# PHYSIK PERFORMANCE PLUS BROAD SPECTRUM SPF 42homosalate, octinoxate, zinc oxide lotion Spoke Sciences, Inc.

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# **Active Ingredients**

Homosalate 8.0% Octinoxate 7.5% Zinc Oxide 8.1 %

## **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.

### **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 occurs.
- · Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

## **Directions:**

- Apply liberally 15 minutes before sun exposure.
- Children under 6 months of age: Ask a doctor.

## **REAPPLY:**

- After 80 minutes of 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 sleeves shirts, pants, hats, and sunglasses.

## Other Information:

- Protect the product in this container from excessive heat and direct sun.
- May stain some fabrics.

ALUMINUM STARCH OCTENYLSUCCINATE, ASCORBYL PALMITATE, BIS-PEG-12 DIMETHICONE (70 MPA.S) (BEESWAX), CAPRYLHYDROXAMIC ACID, CAPRYLYL GLYCOL, CYCLOPENTASILOXANE, DECYL GLUCOSIDE, DIETHYLHEXYL SEBACATE, ETHYLHEXYL METHOXYCINNAMATE, ETHYLHEXYL PALMITATE, ETHYLHEXYL GLYCERIN, HYDROGENATED CASTOR OIL, METHYLPROPANEDIOL, PEG/PPG-20/15 DIMETHICONE, PEG-30 DIPOLYHYDROXYSTEARATE, DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER Soft (POLYSILICONE-11), PROPANEDIOL, SILICON DIOXIDE (SILICA), SODIUM CHLORIDE, .ALPHA.-TOCOPHEROL ACETATE (TOCOPHERYL ACETATE), TRIETHOXYCAPRYLYLSILANE, WATER

## Description

PERFORMANCE+
BROAD SPECTRUM SPF 42 SUNSCREEN FOR SPORT
NON-GREASY
CLEAR ZINC OXIDE
WATER RESISTANT (80 MIN)
FRAGRANCE + PARABEN FREE

42 SPF Broad Spectrum Sunscreen for Sports Water Resistant 80 minutes NET WT. 3.4fl.oz / 100mL



BROAD SPECTRUM SPF 42
SUNSCREEN FOR SPORT
NON-GREASY | CLEAR ZINC OXIDE
WATER RESISTANT (80 MIN)
FRAGRANCE + PARABEN FREE



ASURES: Spending time in the sun increases naging. To decrease this risk, regularly user SPF value of 15 or higher and other sur value of 14 or higher and other sur it time in the sun, especially from 10 a.m. to 2, hats and sunglasses.

# PERFORMANCE+

#### DRUG FACTS

Active Ingredient	Purpose
Homosalate 8.0%	
Octinoxate 7.5%Zinc Oxide 8.1%	

Use 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

#### Warnings

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- Do not use on damaged or broken skin
   When using this product keep out of eyes
- Stop use and ask a doctor if rash occurs.
   Keep out of reach of children. If swallowed, get medical help

#### Directions

- Apply liberally 15 minutes before sun exposure.
   Children under 6 months of age: Ask a doctor.
   DEADDLY: After 90 minutes of evironing or sweeting.
- Immediately after towel drying. At least every 2 hours.

#### Protect the product in this container from excessive

heat and direct sun.

May stain some fabrics.

Inactive Ingredients Aluminum Starch Octorylsuochrist
Ascorthy Palmatte, Bis-PEG-1D intentionce Besevar,
Cappyllydroxamic Acid, Cappyly Glycol, Cyclopentasilioxame
Decyl Glocosic, Diethylhoryl Schazate, Ethylterylyperin,
Hydrogenated Castor Ol, Methylpropanediol, PEG
PPG-20/15 Dimethicore, PEG-60 to Dechyldroxylgerante,
Polysiliotore-11, Propanediol, Slics, Sodium Chloride,
Torostock Acethyl Techsonosophedisten. Meter (Amu).

#### Spoke

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# homosalate, octinoxate, zinc oxide lotion

Product Type HUMAN OTC DRUG Item Code (Source) NDC:85316-100

**Route of Administration** TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	8.1 g in 100 mL	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	8 g in 100 mL	

Inactive Ingredients	
Ingredient Name	Strength
BIS-PEG-12 DIMETHICONE (70 MPA.S) (UNII: 2JDK5W22H4)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
DIETHYLHEXYL SEBACATE (UNII: U9LS47Q72Q)	
PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PROPANEDIOL (UNII: 5965N8W85T)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
PEG/PPG-20/15 DIMETHICONE (UNII: 06R6X77P9C)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: 19PJ006294)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WATER (UNII: 059QF0KO0R)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:85316-100- 01	100 mL in 1 TUBE; Type 0: Not a Combination Product	04/21/2025	

# **Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	04/21/2025	

# Labeler - Spoke Sciences, Inc. (118672931)

# Registrant - Fragrance Manufacturing, Inc. (793406000)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Fragrance Manufacturing, Inc.		793406000	manufacture(85316-100)	

Revised: 3/2025 Spoke Sciences, Inc.