

RINSE FREE HAND SANITIZING GEL- rinse free hand sanitizing gel gel
Guangzhou Qianxiancao Cosmetics 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.

Active Ingredient(s)

Alcohol 75% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand sanitizinggel to help reduce bacteria on skin.

Warnings

WarningI This product is for external use and should not be takenorally

2. Use with caution for people with alcohol allergy

3. Keep out of reach of children

4. Highly flammable, keep away from fire and flame

5. Store in a cool, dry placeWhen using this product, do not use in or near eyes. Incase of contact, rinse eyes thoroughly with water. Stopuse and ask doctor if irritation or rash appears and lastsIf swallowed, get medical help or contact a Poison ControlCenter right away

Do not use

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Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Direction: Wet and Rub where needed to be sanitizedwith the product thoroughly and allow to dry withoutwiping.

Rinse free.Children under 6 years of age should be supervised whenusing this product.

Other information

- Other information:Store below 106F(41 C)May discolor certain fabric or surfaces

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78963-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0K00R)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78963-005-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:78963-005-05	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:78963-005-03	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:78963-005-04	80 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
5	NDC:78963-005-02	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
6	NDC:78963-005-06	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
7	NDC:78963-005-07	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
8	NDC:78963-005-08	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
9	NDC:78963-005-09	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
10	NDC:78963-005-10	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
11	NDC:78963-005-11	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
12	NDC:78963-005-12	1200 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
13	NDC:78963-005-13	4000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
14	NDC:78963-005-14	5000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
15	NDC:78963-005-15	10000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
16	NDC:78963-005-16	20000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
17	NDC:78963-005-17	50000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

18	NDC:78963-005-18	100000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
19	NDC:78963-005-19	150000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
20	NDC:78963-005-20	1000000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Guangzhou Qianxiancao Cosmetics Co.,Ltd. (560953777)

Establishment

Name	Address	ID/FEI	Business Operations
Guangzhou Qianxiancao Cosmetics Co.,Ltd.		560953777	manufacture(78963-005)

Revised: 7/2020

Guangzhou Qianxiancao Cosmetics Co.,Ltd.