

**SAFEGUARD SPF 40- zinc oxide cream**  
**Skinsalvation Skincare, 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.*

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**Drug Facts**

**Active Ingredient**

Zinc Oxide 20%

**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 product is swallowed, get medical help or contact a Poison Control Center right away

**Directions**

- Apply liberally 15 minutes before sun exposure
- Reapply: - after 40 minutes of swimming or sweating - immediately after towel drying - at least every two 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 skin protection measures including:
  - limit time in the sun, especially from 10 a.m.-2 p.m.
  - wear long-sleeve shirts, pants, hats and sunglasses
- Children under 6 months: ask a doctor

## **Inactive Ingredients**

C12-15 Alkyl Benzoate, Caprylhydroxamic Acid, Caprylyl Glycol, Cetyl PEG/ PPG 10/1 Dimethicone, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/ Vinyl Dimethicone Crosspolymer, Dimethiconol, Disodium EDTA, Glycerin, Hydrogen Dimethicone, Microcrystalline Wax, PEG-10 Dimethicone, PEG-30 Dipolyhydroxystearate, Polyglyceryl-4 Isostearate, Polyhydroxystearic Acid, Polysorbate 20, Sodium Chloride, Stearyl Dimethicone, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Triethanolamine, Triethoxycaprylylsilane, Water

## **Other Information**

- Protect this product from excessive heat and direct sun
- May stain some fabrics
- For easier application, dispense onto and rub between fingertips to warm before applying.

## **Questions or Comments?**

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san francisco, ca 94109 | withandwithin.co

## **Principal Display Panel - 100 g Tube Label**

**with &  
within**

**safeguard  
SPF 40**

**clear skin for everyone**

**FACE  
& BODY**

**broad spectrum spf 40**

**water resistant (40 minutes)**

**Net wt. 3.5 oz / 100 g**

with & within

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clear skin for everyone



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## SAFEGUARD SPF 40

zinc oxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:83578-205
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	200 mg in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 5) (UNII: 035JKJ76MT)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
DIMETHICONE 100 (UNII: RO266O364U)	
DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
PEG-30 DIPOLYHYDROXYSTEARATE (4000 MW) (UNII: 9713Q0S7FO)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
STEARYL DIMETHICONE (400 MPA.S AT 50C) (UNII: R327X197HY)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
WATER (UNII: 059QF0KO0R)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83578-205-35	100 g in 1 TUBE; Type 0: Not a Combination Product	06/30/2023	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	06/30/2023	

**Labeler** - Skinsalvation Skincare, Inc. (013319151)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Custom Analytics LLC		144949372	ANALYSIS(83578-205)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Fragrance Manufacturing Inc. (FMI)		793406000	MANUFACTURE(83578-205) , PACK(83578-205)

Revised: 7/2023

Skinsalvation Skincare, Inc.