

**MINERAL SUNSCREEN SPF 30- zinc oxide lotion**  
**Lee Indie & Co 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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**INDIE LEE - MINERAL SUNSCREEN SPF 30 (81545-101)**

**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 CONSULT A PHYSICIAN IF RASH OCCURS.

KEEP OUT OF REACH OF CHILDREN. IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

**DIRECTIONS**

Shake before use.

- Apply generously to skin 15 minutes before sun exposure.
- During 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 the risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with broad spectrum SPF value of 15 or higher and other sun protection measures including: limit time in the sun, especially from 10a.m. to 4 p.m.; wear long sleeve shirts, pants, hats and

sunglasses. Children under 6 months: ask a doctor

### **INACTIVE INGREDIENTS**

Water (aqua), Helianthus Annuus (Sunflower) Seed Oil, Caprylic/Capric Triglyceride, Squalane, Dicapryl Carbonate, Cetearyl Oliviate, Sorbitan Oliviate, Glycerin, Shea Butter Cetyl Esters, Sorbitan Sesquioleate, Polyhydroxystearic Acid, Diglycerin, Pinus Pinaster (Cluster Pine) Bark Extract, Punica Granatum (Pomegranate) Seed Oil, Phenethyl Alcohol, Pentylene Glycol, Propanediol, Aloe Barbadensis (Aloe Vera) Leaf Juice Powder, Panthenol, Xanthan Gum, Lauroyl Lysine

### **OTHER INFORMATION**

Protect this product from excessive heat and direct sun. Store below 90°F (32°C).

### **QUESTIONS OR COMMENTS?**

INDIELEE.COM

+1 (866) 488-1638 MON-FRI (9 A.M. - 5 P.M. EST)

1/4" NO PRINT AREA

Quiet zone. All copy must be 1/16" below the eye-mark.



Center Art Work

Center Front Panel

Eye-mark

Center Back Panel

INDIE LEE

MINERAL SUNSCREEN

SPF 30 Broad Spectrum

FPS 30 A Large Spectre. Écran Solaire Minéral, Résistant à L'eau 40min

Label size  
2.1406" x 3.875"

2 25/64"

4 25/32" Actual Tube Circumference

100ml / 3.3 fl. oz

1/4" NO PRINT AREA

**Drug Facts**

**Active ingredient** ..... **Purpose**  
Zinc Oxide 20% ..... Sunscreen

**Uses** Helps prevent sunburn ■ If used as directed with other sun protection measure (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 consult a physician** if irritation occurs. **Keep out of reach of children.** If swallowed, get medical help or contact Poison Control Center right away.

**Directions** Shake before use. ■ Apply generously to skin 15 minutes before sun exposure. ■ During 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 the risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with broad spectrum SPF value of 15 or higher and other sun protection measures including: limit time in the sun, especially from 10a.m. to 2 p.m.; wear long sleeve shirts, pants, hats and sunglasses. Children under 6 months: ask a doctor

**Other information** Protect this product from excessive heat and direct sun. Store below 90° F (32°C).

**Questions or comments?** [indielee.com](http://indielee.com)  
+1 (866) 488-1638 Mon-Fri (9 a.m. - 5 p.m. EST)

Dist. by Indie Lee & Co., South Salem, NY 10590 / [indielee.com](http://indielee.com)  
Made in USA for Indie Lee / Fabriqué aux États-Unis pour Indie Lee  
EU RP: Répertoire Compliances Dublin D07 P4AX, IE  
UK RP: Répertoire Compliances London WC2H 9JQ, UK

**Drug Facts**

**Ingrédient actif** ..... **But**  
Zinc Oxide 20% ..... Ecran Solaire

**Usages** Aide à protéger contre les coups de soleil. ■ Si le produit est utilisé sur une peau abîmée ou éraflée, diminue les risques de cancer de la peau et de vieillissement cutané prématuré causé par le soleil.

