

HAND SANITIZER- alcohol gel
NingBo Huize Commodity 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.

HAND SANITIZER

Active Ingredient

Ethyl Alcohol 62%

Purpose

Antiseptic

Use

Decreases bacteria on hands

Warning

for external use only

Do not use

on broken skin

on large areas of the body

Keep out of reach of children

Keep out of reach of children

If swallowed ,get medical help or contact a Poison on Control Center immediately

Directions

Squeeze ont oh ands and rub hands and rub hands together briskly until dry

Can be used anytime any place, without water or towels

Contains moisturizers and vitamin E to leave hands feeling refreshed ,soft and smooth without stickiness or residue.

INACTIVE INGREDIENT

Deionized Water, Carbomer ,Triethanolamine, Aloe barbadensis Gel, Fragrance Glycerin, Propylene Glycol, Vitamin E

Drug Facts		Drug Facts(continued)	
Active Ingredient Ethyl Alcohol 62%.....	Purpose Antiseptic	Directions <ul style="list-style-type: none"> ■ Squeeze onto hands and rub hands and rub hands together briskly until dry ■ Can be used anytime any place, without water or towels ■ Contains moisturizers and vitamin E to leave hands feeling refreshed ,soft and smooth without stickiness or residue. 	
Uses ■Decreases bacteria on hands		other information: store at 20-25°C (68-77 °F)	
Warnings For external use only			
Do not use ■on broken skin ■on large areas of the body		Inactive ingredients Deionized Water, Carbomer ,Triethanolamine, Aloe barbadensis Gel, Fragrance Glycerin, Propylene Glycol, Vitamin E	
When using this products <ul style="list-style-type: none"> ■apply to the hands ■kills 99.99% of many common germs that may cause illness. ■do not use in or near the eyes ■Keep away from fire or flame ■Using other topical acne drugs at the same time or right after use of this product may increase dryness or irritation of the skin . Only one drug should be used unless directed by a doctor. 			
Stop use and ask a doctor if rash occurs			
Keep out of reach of children .If swallowed ,get medical help or contact a Poison on Control Center immediately			

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:710 11-00 1
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
TRIETHANOLAMINE DIOLEATE (UNII: 40Q022F4GX)	
24-HOMO-1,25-DIHYDRO XYVITAMIN D3 (UNII: F35KTH803S)	

ALOE VERA LEAF (UNII: ZY81Z83H0X)

CARBOMER 934 (UNII: Z135WT9208)

PROPYLENE GLYCOL DIACETATE (UNII: 5Z492UNF9O)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71011-001-01	5 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/20/2016	
2	NDC:71011-001-02	8 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/20/2016	
3	NDC:71011-001-03	10 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/20/2016	
4	NDC:71011-001-04	15 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/20/2016	
5	NDC:71011-001-05	20 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/19/2016	
6	NDC:71011-001-06	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/19/2016	
7	NDC:71011-001-07	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/20/2016	
8	NDC:71011-001-08	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/20/2016	
9	NDC:71011-001-09	80 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/20/2016	
10	NDC:71011-001-10	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/20/2016	
11	NDC:71011-001-11	150 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/20/2016	
12	NDC:71011-001-12	200 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/20/2016	
13	NDC:71011-001-13	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/20/2016	
14	NDC:71011-001-14	300 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/20/2016	
15	NDC:71011-001-15	400 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/20/2016	
16	NDC:71011-001-16	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/20/2016	
17	NDC:71011-001-17	600 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/20/2016	
18	NDC:71011-001-18	700 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/20/2016	
19	NDC:71011-001-19	800 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/20/2016	
20	NDC:71011-001-20	900 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/20/2016	
21	NDC:71011-001-21	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/20/2016	
22	NDC:71011-001-22	2000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/20/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC monograph not final	part333A	09/29/2016	
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Labeler - NingBo Huize Commodity Co.,Ltd. (544434795)

Establishment

Name	Address	ID/FEI	Business Operations
NingBo Huize Commodity Co.,Ltd.		544434795	manufacture(71011-001)

Revised: 1/2018

NingBo Huize Commodity Co.,Ltd.