

HAND SANITIZER SMELLS CLEAN- ethanol gel
IWANNA CORP SAS

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.

HAND SANITIZER

HAND SANITIZER

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (70%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.00% v/v).
- c. Phenoxyethanol and chlorphenesin (0.3% v/v).
- d. Sterile distilled water or boiled cold water.

Active Ingredient(s)

Alcohol 70% v/v. Purpose: Antiseptic

Phenoxyethanol (and) chlorphenesin: 0.3%

Purpose

Antiseptic, Hand Sanitizer

To help reduce bacteria on the skin that could cause disease.

Indications and Usage

Apply enough hand Sanitizer to cover all hands surface

Rub hands palm to palm

Right palm over left dorsum with interfaced fingers and vice versa.

Palm to palm with fingers interfaced.

Backs of fingers to opposing palms with fingers interlocked.

Rotational rubbing of left thumbs clasped in right palmed and vice versa.

Rotational rubbing backwards and forwards with clasped fingers of right hand and left palm and vice versa.

And your hands are disinfected.

Warnings

Flammable. Keep away from fire or flame

For external use only.

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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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.

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.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Other information

- Store between 15-30C (59-86F)
- May discolor certain fabrics or surfaces.

Inactive ingredients

Water, glycerin, Carbomer, DMDM Hydantoin, Triethanolamine

Package Label - Principal Display Panel

Hand Sanitizer

moisturizes+sanitizes+gel

Hand Sanitizer- 500 ML

Hand Sanitizer

moisturizes+sanitizes+gel

16.9 fl. oz (500 mL) NDC: 75525-001-50

Production date: March 17, 2020
Lot: 30032009

Drug Facts	
Active Ingredients: Ethanol 70% V/V..... Phenoxyethanol (and) Chlorphenesin 0.3%	Purpose Antiseptic
Use Antiseptic, Hand Sanitizer to help reduce bacteria on the skin that could cause disease.	
Warnings Flammable, keep away from fire/ flame.	
For external use only.	
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). May discolor certain fabrics or surfaces.	
Inactive Ingredients Water, Glycerin, Carbomer, DMDM Hydantoin, Triethanolamine.	

NDC: 75525-001-50

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Colombia
NIT: 900570295
www.iwanna.life

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Ocean.. Life USA @
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6991 NW 82 Ave. Unit 11
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Phone: (1)305-384-7555 ext. 106
www.oceanpusa.com

moisturizes + sanitizes + gel

SMELLS CLEAN

Vitamin E
DISINFECTANT
INSTANT HIGH
SPECTRUM
ANTIBACTERIAL

99.9%
MICROBIAL POWER
EFFECTIVE
AGAINST MOST
COMMONS GERMS

16.9 fl Oz. (500 ml)

IWSC021

HAND SANITIZER 60 ML

Hand Sanitizer

moisturizes+sanitizes+gel

2.02 fl. oz (60 mL) NDC: 75525-001-06

Production date: March 17, 2020
Lot: 30032009

Drug Facts	
Active Ingredients Ethanol 70% V/V..... Phenoxyethanol (and) Chlorphenesin 0.3%	Purpose Antiseptic
Use Antiseptic, Hand Sanitizer to help reduce bacteria on the skin that could cause disease.	
Warnings Flammable, keep away from fire/ flame.	
For external use only.	
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). May discolor certain fabrics or surfaces.	
Inactive Ingredients Water, Glycerin, Carbomer, DMDM Hydantoin, Triethanolamine.	

NDC: 75525-001-06

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SMELLS CLEAN

Vitamin E
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MICROBIAL POWER
EFFECTIVE
AGAINST MOST
COMMONS GERMS

2.02 fl Oz. (60 ml)

IWSC018

HAND SANITIZER 1000 ML

Hand Sanitizer

moisturizes+sanitizes+gel

33.8 fl. oz (1000 mL) NDC: 75525-001-10

Drug Facts

Active Ingredients	Purpose
Ethanol 70% V/V..... Antiseptic	
Phenoxyethanol (and) Chlorphenesin 0.3%	
Use	
Antiseptic, Hand Sanitizer to help reduce bacteria on the skin that could cause disease.	
Warnings	
Flammable, keep away from fire/ flame.	
For external use only.	
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) May discolor certain fabrics or surfaces.	
Inactive Ingredients	
Water, Glycerin, Carbomer, DMDM Hydantoin, Triethanolamine.	

moisturizes + sanitizes + gel

HAND Sanitizer

**DISINFECTANT
INSTANT HIGH
SPECTRUM
ANTIBACTERIAL**

**99.9%
MICROBIAL POWER
EFFECTIVE
AGAINST MOST
COMMONS GERMS**

**SMELLS
CLEAN**

NDC: 75525-001-10



Apply enough hand sanitizer to cover all hands surface.



Rub hands palm to palm.



Right palm over left dorsum with interlaced fingers and vice versa.



Palm to palm with fingers interlaced.



Backs of fingers to opposing palms with fingers interlocked.



Rotational rubbing of left thumb clasped in right palm and vice versa.



Rotational rubbing, backwards and forwards with clasped fingers of right hand left palm and vice versa.



And your hands are disinfected.

