

INTERNATIONAL HARBOR- alcohol gel
INTERNATIONAL HARBOR 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.

International Harbor gel Antibacterial (60 ml, 250 ml, 500 ml, 1 l, 1.8 l 1 gal)

Active Ingredient(s)

Alcohol 75% 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

water, glycerin, carbomer, triethanolamine.

International Harbor
Hand Sanitizer
 70% Ethyl Alcohol



ADVANCED FORMULA

- Antibacterial Gel
- Gentle on Skin
- No Residue Application

2.03 fl. oz. (60 mL)

Drug Facts	
Active ingredient(s)	Purpose
Ethyl alcohol 70% v/v	Antiseptic
Use (s) Hand sanitizer to help reduce bacteria that can potentially 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"> 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 thoroughly with water. Stop use and ask a doctor if irritation or rash occurs. There may be signs of a allergic condition.	
Keep out of reach of children if swallowed, get medical help or contact a Poison Control Center right away.	
Directions <ul style="list-style-type: none"> 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 15-30°C (59-86 °F)	
Inactive ingredients: water, glycerin, carbomer and benzalkonium.	

Distributed By:
 International Harbor, LLC
 Cheyenne Wyoming 82001
 www.int-harbor.com
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Manufactured By:
 Octopod S.A. de C.V.
 Huetzquilzán, México C.P. 52767
 Made in Mexico

PDP 60 ml NDC:79838-003-01

International Harbor
Hand Sanitizer
 70% Ethyl Alcohol



ADVANCED FORMULA

- Antibacterial Gel
- Gentle on Skin
- No Residue Application

8.45 fl. oz. (250 mL)

Drug Facts	
Active ingredient(s)	Purpose
Ethyl alcohol 70% v/v	Antiseptic
Use (s) Hand sanitizer to help reduce bacteria that can potentially 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"> 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 thoroughly with water. Stop use and ask a doctor if irritation or rash occurs. There may be signs of a allergic condition.	
Keep out of reach of children if swallowed, get medical help or contact a Poison Control Center right away.	
Directions <ul style="list-style-type: none"> 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 15-30°C (59-86 °F)	
Inactive ingredients: water, glycerin, carbomer and benzalkonium.	

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Manufactured By: Octopod S.A. de C.V.
 Huetzquilzán, México C.P. 52767
 Made in Mexico

PDP 250 ml NDC:79838-003-02

International Harbor
Hand Sanitizer
 75% Ethyl Alcohol



ADVANCED FORMULA

- Antibacterial Gel
- Gentle on Skin
- No Residue Application

16.91 fl. oz. (500 mL)

Drug Facts	
Active ingredient(s)	Purpose
Ethyl alcohol 75% v/v	Antiseptic
Use (s) Hand sanitizer to help reduce bacteria that can potentially 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"> 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 thoroughly with water. Stop use and ask a doctor if irritation or rash occurs. There may be signs of a allergic condition.	
Keep out of reach of children if swallowed, get medical help or contact a Poison Control Center right away.	
Directions <ul style="list-style-type: none"> 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 15-30°C (59-86 °F)	
Inactive ingredients: water, glycerin, carbomer and benzalkonium.	

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Manufactured By:
 Octopod S.A. de C.V.
 Huetzquilzán, México C.P. 52767
 Made in Mexico

PDP 500 ml NDC:79838-003-03



Hand Sanitizer

70% Ethyl Alcohol



ADVANCED FORMULA

- **Antibacterial Gel**
- **Gentle on Skin**
- **No Residue Application**

33.81 fl. oz. (1 L)

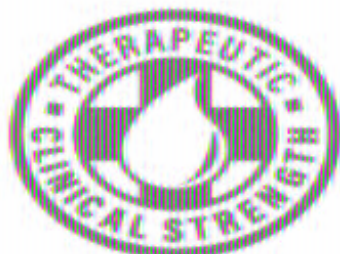
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PDP 1000 ml NDC:79838-003-04



Hand Sanitizer

70% Ethyl Alcohol



ADVANCED FORMULA

- **Antibacterial Gel**
- **Gentle on Skin**
- **No Residue Application**

60.87 fl. oz. (1.8 L)

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PDP 1800 ml NDC:79838-003-05



Hand Sanitize

75% Ethyl Alcohol
128 fl. oz. (1 GAL)

- ADVANCED FORMULA**
- Antibacterial Gel
 - Gentle on Skin
 - No Residue Application

Clasificación	Purpose
Active ingredient(s) Ethyl alcohol 75% v/v	Antiseptic
Indications	
Hand sanitizer for use on hands before and after contact with surfaces. For use when soap and water are not available.	
Warnings	
For external use only. Repeat use. Keep away from heat and flame.	
Directions	
Wash hands thoroughly with water. Rub hands together for 20 seconds. Rinse hands with water. Dry hands thoroughly.	
Contraindications	
None known.	
Adverse effects	
None known.	
Other information	
Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center.	
Other information	
None known.	
Other information	
None known.	
Other information	
None known.	
Other information	
None known.	

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Chattanooga, TN
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Manufactured By:
Cytapod S.A. de C.V.
Hidalgo, Mexico
Mexico, Mexico

PDP 3785 ml NDC:79838-003-06

INTERNATIONAL HARBOR

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79838-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1 mL in 100 mL
CARBOMER 1342 (UNII: 809Y72KV36)	0.45 mL in 100 mL
WATER (UNII: 059QF0K00R)	23.425 mL in 100 mL
TRIETHANOLAMINE HYDRIOIDE (UNII: DT98IT03JK)	0.125 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79838-003-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:79838-003-02	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:79838-003-03	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:79838-003-04	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
5	NDC:79838-003-05	1800 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
6	NDC:79838-003-06	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - INTERNATIONAL HARBOR LLC (117485044)**Registrant** - INTERNATIONAL HARBOR LLC (117485044)**Establishment**

Name	Address	ID/FEI	Business Operations
INTERNATIONAL HARBOR LLC		117485044	label(79838-003)

Establishment

Name	Address	ID/FEI	Business Operations
Octapod, S.A. de C.V.		951578993	manufacture(79838-003)

Revised: 9/2020

INTERNATIONAL HARBOR LLC