

**SHARX - SUNBREAKER MOISTURIZING SUNSCREEN SPF55 BROAD SPECTRUM-  
octinoxate and zinc oxide cream  
Cosmetic Solutions 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.*

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**Sharx - SunBreaker Moisturizing Sunscreen SPF55 Broad Spectrum**

**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. <sup>1</sup>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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<sup>1</sup> 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 - 60 mL Tube Label

SHARX

SUNBREAKER  
MOISTURIZER  
Sunscreen SPF55  
Broad Spectrum  
2 Fl Oz / 60mL

SUNBREAKER MOISTURIZER  
Sunscreen SPF55 Broad Spectrum

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SHARX

SUNBREAKER  
MOISTURIZER  
Sunscreen SPF55  
Broad Spectrum

2 Fl Oz / 60mL

Manufactured for  
LC TideBreaker  
Half Moon Bay, CA 94019

## SHARX - SUNBREAKER MOISTURIZING SUNSCREEN SPF55 BROAD SPECTRUM

octinoxate and zinc oxide cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:66 163-26 13
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Octinoxate</b> (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	75 mg in 1 g
<b>Zinc Oxide</b> (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	48 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>Water</b> (UNII: 059QF0KO0R)	
<b>Isocetyl Stearate</b> (UNII: 3RJ7186O9W)	
<b>Sorbitol</b> (UNII: 506T60A25R)	
<b>Cetostearyl Alcohol</b> (UNII: 2DMT128M1S)	
<b>Cyclomethicone 5</b> (UNII: 0THT5PC10R)	
<b>Glyceryl Monostearate</b> (UNII: 230OU9XXE4)	
<b>PEG-100 Stearate</b> (UNII: YD01N1999R)	
<b>Alcohol</b> (UNII: 3K9958V90M)	
<b>Octisalate</b> (UNII: 4X49Y0596W)	
<b>Polyoxyl 20 Cetostearyl Ether</b> (UNII: YRC528SWUY)	
<b>.Alpha.-Tocopherol Acetate</b> (UNII: 9E8X80D2L0)	
<b>Vinylpyrrolidone/Eicosene Copolymer</b> (UNII: 035MV9S1C3)	
<b>Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer (100000 MPA.S AT 1.5%)</b> (UNII: 86FQE96TZ4)	
<b>Ethylhexylglycerin</b> (UNII: 147D247K3P)	
<b>Betula Pubescens Bark</b> (UNII: 3R504894L9)	
<b>Garden Cress Sprout</b> (UNII: PWQ18YNR62)	
<b>Sage</b> (UNII: 065C5D077J)	
<b>Cola Acuminata Seed</b> (UNII: 1F8VIW1479)	
<b>Camellia Oleifera Leaf</b> (UNII: 5077EL0C60)	
<b>Aloe Vera Leaf</b> (UNII: ZY81Z83H0X)	
<b>Xanthan Gum</b> (UNII: TTV12P4NEE)	
<b>Isomalt</b> (UNII: S870P55O2W)	
<b>Edetate Disodium Anhydrous</b> (UNII: 8NLQ36F6MM)	
<b>Triethoxycaprylylsilane</b> (UNII: LDC331P08E)	
<b>Sodium Benzoate</b> (UNII: OJ245FE5EU)	
<b>Caprylyl Glycol</b> (UNII: 00YIU5438U)	
<b>Phenoxyethanol</b> (UNII: HIE492ZZ3T)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66 163-26 13-2	60 g in 1 TUBE; Type 0: Not a Combination Product	01/01/2019	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	01/01/2019	

**Labeler** - Cosmetic Solutions LLC (807907928)

Revised: 9/2019

Cosmetic Solutions LLC