

**AROCELL TONE UP PERFECT SUN- zinc oxide, titanium dioxide cream**  
**FICC Co., Ltd.**

*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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**ACTIVE INGREDIENTS**

ZINC OXIDE 11.64%  
TITANIUM DIOXIDE 3.68%

**INACTIVE INGREDIENTS**

Cyclomethicone, Dicaprylyl Carbonate, Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone, Glycerin, Ethylhexyl Palmitate, Caprylyl Methicone, Diphenylsiloxy Phenyl Trimethicone, Dipropylene Glycol, Niacinamide, Polyglyceryl-2 Dipolyhydroxystearate, Polymethylsilsesquioxane, Calamine, Polyhydroxystearic Acid, Disteardimonium Hectorite, Sodium Chloride, Triethoxycaprylylsilane, Aluminum Hydroxide, Synthetic Beeswax, Caprylic/Capric Triglyceride, Stearic Acid, Caprylyl Glycol, Fragrance(Parfum), Glyceryl Caprylate, C12-15 Alkyl Benzoate, Adenosine, Polyglyceryl-2 Triisostearate, Iron Oxides (CI 77492), Iron Oxides (CI 77491), Tocopherol, Isostearic Acid, Citrus Junos Fruit Oil, Polymethyl Methacrylate, Polyvinyl Alcohol

**PURPOSE**

Sunscreen

**WARNINGS**

For external use only  
Consult a specialist if there are abnormal symptoms or side effects such as redness, swelling or itchiness due to direct sunlight during or after use.  
Avoid using on wounded areas.  
Keep out of reach of children

**KEEP OUT OF REACH OF CHILDREN**

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**Uses**

■ Helps prevent sun burn

**Directions**

■ Apply liberally and uniformly to all exposed areas 15-20 minutes before sun exposure.

## Other Information

■ Keep away from direct sunlight.

## PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

<p>주름개선·미백·자외선차단 3중 기능성 화장품</p> <p><b>아로셀 톤업 퍼펙트 선</b></p> <table border="1"> <tr> <td colspan="2"><b>Drug Facts</b></td> </tr> <tr> <td><b>Active ingredients</b></td> <td><b>Purpose</b></td> </tr> <tr> <td>ZINC OXIDE 11.64%</td> <td>Sunscreen</td> </tr> <tr> <td>TITANIUM DIOXIDE 3.68%</td> <td>Sunscreen</td> </tr> <tr> <td colspan="2"><b>Uses</b></td> </tr> <tr> <td colspan="2">; Helps prevent sun burn.</td> </tr> <tr> <td colspan="2"><b>Warnings</b></td> </tr> <tr> <td colspan="2">For external use only Consult a specialist if there are abnormal symptoms or side effects such as redness, swelling or itchiness due to direct sunlight during or after use. Avoid using on wounded areas. Keep out of reach of children.</td> </tr> <tr> <td colspan="2"><b>Directions</b></td> </tr> <tr> <td colspan="2">; Apply liberally and uniformly to all exposed areas 15-20 minutes before sun exposure.</td> </tr> <tr> <td colspan="2"><b>Other Information</b></td> </tr> <tr> <td colspan="2">; Keep away from direct sunlight.</td> </tr> <tr> <td colspan="2"><b>Inactive ingredients</b></td> </tr> <tr> <td colspan="2">Cyclomethicone, Dicaprylyl Carbonate, Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone, Glycerin, Ethylhexyl Palmitate, Caprylyl Methicone, Diphenylsiloxy Phenyl Trimethicone, Dipropylene Glycol, Niacinamide, Polyglyceryl-2 Dipolyhydroxystearate, Polymethylsilsesquioxane, Calamine, Polyhydroxystearic Acid, Disteardimonium Hectorite, Sodium Chloride, Triethoxycaprylylsilane, Aluminum Hydroxide, Synthetic Beeswax, Caprylic/Capric Triglyceride, Stearic Acid, Caprylyl Glycol, Fragrance(Parfum), Glyceryl Caprylate, C12-15 Alkyl Benzoate, Adenosine, Polyglyceryl-2 Trisostearate, Iron Oxides (CI 77492), Iron Oxides (CI 77491), Tocopherol, Isostearic Acid, Citrus Junos Fruit Oil, Polymethyl Methacrylate, Polyvinyl Alcohol</td> </tr> </table> <p>Distributor: FICC Co., Ltd. 40 Jamwon-ro 3-gil, Seocho-gu, Seoul, S. Korea</p> <p>Manufacturer: Cosmax, Inc. 46 Jeyakgongdan 2-gil, Hyangnam-eup, Hwaseong, Gyeonggi-do, S. Korea</p> <p>1.69 fl.oz (50ml)</p> <p>본 제품에 이상이 있을 경우 공정거래위원회 고시 소비자분쟁해결기준에 의하여 보상해 드립니다.</p>	<b>Drug Facts</b>		<b>Active ingredients</b>	<b>Purpose</b>	ZINC OXIDE 11.64%	Sunscreen	TITANIUM DIOXIDE 3.68%	Sunscreen	<b>Uses</b>		; Helps prevent sun burn.		<b>Warnings</b>		For external use only Consult a specialist if there are abnormal symptoms or side effects such as redness, swelling or itchiness due to direct sunlight during or after use. Avoid using on wounded areas. Keep out of reach of children.		<b>Directions</b>		; Apply liberally and uniformly to all exposed areas 15-20 minutes before sun exposure.		<b>Other Information</b>		; Keep away from direct sunlight.		<b>Inactive ingredients</b>		Cyclomethicone, Dicaprylyl Carbonate, Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone, Glycerin, Ethylhexyl Palmitate, Caprylyl Methicone, Diphenylsiloxy Phenyl Trimethicone, Dipropylene Glycol, Niacinamide, Polyglyceryl-2 Dipolyhydroxystearate, Polymethylsilsesquioxane, Calamine, Polyhydroxystearic Acid, Disteardimonium Hectorite, Sodium Chloride, Triethoxycaprylylsilane, Aluminum Hydroxide, Synthetic Beeswax, Caprylic/Capric Triglyceride, Stearic Acid, Caprylyl Glycol, Fragrance(Parfum), Glyceryl Caprylate, C12-15 Alkyl Benzoate, Adenosine, Polyglyceryl-2 Trisostearate, Iron Oxides (CI 77492), Iron Oxides (CI 77491), Tocopherol, Isostearic Acid, Citrus Junos Fruit Oil, Polymethyl Methacrylate, Polyvinyl Alcohol		<p><b>화장품책임판매업자</b> 에프아이씨씨(주) 서울시 서초구 잠원로3길 40</p> <p><b>화장품제조업자</b> 코스맥스(주) 경기도 화성시 향남읍 제약공단길 27, 2길 46</p> <p>용량 50 ml</p> <p>Manufactured by COSMAX, INC. Distributed by AROCCELL INC, NY USA www.arocell.co.kr</p> <p>MADE IN KOREA</p>	<p><b>TONE UP PERFECT SUN</b></p> <p>SPF50+ PA++++ IR protection</p> <p>50 ml / 1.69 fl.oz.</p>	
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## AROCCELL TONE UP PERFECT SUN

zinc oxide, titanium dioxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:81647-070
<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	5.82 g in 50 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	1.84 g in 50 g

## Inactive Ingredients

Ingredient Name	Strength
CYCLOMETHICONE (UNII: NMQ347994Z)	
Dicaprylyl Carbonate (UNII: 609A3V1SUA)	
Glycerin (UNII: PDC6A3C00X)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81647-070-02	1 in 1 CARTON	03/01/2021	
1	NDC:81647-070-01	50 g 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	03/01/2021	

**Labeler** - FICC Co., Ltd. (695721074)

**Registrant** - FICC Co., Ltd. (695721074)

## Establishment

Name	Address	ID/FEI	Business Operations
Cosmax, Inc.		689049693	manufacture(81647-070)

Revised: 11/2022

FICC Co., Ltd.