HAND SANITIZER- ethyl alcohol gel Y&R International (Wuhu) Industrial Limited

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.

74834-001 Hand Sanitizer

Alcohol 70%

Purpose

Antiseptic

Use

Hand sanitizer to help reduce bacteria that potentially can cause disease.

For use when soap and water and not available.

WARNINGS

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

Do not use

■ in children less than 2 months of age ■on open skin wounds

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

Keep out of reach of children. If swallowed, get medicalhelp or contact a Poison Control Center.

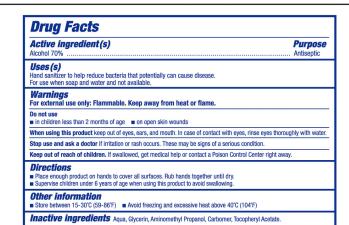
Directions

- ■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.

Inactive ingredients

Aqua, Glycerin, Aminomethyl Propanol, Carbomer, Tocopheryl Acetate





*Effective at eliminating more than 99.9% of many common harmful germs and bacteria in as little as 15 seconds.



HAND SANITIZER

ethyl alcohol gel

 Product Information

 Product Type
 HUMAN OTC DRUG
 Item Code (Source)
 NDC:74834-001

 Route of Administration
 TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
GLYCERIN (UNII: PDC6A3C0OX)		
TOCOPHERYL RETINO ATE (UNII: 0 WN694NBMM)		
AMINOMETHYL PROPANEDIOL (UNII: CZ7BU4QZJZ)		
CARBOMER 934 (UNII: Z135WT9208)		
WATER (UNII: 059QF0KO0R)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74834-001-01	100 in 1 CARTON	03/21/2020	
1		60 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:74834-001- 02	100 in 1 CARTON	03/21/2020	
2		30 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:74834-001- 03	50 in 1 CARTON	03/21/2020	
3		100 mL in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:74834-001- 04	20 in 1 CARTON	03/21/2020	

4		240 mL in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:74834-001- 05	20 in 1 CARTON	03/21/2020	
5		250 mL in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:74834-001-	20 in 1 CARTON	03/21/2020	
6		300 mL in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:74834-001- 07	20 in 1 CARTON	03/21/2020	
7		500 mL in 1 BOTTLE; Type 0: Not a Combination Product		
8	NDC:74834-001- 08	12 in 1 CARTON	03/21/2020	
8		1000 mL in 1 BOTTLE; Type 0: Not a Combination Product		
9	NDC:74834-001- 09	6 in 1 CARTON	03/21/2020	
9		2000 mL in 1 BOTTLE; Type 0: Not a Combination Product		
10	NDC:74834-001-10	4 in 1 CARTON	03/21/2020	
10		4500 mL in 1 BOTTLE; Type 0: Not a Combination Product		
11	NDC:74834-001-11	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020	
12	NDC:74834-001-12	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020	
13	NDC:74834-001-13	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020	
14	NDC:74834-001-14	240 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020	
15	NDC:74834-001-15	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020	
16	NDC:74834-001-16	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020	
17	NDC:74834-001-17	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020	
18	NDC:74834-001-18	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020	
19	NDC:74834-001-19	2000 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020	
20	NDC:74834-001- 20	4500 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020	
21	NDC:74834-001-21	10 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020	
22	NDC:74834-001-22	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020	
23	NDC:74834-001-23	150 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020	
24	NDC:74834-001-24	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020	
25	NDC:74834-001-25	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020	
26	NDC:74834-001- 26	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020	
27	NDC:74834-001-27	499 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020	
28	NDC:74834-001- 28	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020	
29	NDC:74834-001- 29	1005 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020	
30	NDC:74834-001- 30	5000 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	03/21/2020		

Labeler - Y&R International (Wuhu) Industrial Limited (543000610)

Establishment				
Name	Address	ID/FEI	Business Operations	
H&O International Pty Ltd		528016993	manufacture (748 34-0 0 1)	

Revised: 5/2020

Y&R International (Wuhu) Industrial Limited