

HAND SANITIZER- alcohol (ethyl alcohol) gel

Western Acceptance, 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.

Gel Hand Sanitizer

Active Ingredient(s)

Isopropyl Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Gel Hand Sanitizer

Use

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.

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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

purified water USP, glycerin, hydrogen peroxide, carbomer, triethanolamine

Package Label - Principal Display Panel



3785.41 ml NDC: 80206-020-02

Drug Facts	
Active ingredient	Purpose
Ethyl alcohol 70% v/v	Antiseptic
Uses ■ Hand sanitizer to help reduce bacteria that potentially can cause disease. ■ For use when soap and water are not available. ■ Recommended for repeated use.	
Warnings For external use only Flammable. Keep away from heat or flame. Do not use ■ In children less than 2 months of age. ■ On broken or irritated skin.	
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 59°-86°F. ■ Avoid freezing and excessive heat above 104°F. ■ May discolor certain fabrics and surfaces.	
Inactive ingredients Purified Water, Glycerin, Hydrogen Peroxide Solution, Carbomer, Triethanolamine.	
DISTRIBUTED BY: AMERICAN SANITIZER SOLUTIONS MANUFACTURED BY WESTERN ACCEPTANCE, LLC	



1879.71 ml NDC: 80206-020-01

Drug Facts	
Active ingredient Ethyl alcohol 70% v/v	Purpose Antiseptic
Uses ■ Hand sanitizer to help reduce bacteria that potentially can cause disease. ■ For use when soap and water are not available. ■ Recommended for repeated use.	
Warnings For external use only Flammable. Keep away from heat or flame. Do not use ■ In children less than 2 months of age. ■ On broken or irritated skin.	
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 59°-86°F. ■ Avoid freezing and excessive heat above 104°F. ■ May discolor certain fabrics and surfaces.	
Inactive ingredients Purified Water, Glycerin, Hydrogen Peroxide Solution, Carbomer, Triethanolamine.	
DISTRIBUTED BY AMERICAN SANITIZER SOLUTIONS MANUFACTURED BY WESTERN ACCEPTANCE, LLC	

500 ml NDC: 80206-020-03

HAND SANITIZER

70% Ethyl Alcohol

Fragrance-free
formula



**QUESTIONS OR
TO RE-ORDER**

Please call 720-505-7214
Mon-Fri 8:00-5:00 MST
info@americansanitizer.com

GEL



HAND SANITIZER
KILLS 99.9% OF MOST GERMS

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16.907 fl. oz. (500 ml)

Drug Facts	
Active ingredient Ethyl alcohol 70% v/v.	Purpose Antiseptic
Uses ■ Hand sanitizer to help reduce bacteria that potentially can cause disease. ■ For use when soap and water are not available. ■ Recommended for repeated use.	
Warnings For external use only Flammable. Keep away from heat or flame. Do not use ■ In children less than 2 months of age. ■ On broken or irritated skin. 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.	
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Other information ■ Store between 59°-86°F. ■ Avoid freezing and excessive heat above 104°F. ■ May discolor certain fabrics and surfaces.	
Inactive ingredients Purified Water, Glycerin, Hydrogen Peroxide Solution, Carbomer, Triethanolamine.	
DISTRIBUTED BY AMERICAN SANITIZER SOLUTIONS MANUFACTURED BY WESTERN ACCEPTANCE, LLC	

250ml NDC: 80206-020-04

HAND SANITIZER

70% Ethyl Alcohol

Fragrance-free
formula



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GEL



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8.45351 fl. oz. (250 ml)

Drug Facts	
Active ingredient Ethyl alcohol 70% v/v.	Purpose Antiseptic
Uses ■ Hand sanitizer to help reduce bacteria that potentially can cause disease. ■ For use when soap and water are not available. ■ Recommended for repeated use.	
Warnings For external use only Flammable. Keep away from heat or flame. Do not use ■ In children less than 2 months of age. ■ On broken or irritated skin.	
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Other information ■ Store between 59°-86°F. ■ Avoid freezing and excessive heat above 104°F. ■ May discolor certain fabrics and surfaces.	
Inactive ingredients Purified Water, Glycerin, Hydrogen Peroxide Solution, Carbomer, Triethanolamine.	
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118.294 ml NDC: 80206-020-05

HAND SANITIZER

GEL

70% Ethyl Alcohol

Fragrance-free
formula



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4 fl. oz. (118.294 ml)

