# THE QUEEN ROSE- witch hazel liquid LaLa 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 INGREDIENT

Active ingredient: Witch Hazel 0.1%

#### INACTIVE INGREDIENT

Inactive ingredients:

ANISE OIL, BERGAMOT OIL, CHAMOMILLE ROMAN OIL, GERANIUM OIL, LAVENDER OIL, LEMON OIL, ORANGE OIL, OLIVE OIL, ROSE BULGARIA OIL, YLANG YLANG OIL, SUN FLOWER OIL, LEONURUS SIBIRICUS EXTRACT, ANGELICA GIGAS ROOT EXTRACT, ARTEMISIA PRINCEPS LEAF EXTRACT, CHRYSANTHEMUM ZAWADSKII EXTRACT

#### **PURPOSE**

Purpose: Skin Protectant, Fragrance

#### **WARNINGS**

Warnings:

In case of having following symptoms after using this, you're advised to stop using it immediately. If you keep using it, the symptoms will get worse and need to consult a dermatologist.

- 1) In case of having problems such as red rash, swollenness, itching, stimulation during usage.
- 2) In case of having the same symptoms above on the part you put this product on by direct sunlight. You are banned to use it on the part where you have a scar, eczema, or dermatitis.

In case of getting it into your eyes, you have to wash it immediately.

#### KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children: Keep out of reach of babies and children.

#### INDICATIONS AND USAGE

Indication and usage:

Tighten the lid after using it.

Keep it out of infants or children's reach.

Don't keep it in the place where the temperature is extremely hot or low and exposed to the direct sunlight.

#### DOSAGE AND ADMINISTRATION

Dosage and administration:

Tighten the lid after using it.

Keep it out of infants or children's reach.

Don't keep it in the place where the temperature is extremely hot or low and exposed to the direct

#### PACKAGE LABEL. PRINCIPAL DISPLAY PANEL











## THE QUEEN ROSE

witch hazel liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55885-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
WITCH HAZEL (UNII: 10 114J0 U34) (WITCH HAZEL - UNII:10 114J0 U34)	WITCH HAZEL	0.005 mg in 5 mL	

Inactive Ingredients		
Ingredient Name	Strength	
ANISE OIL (UNII: 6 Y89 129 C8 H)		
BERGAMOT OIL (UNII: 39W1PKE3JI)		
GERANIUM O IL, ALGERIAN TYPE (UNII: 5Q1194P4WG)		

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	1 NDC:55885-010-01 5 mL in 1 CARTON				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part347	12/0 1/20 12		

# **Labeler -** LaLa Co., Ltd. (688380004)

## **Registrant -** LaLa Co., Ltd. (688380004)

Establishment				
Name	Address	ID/FEI	Business Operations	
LaLa Co., Ltd.		688380004	manufacture(55885-010)	

Revised: 2/2013 LaLa Co., Ltd.