

JOETEN HAND SANITIZER- alcohol liquid
Bender Consulting 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.

Active Ingredient(s)

Alcohol 80% v/v. Purpose: Antiseptic

Purpose

Antiseptic, 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.

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

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

000 mL / 00.0 fl oz

JOETEN Hand Sanitizer 2700 mL

PRINT ART

4.27.2020

The Principal Display Panel for the 2700 mL bottle features a teal and white color scheme. At the top center is a stylized logo consisting of a blue water drop shape with a white plus sign inside, set against a circular background of overlapping teal and blue rings. Below the logo is the brand name "JOETEN" in a bold, blue, sans-serif font. A white horizontal banner with a blue border contains the word "HANDSANITIZER" in large, bold, blue, sans-serif capital letters. Below the banner, three bullet points are listed: "+ Alcohol Antiseptic 80%", "+ Topical Solution", and "+ Non-sterile Solution". At the bottom, the volume "2700 mL / 91.3 fl oz" is printed in a smaller blue font.

The back panel of the 2700 mL bottle contains regulatory information. It features a white background with a black border. At the top, the heading "Drug Facts" is in bold. Below it, a table lists the "Active ingredient[s]" as "Alcohol 80% v/v" and the "Purpose" as "Antiseptic". The "Use[s]" section states the product is for external use to reduce bacteria and should be used when soap and water are unavailable. The "Warnings" section includes a flammability warning and instructions for use. The "Directions" section provides instructions for application. The "Other information" section lists storage conditions. The "Inactive ingredients" section lists glycerin, hydrogen peroxide, and purified water USP. At the bottom, the manufacturer's name and address are listed: "Bender Consulting Ltd., 1188 Bishop St. Ste. 811, Honolulu, HI 96813 USA". A barcode is located at the bottom right, with the number "8 60001 62197 6" printed below it.

JOETEN Hand Sanitizer 2000 mL

PRINT ART

4.27.2020

The Principal Display Panel for the 2000 mL bottle features a teal and white color scheme. At the top center is a stylized logo consisting of a blue water drop shape with a white plus sign inside, set against a circular background of overlapping teal and blue rings. Below the logo is the brand name "JOETEN" in a bold, blue, sans-serif font. A white horizontal banner with a blue border contains the word "HANDSANITIZER" in large, bold, blue, sans-serif capital letters. Below the banner, three bullet points are listed: "+ Alcohol Antiseptic 80%", "+ Topical Solution", and "+ Non-sterile Solution". At the bottom, the volume "2000 mL / 67.6 fl oz" is printed in a smaller blue font.

The back panel of the 2000 mL bottle contains regulatory information. It features a white background with a black border. At the top, the heading "Drug Facts" is in bold. Below it, a table lists the "Active ingredient[s]" as "Alcohol 80% v/v" and the "Purpose" as "Antiseptic". The "Use[s]" section states the product is for external use to reduce bacteria and should be used when soap and water are unavailable. The "Warnings" section includes a flammability warning and instructions for use. The "Directions" section provides instructions for application. The "Other information" section lists storage conditions. The "Inactive ingredients" section lists glycerin, hydrogen peroxide, and purified water USP. At the bottom, the manufacturer's name and address are listed: "Bender Consulting Ltd., 1188 Bishop St. Ste. 811, Honolulu, HI 96813 USA". A barcode is located at the bottom right, with the number "8 60001 62198 3" printed below it.

JOETEN

HANDSANITIZER

- + Alcohol Antiseptic 80%
- + Topical Solution
- + Non-sterile Solution

1800 mL / 60.9 fl oz

Drug Facts

Active ingredient[s]	Purpose
Alcohol 80% 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 glycerin, hydrogen peroxide, purified water USP

Bender Consulting Ltd.
1188 Bishop St. Ste. 811
Honolulu, HI 96813 USA

JOETEN

HANDSANITIZER

- + Alcohol Antiseptic 80%
- + Topical Solution
- + Non-sterile Solution

1000 mL / 33.8 fl oz

Drug Facts

Active ingredient[s]	Purpose
Alcohol 80% 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 glycerin, hydrogen peroxide, purified water USP

Bender Consulting Ltd.
1188 Bishop St. Ste. 811
Honolulu, HI 96813 USA

The front of the 300 mL Hand Sanitizer bottle label features a teal and white color scheme. At the top center is a stylized logo consisting of a blue water drop shape with a white plus sign inside a circular frame. Below the logo is the brand name "JOETEN" in a bold, blue, sans-serif font. A white horizontal bar with a blue border contains the word "HANDSANITIZER" in large, bold, blue, sans-serif capital letters. Below this bar, three bullet points are listed: "+ Alcohol Antiseptic 80%", "+ Topical Solution", and "+ Non-sterile Solution". At the bottom of the label, the volume "300 mL / 10.1 fl oz" is printed in a smaller blue font.

The back of the 300 mL Hand Sanitizer bottle label contains a white rectangular box with a black border containing the following text:

Drug Facts

Active ingredient[s]	Purpose
Alcohol 80% 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 glycerin, hydrogen peroxide, purified water USP

Bender Consulting Ltd.
1188 Bishop St. Ste. 811
Honolulu, HI 96813 USA

8 60001 62194 5

The front of the 100 mL Hand Sanitizer bottle label features a teal and white color scheme. At the top center is a stylized logo consisting of a blue water drop shape with a white plus sign inside a circular frame. Below the logo is the brand name "JOETEN" in a bold, blue, sans-serif font. A white horizontal bar with a blue border contains the word "HANDSANITIZER" in large, bold, blue, sans-serif capital letters. Below this bar, three bullet points are listed: "+ Alcohol Antiseptic 80%", "+ Topical Solution", and "+ Non-sterile Solution". At the bottom of the label, the volume "100 mL / 3.4 fl oz" is printed in a smaller blue font.

The back of the 100 mL Hand Sanitizer bottle label contains a white rectangular box with a black border containing the following text:

Drug Facts

Active ingredient[s]	Purpose
Alcohol 80% 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 glycerin, hydrogen peroxide, purified water USP

Bender Consulting Ltd.
1188 Bishop St. Ste. 811
Honolulu, HI 96813 USA

8 60001 62193 8



JOETEN HAND SANITIZER				
alcohol liquid				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74918-001	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	80 mL in 100 mL	
Inactive Ingredients				
Ingredient Name			Strength	
GLYCERIN (UNII: PDC6A3C0OX)			1.45 mL in 100 mL	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)			0.125 mL in 100 mL	
WATER (UNII: 059QF0K00R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:74918-001-27	2700 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	
2	NDC:74918-001-20	2000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	
3	NDC:74918-001-18	1800 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	
4	NDC:74918-001-10	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/15/2020	
5	NDC:74918-001-03	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	
6	NDC:74918-001-01	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	
7	NDC:74918-001-00	100 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/15/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/15/2020	

Labeler - Bender Consulting Ltd (036411509)

Registrant - Bender Consulting Ltd (036411509)

Establishment

Name	Address	ID/FEI	Business Operations
Binh Tay Lico		555362337	manufacture(74918-001) , label(74918-001)

Revised: 4/2020

Bender Consulting Ltd