Drug Facts	
Active ingredient Ethyl alcohol 70% v/v.	Purpose Antiseptic
Uses ■ Hand sanitizer to help reduce bacteria that potentially can cause disease. ■ For use when soap and water are not available. ■ Recommended for repeated use.	
Warnings For external use only Flammable. Keep away from heat or flame. Do not use ■ In children less than 2 months of age. ■ On broken or irritated skin.	
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Inactive ingredients Purified Water, Glycerin, Hydrogen Peroxide Solution, Carbomer, Triethanolamine.	
DISTRIBUTED BY AMERICAN SANITIZER SOLUTIONS MANUFACTURED BY WESTERN ACCEPTANCE, LLC	

88.2706 ml NDC: 80206-020-06

HAND SANITIZER

70% Ethyl Alcohol

**Fragrance-free
formula**



**QUESTIONS OR
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Mon-Fri 8:00-5:00 MST
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GEL



HAND SANITIZER
KILLS 99.9% OF MOST GERMS

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3 fl. oz. (88.2706 ml)

Drug Facts	
Active ingredient Ethyl alcohol 70% v/v	Purpose Antiseptic
Uses ■ Hand sanitizer to help reduce bacteria that potentially can cause disease. ■ For use when soap and water are not available. ■ Recommended for repeated use.	
Warnings For external use only Flammable. Keep away from heat or flame. Do not use ■ In children less than 2 months of age. ■ On broken or irritated skin.	
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Other information ■ Store between 59°-86°F. ■ Avoid freezing and excessive heat above 104°F. ■ May discolor certain fabrics and surfaces.	
Inactive ingredients Purified Water, Glycerin, Hydrogen Peroxide Solution, Carbomer, Triethanolamine.	
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100 ml NDC: 80206-020-07

HAND SANITIZER

70% Ethyl Alcohol

Fragrance-free
formula



**QUESTIONS OR
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Mon-Fri 8:00-5:00 MST
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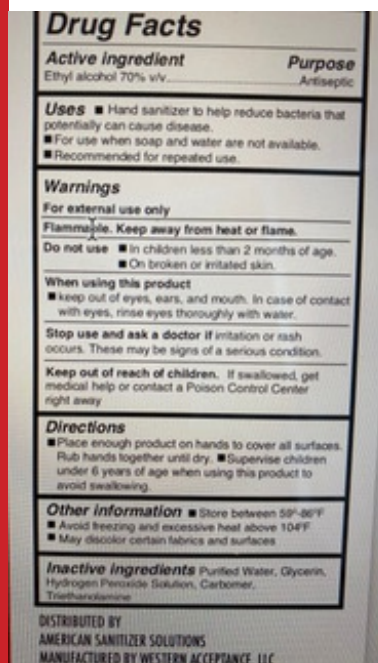
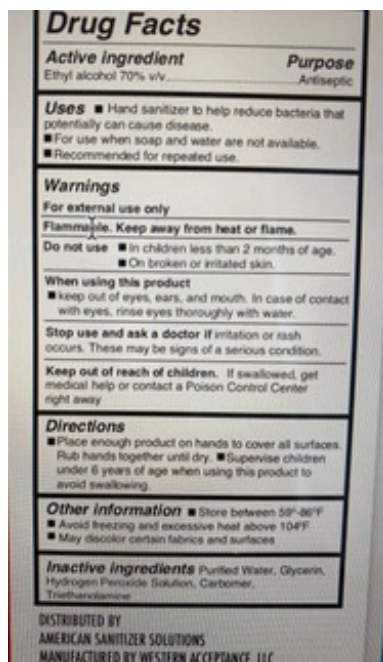
GEL



HAND SANITIZER
KILLS 99.9% OF MOST GERMS

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3.3814 oz (100 ml)



65.0618 ml NDC: 80206-020-08

HAND SANITIZER

alcohol (ethyl alcohol) gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80206-020
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	70 mL in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
TRIETHANOLAMINE LAURYL SULFATE (UNII: E8458C1KAA)	1 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	1 mL in 100 mL
WATER (UNII: 059QF0KO0R)	26 mL in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	1 mL in 100 mL

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80206-020-01	1879.71 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	
2	NDC:80206-020-02	3785.41 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	
3	NDC:80206-020-03	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	
4	NDC:80206-020-04	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	
5	NDC:80206-020-05	118.294 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	
6	NDC:80206-020-06	88.7206 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	
7	NDC:80206-020-07	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	
8	NDC:80206-020-08	65.0618 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/01/2020	

Labeler - Western Acceptance, LLC (117410424)

Registrant - Western Acceptance, LLC (117410424)

Establishment			
Name	Address	ID/FEI	Business Operations
Western Acceptance, LLC		117410424	manufacture(80206-020)