

# **ITSRT TEA TREE OIL AND ARGAN OIL- itsrt tea tree oil and argan oil emulsion**

## **Guangzhou Qiaoyangzi Cosmetics Technology Co Ltd**

### **Active ingredients**

Glycerin 1.500%  
Aloe Barbadensis Leaf Water 1.000%  
Sorbic Acid 0.300%  
Rosmarinus Officinalis (Rosemary) Leaf Extract 0.09%  
Biotin 0.01%

### **INACTIVE INGREDIENT SECTION**

Aqua 71.650%  
Sodium Laureth Sulfate 8.300%  
Decyl Glucoside 2.000%  
Butylene Glycol 2.000%  
Sodium Chloride 1.750%  
Cetrimonium Chloride 1.650%  
Potassium Cocoate 1.500%  
Cocamidopropyl Betaine 1.500%  
Glycol Distearate 1.000%  
Silanetriol Arginate 1.000%  
Fragrance 0.500%  
Glycerol Formal 0.500%  
Glyceryl Stearate 0.500%  
Ethylhexylglycerin 0.500%  
Hydroxyacetophenone 0.350%  
Magnesium Chloride 0.100%  
Magnesium Nitrate 0.100%  
Glycyrrhiza Glabra Root Extract 0.30%  
Scutellaria Baicalensis Root Extract 0.30%  
Salicylic Acid 0.10%  
Melaleuca Alternifolia (Tea Tree) Leaf Oil 0.05%  
Centella Asiatica Extract 0.05%  
Polygonum Cuspidatum Root Extract 0.05%

### **Purpose**

Purpose:

Cleansing: Removes dirt, oil, and buildup from hair and scalp.

Moisturizing: Helps to hydrate and retain moisture in hair.

Soothing: Relieves scalp irritation and discomfort.

Antioxidant Protection: Provides protection against environmental damage.

Promotes Hair Health: Strengthens and nourishes hair to promote healthy growth.

Exfoliation: Helps to gently exfoliate the scalp to reduce flakiness and buildup.

## Uses

### Indications & Usage:

This shampoo is indicated for:

Cleansing the hair and scalp: Effectively removes dirt, excess oil, and product buildup.

Moisturizing and hydrating: Helps maintain the moisture balance of the hair and scalp, leaving hair soft and nourished.

Soothe irritated or sensitive scalps: Soothes the scalp to reduce itching, dryness, and inflammation.

Promoting hair health: Strengthens hair, supports healthy growth, and helps reduce hair breakage.

Preventing and treating dandruff: Gently exfoliates the scalp to remove dead skin cells, reducing flakiness and preventing dandruff.

Providing antioxidant protection: Protects the scalp and hair from damage caused by environmental stressors.

## Warnings

### Warnings:

For external use only.

Avoid contact with eyes. In case of contact, rinse immediately with plenty of water. If irritation persists, consult a healthcare professional.

Do not swallow. If swallowed, seek medical advice immediately or contact a Poison Control Center.

If irritation or redness develops, discontinue use immediately and consult a healthcare provider. This includes any signs of scalp sensitivity, such as itching, burning, or rash. Keep out of reach of children. In case of accidental ingestion, seek medical help right away.

Do not use if you are allergic to any ingredients listed. If you are unsure, perform a patch test before full use.

Patch Test Instructions: Apply a small amount of product to the inside of your elbow or behind your ear and wait 24 hours. If irritation, redness, or swelling occurs, do not use the product.

Use only as directed. Overuse or misuse may lead to scalp dryness or irritation.

Use caution if you have a sensitive scalp or skin. Some active ingredients (e.g., Tea Tree Oil, Salicylic Acid) may cause mild irritation for those with extremely sensitive skin.

If pregnant or breastfeeding, consult a healthcare provider before use to ensure the safety of the product for you and your baby.

Keep the cap tightly closed to prevent contamination. Store in a cool, dry place, away from excessive heat or sunlight.

## Stop use

### Stop Use and Consult a Doctor If:

Irritation or redness develops on the scalp or skin, including symptoms like itching, burning, or swelling.

Severe or persistent scalp irritation occurs after use, such as a rash, blistering, or open sores.

Eyes become irritated after accidental contact with the shampoo. If irritation persists, seek medical advice.

Condition worsens or does not improve after using the product regularly.

Allergic reactions occur, such as hives, difficulty breathing, or swelling of the face, lips, or tongue.

Excessive dryness or flakiness of the scalp is noticed after use. If this occurs, reduce the frequency of use or discontinue use and consult a healthcare provider.

## **Do not use**

Stop Use and Consult a Doctor If:

Irritation or redness develops on the scalp or skin, including symptoms like itching, burning, or swelling.

Severe or persistent scalp irritation occurs after use, such as a rash, blistering, or open sores.

Eyes become irritated after accidental contact with the shampoo. If irritation persists, seek medical advice.

Condition worsens or does not improve after using the product regularly.

Allergic reactions occur, such as hives, difficulty breathing, or swelling of the face, lips, or tongue.

