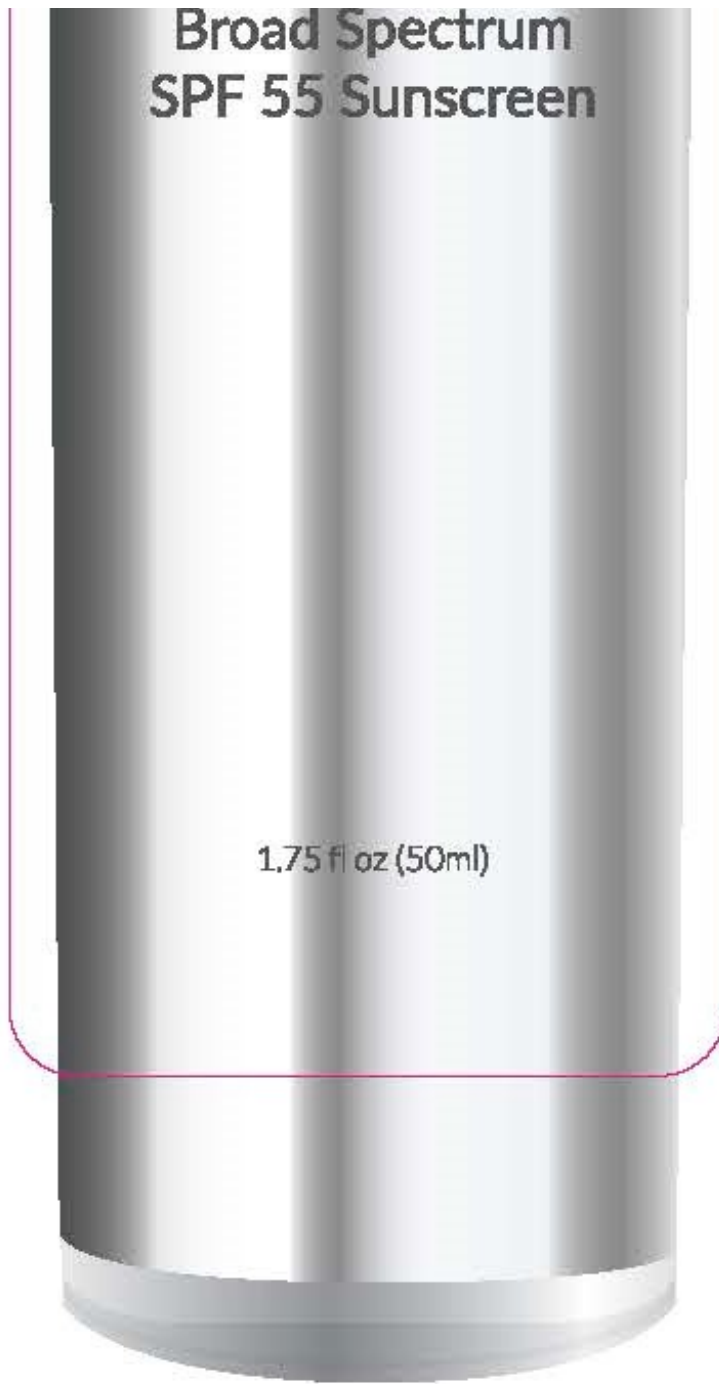
Polyglyceryl-3-Oleate, Silica, Hexyl Laurate, Triethoxycaprylylsilane, Capryly Glycol, Methylisothiazolinone.

OTHER INFORMATION

Store at controlled temperature 15C – 30C (59F-86F). Protect the product in this container from excessive heat and direct sun.

PRINCIPAL DISPLAY PANEL - 50 ml Bottle Label

Broad Spectrum
SPF 55 Sunscreen

1.75 fl oz (50ml)

NHL

SUN DEFENSE

broad spectrum
SPF 55 Sunscreen

1.75 fl oz. (50ml)

DYNAMIC BROAD SPECTRUM SUNSCREEN SPF 55
octinoxate and zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81368-5550

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 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	48 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ISOCETYL STEARATE (UNII: 3RJ7186O9W)	
SORBITOL (UNII: 506T60A25R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
ALCOHOL (UNII: 3K9958V90M)	
OCTISALATE (UNII: 4X49Y0596W)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
VINYLPYRROLIDONE/EICOSENE COPOLYMER (UNII: 035MV9S1C3)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%) (UNII: 86FQE96TZ4)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
BETULA PUBESCENS BARK (UNII: 3R504894L9)	
GARDEN CRESS SPROUT (UNII: PWQ18YNR62)	
SAGE (UNII: 065C5D077J)	
COLA ACUMINATA SEED (UNII: 1F8VIW1479)	
CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ISOMALT (UNII: S870P55O2W)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81368-5550-3	50 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/04/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/04/2021	

Labeler - National Hair Loss LLC (050422444)

Revised: 1/2021

National Hair Loss LLC

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