### OIL-FREE FOAMING ACNE WASH TEA TREE OIL- salicylic acid gel China Ningbo Shangge Cosmetic Technology Corp.

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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### Oil-Free Foaming Acne Wash

# Active Ingredient

**Purpose** 

Salicylic Acid 2.0% ...... Acne Treatment

XtraCare Oil-Free Foaming Acne Wash Facial Scrub

WITH TEA TREE OIL

helps clear breakouts

Salicylic Acid 2%

Net Wt 5.3 Oz (150g)

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away. Avoid contact with eyes. If contact occurs, flush thoroughly with water.

This XtraCare foaming acne facial scrub gently cleanses breakouts you already have and helps prevent them from returning. It works deep to clean and soothe without overdrying or irritating skin. Rinses clean, leaving no residue to clog pores.

### □ Uses

For acne-prone skin.

## **□Warnings**

# For external use only

**When using this product** and other topical acne medications at the same time or immediately following use of this product, dryness or irritation of the skin may be increased. If this occurs, only one medication should be used unless directed by a doctor.

### **□** Directions

Wet face. Dispense into palm, apply to face and massage gently. Rinse thoroughly and pat dry.

### **||Other Information|**

store at 20o to 25oC (68o to 77oF)

**DISTRIBUTED BY** 

REJOICE INTERNATIONAL INC

48325 BINGHAMPTON DR

### **□**Inactive ingredients

water, sodium c14-16 olefin sulfonate, cocamidopropyl betaine, acrylates copolymer, sodium chloride, microcrystalline wax, DMDM hydantoin, fragrance, disodium EDTA, sodium lauryl sulfate, sodium hydroxide, propylene glycol, melaleuca altemifolia (tea tree) leaf oil, fd&c blue no.1, fd&c yellow no.5.



# OIL-FREE FOAMING ACNE WASH TEA TREE OIL salicylic acid gel Product Information Product Type HUMAN OTC DRUG Item Code (Source) Route of Administration TOPICAL Active Ingredient/Active Moiety

Ingredient Name	<b>Basis of Strength</b>	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	3 g in 150 g

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U)	
COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
MELALEUCA ALTERNIFOLIA LEAF (UNII: G43C57162K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
BUTYL ACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID COPOLYMER (18000 MW) (UNII: JZ 1374NL9E)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58503-032- 01	50 g in 1 BOTTLE; Type 0: Not a Combination Product	11/20/2013	05/19/2023
2	NDC:58503-032- 02	150 g in 1 BOTTLE; Type 0: Not a Combination Product	11/20/2013	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	11/20/2013	

# **Labeler -** China Ningbo Shangge Cosmetic Technology Corp. (529287434)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
China Ningbo Shangge Cosmetic Technology Corp.		529287434	manufacture(58503-032)	

Revised: 5/2023 China Ningbo Shangge Cosmetic Technology Corp.