Excessive dryness or flakiness of the scalp is noticed after use. If this occurs, reduce the frequency of use or discontinue use and consult a healthcare provider.

## **Keep out of reach of children!**

Rationale:

Accidental ingestion: The presence of ingredients like Tea Tree Oil, Salicylic Acid, and other active botanicals can be harmful if ingested in large amounts. If a child accidentally swallows the shampoo, it may cause gastrointestinal discomfort or other symptoms.

Children under 2 years of age: Young children have more sensitive skin and are more susceptible to irritation or adverse reactions from certain active ingredients like Tea Tree Oil and Salicylic Acid. It is important to consult a healthcare provider before using such products on children under 2.

General safety: Since this is a topical product, it's always essential to keep it out of reach of children to avoid any potential misuse or accidental exposure.

## **Precautions for Use**

When Using This Product:

Avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water. If irritation persists, seek medical attention.

Do not ingest. If swallowed, contact a Poison Control Center or seek medical help immediately.

Use only as directed. Excessive use or misuse may cause scalp dryness or irritation. If irritation or redness occurs, discontinue use immediately and consult a healthcare provider. This includes itching, burning, or rash on the scalp.

Keep out of reach of children. In case of accidental ingestion, seek medical advice immediately.

For external use only. Do not apply to open wounds or broken skin.

Use with caution if you have sensitive skin. Some ingredients, such as Tea Tree Oil or Salicylic Acid, may cause irritation in individuals with particularly sensitive skin or scalp. Do not use more frequently than recommended. Overuse may lead to dryness or scalp irritation.

Avoid applying to irritated or damaged skin. Use only on healthy, intact scalp and hair.

## **Instructions for Use**

Instructions for Use:

Wet hair thoroughly with lukewarm water.

Apply a generous amount of shampoo to your palm. The amount may vary depending on hair length and thickness.

Massage gently into the scalp and hair, working the shampoo through to the ends. Use your fingertips (not nails) to massage the scalp in circular motions to create a rich lather.

Leave the shampoo on the scalp for 1-2 minutes to allow the active ingredients to work. Rinse thoroughly with lukewarm water, ensuring all shampoo is removed from the hair and scalp.

For best results, follow with a conditioner that suits your hair type to lock in moisture and enhance the shampoo's benefits.

Use regularly for optimal results. For daily use, adjust frequency based on your scalp and hair type. If you have a dry scalp, consider using it every other day or as needed.

## **DOSAGE & ADMINISTRATION SECTION**

Dosage & Administration:

Amount to Use:

Dispense a quarter-sized amount (approximately 5–10 mL) of shampoo onto your palm. The exact amount may vary depending on your hair length, thickness, and personal preference.

Frequency of Use:

For normal to oily hair/scalp: Use the shampoo 1 to 2 times per week or as needed to cleanse and refresh the scalp and hair.

For dry or sensitive scalp: Use the shampoo every other day or 2-3 times a week to avoid over-drying the scalp.

For dandruff or scalp issues: Use the shampoo 2-3 times per week or as directed by a healthcare provider.

How to Apply:

Wet hair thoroughly before applying the shampoo.

Massage gently into the scalp and hair, working the product through to the ends of the hair.

Allow the shampoo to sit for 1-2 minutes to let the active ingredients work, especially for exfoliating or soothing effects.

Rinse thoroughly with water.

Follow-Up: For best results, follow with a conditioner that suits your hair type to lock in moisture and maintain scalp health.

## **PRINCIPAL DISPLAY PANEL**



盒子尺寸：75\*75\*200

## ITSRT TEA TREE OIL AND ARGAN OIL

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### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:84751-097
<b>Route of Administration</b>	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X) (ALOE VERA LEAF - UNII:ZY81Z83H0X)	ALOE VERA LEAF	0.1 mg in 500 mL
<b>BIOTIN</b> (UNII: 6SO6U10H04) (BIOTIN - UNII:6SO6U10H04)	BIOTIN	0.01 mg in 500 mL
<b>ROSEMARY</b> (UNII: IJ67X351P9) (ROSEMARY - UNII:IJ67X351P9)	ROSEMARY	0.009 mg in 500 mL
<b>SORBIC ACID</b> (UNII: X045WJ989B) (SORBIC ACID - UNII:X045WJ989B)	SORBIC ACID	0.03 mg in 500 mL
<b>GLYCERIN</b> (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	0.15 mg in 500 mL

Inactive Ingredients

Ingredient Name	Strength
<b>AQUA</b> (UNII: 059QF0KO0R)	7.165 mg in 500 mL

Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84751-097-01	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/01/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M032	10/01/2024	

Labeler - Guangzhou Qiaoyangzi Cosmetics Technology Co Ltd (705198354)

Registrant - Guangzhou Qiaoyangzi Cosmetics Technology Co Ltd (705198354)

Establishment

Name	Address	ID/FEI	Business Operations
Guangzhou Qiaoyangzi Cosmetics Technology Co Ltd		705198354	manufacture(84751-097)