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IWSC017



33.8 fl Oz. (1000 ml)



HAND SANITIZER 2000 ML

Hand Sanitizer

moisturizes+sanitizes+gel

67.6 fl. oz (2000 mL) NDC: 75525-001-20

Drug Facts	
Active Ingredients	Purpose
Ethanol 70% V/V..... Antiseptic Phenoxyethanol (and) Chlorphenesin 0.3%	
Use	
Antiseptic, Hand Sanitizer to help reduce bacteria on the skin that could cause disease.	
Warnings	
Flammable, keep away from fire/flare.	
For external use only.	
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) May discolor certain fabrics or surfaces.	
Inactive Ingredients	
Water, Glycerin, Carbomer, DMDM Hydantoin, Triethanolamine.	

IWSC019



moisturizes + sanitizes + gel

HAND Sanitizer

Vitamin E
DISINFECTANT
INSTANT HIGH
SPECTRUM
ANTIBACTERIAL

99.9%
MICROBIAL POWER
EFFECTIVE
AGAINST MOST
COMMONS GERMS



67.6 fl Oz. (2000 ml)

NDC: 75525-001-20



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Production date: March 17 2020
Lot: 30032009

HAND SANITIZER 120 ML

Hand Sanitizer

moisturizes+sanitizes+gel

4.0 fl. oz (120 mL) NDC: 75525-001-12

NDC: 75525-001-12

Drug Facts

Active Ingredients	Purpose
Ethanol 70% V/V.....	Antiseptic
Phenoxyethanol (and) Chlorphenesin 0.3%	

Use
Antiseptic, Hand Sanitizer to help reduce bacteria on the skin that could cause disease.

Warnings
Flammable, keep away from fire/flare.

For external use only.

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
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Other Information
Store between 15-30C (59-86F)
May discolor certain fabrics or surfaces.

Inactive Ingredients
Water, Glycerin, Carbomer, DMDM Hydantoin, Triethanolamine.

Production date: March 17 2020
Lot: 30032009



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IWSC025

moisturizes + sanitizes + gel

HAND Sanitizer



Vitamin E
DISINFECTANT
INSTANT HIGH
SPECTRUM
ANTIBACTERIAL

99.9%
MICROBIAL POWER
EFFECTIVE
AGAINST MOST
COMMONS GERMS

4.0 fl Oz. (120 ml)

HAND SANITIZER 250 ML

Hand Sanitizer

moisturizes+sanitizes+gel

8.4 fl. oz (250 mL) NDC: 75525-001-25

NDC: 75525-001-25

Drug Facts

Active Ingredients	Purpose
Ethanol 70% V/V.....	Antiseptic
Phenoxyethanol (and) Chlorphenesin 0.3%	

Use
Antiseptic, Hand Sanitizer to help reduce bacteria on the skin that could cause disease.

Warnings
Flammable, keep away from fire/ flame.

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

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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)
May discolor certain fabrics or surfaces.

Inactive Ingredients
Water, Glycerin, Carbomer, DMDM Hydantoin, Triethanolamine.

Production date: March 17 2020
Lot: 30032009



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IWSC026

HAND Sanitizer

moisturizes + sanitizes + gel



Vitamin E
DISINFECTANT
INSTANT HIGH
SPECTRUM
ANTIBACTERIAL

99.9%
MICROBIAL POWER
EFFECTIVE
AGAINST MOST
COMMONS GERMS

8.4 fl Oz. (250 ml)

HAND SANITIZER 60 ML-DISPENSER

Hand Sanitizer

moisturizes+sanitizes+gel

2.02 FL OZ (60 ML)

NDC:75525-001-07

NDC: 75525-001-07

Drug Facts

Active Ingredients	Purpose
Ethanol 70% V/V.....	Antiseptic
Phenoxyethanol (and) Chlorphenesin 0.3%	

Use
Antiseptic, Hand Sanitizer to help reduce bacteria on the skin that could cause disease.

Warnings
Flammable, keep away from fire/ flame.

For external use only.

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

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Other Information
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May discolor certain fabrics or surfaces.

Inactive Ingredients
Water, Glycerin, Carbomer, DMDM Hydantoin, Triethanolamine.

Production date: March 17 2020
Lot: 30032009



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IWSC018

moisturizes + sanitizes + gel
HAND Sanitizer



Vitamin E
DISINFECTANT
INSTANT HIGH
SPECTRUM
ANTIBACTERIAL

99.9%
MICROBIAL POWER
EFFECTIVE
AGAINST MOST
COMMONS GERMS

2.02 fl Oz. (60 ml)

HAND SANITIZER SMELLS CLEAN

ethanol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75525-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CHLORPHENESIN (UNII: I670DAL4SZ)	0.143 g in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.2685 g in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.95 g in 100 mL
WATER (UNII: 059QF0K00R)	27.8 mL in 100 mL

.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	0.009 g in 100 mL
PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.143 g in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.479 g in 100 mL
DMDM HYDANTOIN (UNII: BYR0546TOW)	0.095 g in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75525-001-06	60 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
2	NDC:75525-001-50	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
3	NDC:75525-001-10	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
4	NDC:75525-001-20	2000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
5	NDC:75525-001-25	250 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020	
6	NDC:75525-001-12	120 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020	
7	NDC:75525-001-07	60 mL in 1 BOTTLE, DISPENSING; 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 - IWANNA CORP SAS (883223177)

Registrant - MASTER CUSTOMS BROKER (054631555)

Establishment

Name	Address	ID/FEI	Business Operations
IWANNA CORP SAS		883223177	manufacture(75525-001)

Revised: 5/2020

IWANNA CORP SAS