

HAPPY HANDS HAND SANITIZER- alcohol liquid

South Tenth Development, LLC

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.

"Happy Hands " Hand Sanitizer

DRUG FACTS

Active Ingredient

Ethyl Alcohol 80%

Purpose

Antiseptic

Use[s]

Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

Warnings

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

Do not use

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

When using this product

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

Stop use & 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

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 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive Ingredients

Distilled water, glycerol, hydrogen peroxide, denatonium benzoate.

Package Labeling: 100ml

Clean Hands are Happy Hands
 Packaged by South Tenth Development LLC
 600 W. South Street Lincoln, NE 68522
 www.HappyHandsUSA.com




8 60001 45312 6



Hand Sanitizer

Alcohol Antiseptic 80%
 Topical Solution
 Non-sterile Solution

3.38 OZ (100mL)

Drug Facts

Active ingredient[s]	Purpose
Ethyl Alcohol 80%	Antiseptic

Use[s]
 Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

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

Do not use

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

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.

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 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients Distilled water, glycerol, hydrogen peroxide, denatonium benzoate


Package Labeling: 300mL



Clean Hands are Happy Hands



8 60001 45313 3



Hand Sanitizer
 Alcohol Antiseptic 80%
 Topical Solution
 Non-sterile Solution
 10 OZ (300mL)

Packaged by South Tenth Development LLC
 600 W. South Street Lincoln, NE 68522
 www.HappyHandsUSA.com

Drug Facts

Active ingredient[s]	Purpose
Ethyl Alcohol 80%	Antiseptic

Use[s]
 Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

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

Do not use

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

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.

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 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients Distilled water, glycerol, hydrogen peroxide, denatonium benzoate

Package Labeling: 500 mL



**Clean
Hands
are
Happy
Hands**



8 60001 45311 9



**Happy
Hands**

Hand Sanitizer
Alcohol Antiseptic 80%
Topical Solution
Non-sterile Solution
16.9 OZ (500mL)

Packaged by South Tenth Development LLC
 600 W. South Street Lincoln, NE 68522
 www.HappyHandsUSA.com

Drug Facts	
Active ingredient(s)	Purpose
Ethyl Alcohol 80%	Antiseptic
Use(s) Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
Warnings For external use only. Flammable. Keep away from heat or flame	
Do not use <ul style="list-style-type: none"> on open skin wounds in children less than 2 months of age 	
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.	
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 <ul style="list-style-type: none"> Store between 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F) 	
Inactive ingredients Distilled water, glycerol, hydrogen peroxide, denatonium benzoate	

HAPPY HANDS HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78 705-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	0.8 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78705-001-00	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	
2	NDC:78705-001-01	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	
3	NDC:78705-001-02	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/01/2020	

