

**ARCA REGNERATIONSHAMPOO- pinus radiata bark extract, glycerin, menthol, citric acid shampoo**

**Hair Arca, 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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**83104-401 ARCA Regeneration Shampoo**

**Active ingredients**

Pinus Radiata Bark Extract 0.05%  
Glycerin 2%  
Menthol 0.5 %  
Citric Acid 0.5%

**Purpose**

Pinus Radiata Bark Extract 0.05% - Skin Protectant  
Glycerin 2% - Skin Protectant  
Menthol 0.5 % - Dandruff Control  
Citric Acid 0.5% - pH Level Control

**Uses**

Helps to keep scalp healthy by controlling follicle and protecting skin.

If used together with other Arca hair products, helps hair enrichment and decreases the risks of hair loss and various scalp troubles.

**Warnings**

For external use only.

**Warnings**

When using this product keep out of eyes.  
Rinse with water to remove.

**Warnings**

Stop use and ask doctor if conditions worsens or does not improve after regular use of this product as directed.

## **Warnings**

Keep out of reach of children.

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

## **Warnings**

Do not use on damaged or broken skin.

## **Directions**

ARCA REGENERATION SHAMPOO recommends the following instructions for scalp improvement and skin troubles.

1 Wet your hair and scalp completely with clean warm water before shampoo

2 Use 1-3 shampoo pumps to massage your scalp and hair.

Then wait 2 to 3 minutes.

3 Rinse thoroughly with warm water.

(Head spa is recommended after hair shampoo use)

## **Inactive ingredients**

Aqua, Coco-glucoside, Lauryl Glucoside, Sodium Cocoyl Isethionate, Coco-Betaine, Polyquaternium-10, Butylene Glycol, Citric Acid, Sodium Chloride, Lavandula Angustifolia (Lavender) Flower Extract, Monarda Didyma Leaf Extract, Mentha Piperita (Peppermint) Leaf Extract, Freesia Refracta Extract, Chamomilla Recutita (Matricaria) Flower Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, Pinus Radiata Bark Extract, Panthenol, Sodium Hyaluronate, Polyquaternium-7, coconut fatty acid, Sodium Isethionate, 1,2-Hexandiol 1,2-, Sodium Benzoate, Caprylyl Glycol, Ethylhexylglycerin, Disodium, fragrance, Limonene, Geraniol, Linalool

## **Display Panel**

83104-401

# ARCA

<b>REGENERATION SHAMPOO</b>		TO KEEP ALIVE AND REGENERATE
ARCAGENOL REGENERATION SCIENCE		
100% NEW ZEALAND GENOL FROM PINUS RADIATA STUMP		FOR PROFESSIONAL CARE
HAIR LOSS CONTROL via SCALP REGENERATION · FOLLICLE CONTROL · HAIR ENRICHMENT		17oz

#### DRUG FACTS

ACTIVE INGREDIENTS	PURPOSE
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Glycerin 2%	Skin Protectant
Menthol 0.5 %	Dandruff Control
Citric Acid 0.5%	pH Level Control

**USES:** Helps to keep scalp healthy by controlling follicle and protecting skin. If used together with other Arca hair products, helps hair enrichment and decreases the risks of hair loss and various scalp troubles.

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#### ARCA REGENERATION SHAMPOO

Manufactured by Korea Beauty Medipharm co., LTD. 402, C-dong, 47beon-gil4, Gajeong-ro, Seo-gu, Incheon, Korea  
 Distributed by HAIR ARCA  
 3660 Whilshire Blvd Suite 101, Los Angeles, CA 90010  
 Quantity: 17oz  
 Contact: 213.380.0247

#### DIRECTIONS:

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MADE IN KOREA  
[www.arcagenolus.com](http://www.arcagenolus.com)

## ARCA REGENERATION SHAMPOO

pinus radiata bark extract, glycerin, menthol, citric acid shampoo

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:83104-401
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>GLYCERIN</b> (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	2 g in 100 mL
<b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.5 g in 100 mL
<b>PINUS RADIATA BARK</b> (UNII: 6XOU3E49T8) (PINUS RADIATA BARK - UNII:6XOU3E49T8)	PINUS RADIATA BARK	0.05 g in 100 mL
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	0.5 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600 KD)</b> (UNII: 0L414VCS5Y)	
<b>FRAGRANCE LEMON ORC2001060</b> (UNII: K1725A7G95)	
<b>FREESIA ALBA FLOWER</b> (UNII: 33X293N6JT)	
<b>MONARDA DIDYMA LEAF</b> (UNII: JY15982UBB)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	

<b>CHAMOMILE</b> (UNII: FGL3685T2X)
<b>SODIUM COCOYL ISETHIONATE</b> (UNII: 518XTE8493)
<b>POLYQUATERNIUM-10 (400 CPS AT 2%)</b> (UNII: HB1401PQFS)
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)
<b>LAURYL GLUCOSIDE</b> (UNII: 76LN7P7UCU)
<b>COCO GLUCOSIDE</b> (UNII: ICS790225B)
<b>COCO-BETAINE</b> (UNII: 03DH2IZ3FY)
<b>LAVANDULA ANGUSTIFOLIA FLOWER</b> (UNII: 19AH1RAF4M)
<b>SODIUM ISETHIONATE</b> (UNII: 3R36J71C17)
<b>1,2-HEXANEDIOL</b> (UNII: TR046Y3K1G)
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)
<b>COCONUT ACID</b> (UNII: 40U37V505D)
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)
<b>LIMONENE, (+)-</b> (UNII: GFD7C86Q1W)
<b>GERANIOL</b> (UNII: L837108USY)
<b>LINALOOL, (+/-)-</b> (UNII: D81QY6I88E)
<b>PANTHENOL</b> (UNII: WW9CM0067Z)
<b>WATER</b> (UNII: 059QF0K00R)
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)
<b>ROSEMARY</b> (UNII: IJ67X351P9)
<b>MENTHA PIPERITA LEAF</b> (UNII: A389O33LX6)
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83104-401-01	503 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/04/2022	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M032	10/04/2022	

**Labeler** - Hair Arca, Inc (106984414)

**Registrant** - Hair Arca, Inc (106984414)

### Establishment

Name	Address	ID/FEI	Business Operations
Gopher Co., Ltd.		695650633	manufacture(83104-401)