

**KORU PERFORMANCE SUNSCREEN SPF40- sunscreen stick**  
**Koru Performance 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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**Koru Performance Sunscreen Stick**

***Active Ingredient***

Zinc Oxide 20%

***Purpose***

Sunscreen

***Uses***

- Helps prevent sunburn.
- Higher SPF gives more sunburn protection.
- Provides high protection against sunburn.
- Retains SPF after 80 minutes of swimming or sweating.

***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 develops and lasts.

**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

- Use a water-resistant sunscreen if swimming or sweating.
- Reapply

Immediately after towel drying  
At least every 2 hours

- Children under 6 months of age: ask a doctor
- 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 value of 15 or higher and other sun protection measures including:
  - limit time in the sun, especially from 10 am to 2 pm
  - wear long-sleeved shirts, pants, hats and sunglasses

### ***Other Information***

Protect this product from excessive heat and direct sun

### ***Inactive Ingredients***

Batilol, Butylene glycol, Ceresin, Cetyl alcohol, Cocoyl caprylocaprate, Dimethicone, Disteardimonium hectorite, Edetate disodium, Ethylhexylglycerin, Ethyl ferulate, Medium-chain triglycerides, Neopentyl glycol dicaprate, Pentaerythrityl tetraethylhexanoate, Phenoxyethanol, Polyglyceryl-3 pentaricinoleate, Polyglyceryl-4 isostearate, Propanediol, Propanediol dicaprylate, Silicon dioxide, Sorbitan isostearate, Styrene/Acrylamide copolymer (MW 500000), Triethoxycaprylylsilane

### **Applicator Label**

DRUG FACTS	
Active Ingredient	Purpose
Zinc Oxide 20%	Sunscreen
<b>Uses</b> - Helps prevent sunburn • Higher SPF gives more sunburn protection • Provides high protection against sunburn • Retains SPF after 80 minutes of swimming or sweating	
<b>Warnings</b> - 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 develops and lasts • Keep out of reach of children • If product is swallowed, get medical help or contact a Poison Control Center right away	
<b>Directions</b> - Apply liberally 15 minutes before sun exposure • Use a water resistant sunscreen if swimming or sweating • Reapply • Immediately after towel drying • At least every 2 hours • Children under 6 months of age: ask a doctor • <b>Sun Protection Measures</b> 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 value of 15 or higher and other sun protection measures including - limit time in the sun, especially from 10 am to 2 pm • wear long-sleeved shirts, pants, hats and sunglasses	
<b>Other Information</b> Protect this product from excessive heat and direct sun.	
<b>Inactive Ingredients</b> Butiril, Butylene glycol, Ceresin, Cetyl alcohol, Cocoyl caprylocaprato, Dimethicone, Distearidimonium hectorite, Edetate disodium, Ethylhexylglycerin, Ethyl ferulate, Medium chain triglycerides, Neopentyl glycol dicaprato, Pentaerythritol tetraethylhexanoate, Phenoxethanol, Polyglyceryl-3 pentaericoate, Polyglyceryl-4 isostearate, Propanediol, Propanediol dicaprylate, Silicon dioxide, Sorbitan isostearate, Styrene/acrylamide copolymer (MFW 500000), Triethoxycaprylylsilane	



## KORU PERFORMANCE SUNSCREEN SPF40

sunscreen stick

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:81129-002
<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
DIMETHICONE (UNII: 92RU3N3Y1O)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PROPANEDIOL DICAPRYLATE (UNII: C5770MC6UH)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
COCOYL CAPRYLOCAPRATE (UNII: 8D9H4QU99H)	
PENTAERYTHRITYL TETRAETHYLHEXANOATE (UNII: XJ7052W897)	
POLYGLYCERYL-3 PENTARICINOLEATE (UNII: 7Q0OK5DOT4)	
CERESIN (UNII: Q1LS2UJ03A)	
NEOPENTYL GLYCOL DICAPRATE (UNII: 77T908SE82)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
PROPANEDIOL (UNII: 5965N8W85T)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

<b>STYRENE/ACRYLAMIDE COPOLYMER (MW 500000)</b> (UNII: 5Z4DPO246A)	
<b>ETHYL FERULATE</b> (UNII: 5B8915UELW)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>BATILOL</b> (UNII: 39YR661C4U)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81129-002-01	62 g in 1 APPLICATOR; Type 0: Not a Combination Product	08/01/2021	

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	08/01/2021	

**Labeler** - Koru Performance LLC (117749158)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
TAKA USA Inc. dba Cosmetic Innovations		802860515	manufacture(81129-002)

Revised: 7/2021

Koru Performance LLC