

HAPPY HANDS HAND SANITIZER- alcohol gel
True Chemical Solutions, 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[s]

Alcohol 70% v/v

Purpose

Antiseptic

Use[s]

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are 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.

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

Water, Carbomer, Glycerin, Triethanolamine, Iodopropynyl Butylcarbamate, Methylisothiazolinone

Package Labeling:118ml



70% Alcohol

Happy Hands

Hand Sanitizer
Topical Gel with Moisturizing Solution
Non-sterile Solution
118mL (4 fl. oz.)

Kills 99% of Germs

8 60005 35571 7

Drug Facts	Purpose
Active ingredient[s] Alcohol 70% v/v.....	Antiseptic
Use[s] Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are 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. 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 Water, Carbomer, Glycerin, Triethanolamine, Iodopropynyl Butylcarbamate, Methylisothiazolinone	

432-425-1137
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Package Labeling:473ml



70% Alcohol

Happy Hands

Hand Sanitizer
Topical Gel with Moisturizing Solution
Non-sterile Solution
473 mL (16 fl. oz.)

Kills 99% of Germs

8 60005 35571 6

Drug Facts	Purpose
Active ingredient[s] Alcohol 70% v/v.....	Antiseptic
Use[s] Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are 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. 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 Water, Carbomer, Glycerin, Triethanolamine, Iodopropynyl Butylcarbamate, Methylisothiazolinone	

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Hand Sanitizer

Topical Gel with Moisturizing Solution
Non-sterile Solution
 473 mL. (16 fl. oz).



Drug Facts

Active ingredient[s]

Alcohol 70% v/v.....Antiseptic

Purpose

Use[s]

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

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

Do not use

- on 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.** 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 Water, Carbomer, Glycerin, Triethanolamine, Iodopropynyl Butylcarbamate, Methylisothiazolinone

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8 60005 35573 0

Package Labeling:946.34ml

HAPPY HANDS

Hand Sanitizer
 Topical Gel with Moisturizing Solution
 Non-sterile Solution
 946.34 mL (32 oz).

70% Alcohol

Kills 99% of Germs

Drug Facts	
Active ingredient(s) Alcohol 70% v/v.....	PurposeAntiseptic
Use(s) Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
Warnings For external use only. Flammable. Keep away from heat or flame	
Do not use <ul style="list-style-type: none"> • 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. 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 Water, Carbomer, Glycerin, Triethanolamine,, Iodopropynyl Butylcarbamate, Methylisothiazolinone	

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Package Labeling:1.8927L



HAPPY HANDS

Hand Sanitizer
 Topical Gel with Moisturizing Solution
 Non-sterile Solution
 1.8927 L. (64 fl. oz.)

70% Alcohol

Kills 99% of Germs

Drug Facts

Active ingredient[s]	Purpose
Alcohol 70% w/v.....	Antiseptic

Use[s]
 Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are 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. 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 Water, Carbomer, Glycerin, Triethanolamine, Iodopropynyl Butylcarbamate, Methylisothiazolinone

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8 60005 35576 1

Package Labeling:2000ml



Hand Sanitizer

Topical Gel with Moisturizing Solution
Non-sterile Solution
2000 mL. (67 fl. oz.)



Drug Facts

Active ingredient(s)

Alcohol 70% v/v.....

Purpose

Antiseptic

Use(s)

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are 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. 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 Water, Carbomer, Glycerin, Triethanolamine, Iodopropynyl Butylcarbamate, Methylisothiazolinone

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8 60005 35570 9

Package Labeling:3.785L

HAPPY HANDS

Hand Sanitizer

Topical Gel with Moisturizing Solution
Non-sterile Solution
3.785 L. (128 fl.oz.)

70% Alcohol

Kills 99% of Germs

Drug Facts	
Active ingredient[s] Alcohol 70% v/v.....	PurposeAntiseptic
Use[s] Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are 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. 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 Water, Carbomer, Glycerin, Triethanolamine,, Iodopropynyl Butylcarbamate, Methylisothiazolinone	

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HAPPY HANDS HAND SANITIZER			
alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77991-004
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 mL in 1 mL
Inactive Ingredients			
	Ingredient Name		Strength
	WATER (UNII: 059QF0K00R)		
	CARBOMER HO MO POL YMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)		
	GLYCERIN (UNII: PDC6A3C0OX)		

TROLAMINE (UNII: 9O3K93S3TK)

IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)

METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77991-004-01	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	
2	NDC:77991-004-02	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	
3	NDC:77991-004-03	946.34 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	
4	NDC:77991-004-04	1892.7 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	
5	NDC:77991-004-05	2000 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	
6	NDC:77991-004-06	3785 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	

Labeler - True Chemical Solutions, LLC (080705292)

Revised: 1/2021

True Chemical Solutions, LLC