SANITIZINGSPRAY 80 V/V- alcohol spray Wuxi Huoban Daily-Use Chemicals Science and Technology 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)

Ethyl Alcohol 80% v/v.

Purpose

Antimicrobial

Use

- for handwashing to decrease on the skin
- recommended for repeated use

Warnings

For external use only. Flammable. Keep away from heat or flame

Do not use

• Do not use in confined space. Open doors and windows for ventilation.

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

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.

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

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

Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store between 20-25C (59-86F)
- may discolor certain fabrics

Inactive ingredients

butane, propane, food grade glycerin 1.45%, hydrogen peroxide 0.125% v/v

Package Label - Principal Display Panel





WATER-FREE HAND SANITIZER



MODEL:M50 16.9FL.OZ/500ML



80% ALCOHOL SANITIZING SPRAY

Drug facts

Active ingredient

Purpose Ethyl Alcohol 80% v/v..... Antimicrobial

Uses · for handwashing to decrease on the skin

· recommended for repeated use

At a distance of 15-30 cm, spray on the hand to allow the liquid to dry naturally in the hand.

Warnings . For external use only.

- · Flammable, keep away from heat and flame.
- · Placed out of the reach of children.
- · Do not use in confined space. Open doors and windows for ventilation.

DO NOT USE in the eyes. In case of contact, rinse eyes thoroughly with water.

Stop usd and ask a doctor if irritation and redness develop and persist for more than 72 hours.

Directions - wet hands thoroughly with product

- · briskly rub hands together until dry
- · supervise children in the of this product

Other information

- store at 20°C to 25°C (68° to 77°F)
- · may discolor certain fabrics

Inactive ingredients Butane, Propane, Food Grade Glycerin 1.45% v/v, Hydrogen Peroxide 0.125% v/v

Distributed by: Rejoice International, INC. Northville, MI 48168 U.S.A. Made in China





SANITIZINGSPRAY 80 V/V

alcohol spray

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:71712-004

TOPICAL **Route of Administration**

Active Ingredient/Active Moiety

ı	Ingredient Name	Basis of Strength	Strength
	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

8	
Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0KO0R)	

Packaging					
#	Item Code	Package Description	Marketing Start Date	t Marketing End Date	
1	NDC:71712-004- 01	60 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020		
2	NDC:71712-004- 02	100 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020		
3	NDC:71712-004- 03	150 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020		
4	NDC:71712-004- 04	200 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020		
5	NDC:71712-004- 05	250 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020		
6	NDC:71712-004- 06	300 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020		
7	NDC:71712-004- 07	300 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020		
8	NDC:71712-004- 08	400 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020		
9	NDC:71712-004- 09	450 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020		
10	NDC:71712-004- 10	500 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020		
11	NDC:71712-004- 11	750 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020		
12	NDC:71712-004- 12	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020		
13	NDC:71712-004- 13	88 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020		
14	NDC:71712-004- 14	147 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020		
15	NDC:71712-004- 15	177 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020		
16	NDC:71712-004- 16	207 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020		
17	NDC:71712-004- 17	236 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020		
18	NDC:71712-004- 18	295 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020		
19	NDC:71712-004- 19	414 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020		
20	NDC:71712-004- 20	443 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020		
21	NDC:71712-004- 21	443 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020		
22	NDC:71712-004- 22	503 mL in 1 BOTTLE, SPRAY; 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		

$\pmb{Labeler} \textbf{-} \textbf{ Wuxi Huoban Daily-Use Chemicals Science and Technology Co., Ltd (421207374)}$

Establishment			
Name	Address	ID/FEI	Business Operations
Wuxi Huoban Daily-Use Chemicals Science and Technology Co., Ltd		421207374	manufacture(71712-004)

Revised: 7/2020

Wuxi Huoban Daily-Use Chemicals Science and Technology Co., Ltd