**Précautions** Pour un usage externe uniquement. ■ Ne pas utiliser sur une peau abîmée ou éraflée. **Lorsque vous utilisez ce produit**, évitez tout contact avec les yeux. Rincer à l'eau afin d'enlever le produit. En cas d'irritation, **interrompez son utilisation et consultez un médecin** Tenir hors de portée des enfants. En cas d'ingestion, demandez un avis médical ou appelez le centre antipoison immédiatement.

**Mode d'emploi** Agitez avant l'emploi. ■ Appliquez généreusement sur la peau 15 minutes avant l'exposition au soleil. ■ Renouvelez l'application durant l'exposition au soleil: Après avoir nagé ou transpiré pendant 40 minutes. ■ Immédiatement après vous être séché(e) avec une serviette. ■ Au minimum toutes les deux heures. **Mesures de protection contre le soleil** l'exposition au soleil augmente les risques de cancer de la peau et de vieillissement cutané prématuré. Pour réduire ces risques, il est recommandé d'utiliser régulièrement un écran solaire avec un FPS de 15 ou plus et de prendre des précautions supplémentaires pour se protéger du soleil. Il faut notamment limiter les expositions au soleil, en particulier entre 10 h et 14 h; porter des vêtements à manches longues, ainsi que des pantalons, un chapeau et des lunettes de soleil. Enfants de moins de 6 mois : demander conseil à un médecin.

**Other information**  
Préservez le produit contenu dans ce récipient contre la chaleur extrême et une exposition directe au soleil.

**Questions or comments?**  
+1(866)488-1638 Mon-Fri (9a.m - 5p.m. EST) [indielee.com](http://indielee.com)

**INDIE LEE**

How to use: Give sunscreen a good shake before using. Apply liberally 15 minutes before sun exposure. Kick back, relax, and reapply every 2 hours for maximum sun protection.

Mode d'emploi: Secouez bien l'écran total avant utilisation. Appliquez généreusement 15 minutes avant de vous exposer au soleil. Et maintenant, décompressez. Appliquez à nouveau toutes les deux heures pour une protection solaire optimale.

Active Ingredients: Zinc Oxide ..... 20%

Inactive Ingredients: Water (aqua), Helianthus Annuus (Sunflower) Seed Oil, Caprylic/Capric Triglyceride, Olea Europea (Olive Fruit) Oil, Dicapryl Carbonate, Cetearyl Oliviate, Sorbitan Oliviate, Glycerin, Shea Butter Cetyl Esters, Sorbitan Sesquioleate, Polyhydroxysteanic Acid, Diglycerin, Pinus Pinaster (Cluster Pine) Bark Extract, Punica Granatum (Pomegranate) Seed Oil, Phenethyl Alcohol, Pentylene Glycol, Propanediol, Aloe Barbadensis (Aloe Vera) Leaf Juice Powder, Panthenol, Xanthan Gum, Lauroyl Lysine

[@indie\\_lee / \[indielee.com\]\(http://indielee.com\)](https://www.instagram.com/indie_lee/)

# MINERAL SUNSCREEN SPF 30

zinc oxide lotion

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:81545-101
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	20 g in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
MARITIME PINE (UNII: 50JZ5Z98QY)	
POMEGRANATE SEED OIL (UNII: 0UI45XV0T6)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PANTHENOL (UNII: WW9CM0067Z)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
PROPANEDIOL (UNII: 5965N8W85T)	
LAUROYL LYSINE (UNII: 113171Q70B)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
WATER (UNII: 059QF0KOOR)	

<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SQUALANE</b> (UNII: GW89575KF9)	
<b>DICAPRYLYL CARBONATE</b> (UNII: 609A3V1SUA)	
<b>CETEARYL OLIVATE</b> (UNII: 58B69Q84JO)	
<b>DIGLYCERIN</b> (UNII: 3YC120743U)	
<b>SHEA BUTTER ETHYL ESTERS</b> (UNII: V2CI786FPG)	
<b>SORBITAN SESQUIOLEATE</b> (UNII: 0W8RRI5W5A)	
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81545-101-50	1 in 1 BOX	09/17/2021	
1	NDC:81545-101-10	100 mL in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	09/17/2021	

**Labeler** - Lee Indie & Co Inc (117191089)

Revised: 1/2023

Lee Indie & Co Inc