# 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.

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#### 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.

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.

#### **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

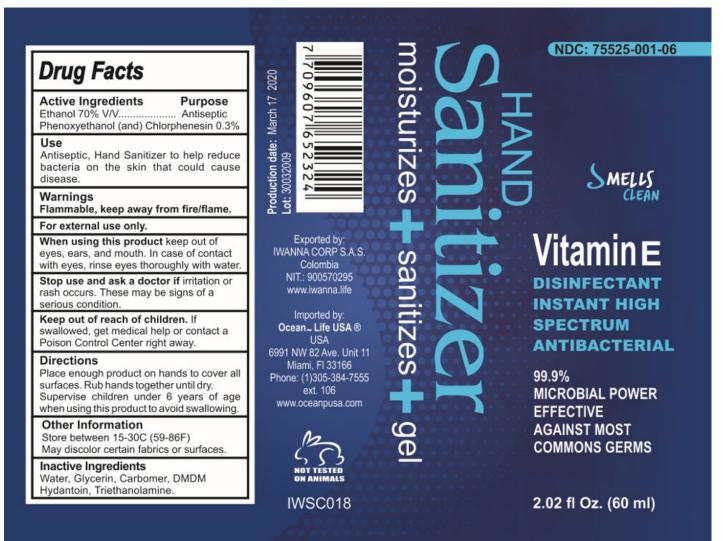


#### HAND SANITIZER 60 ML

Hand Sanitizer

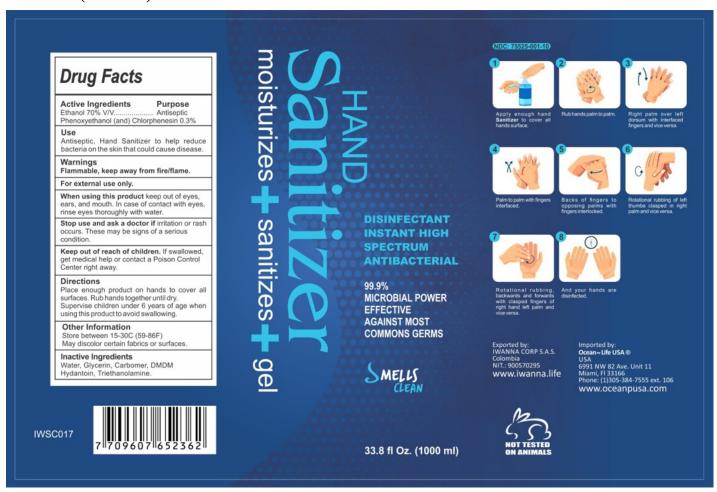
moisturizes+sanitizes+gel

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



#### HAND SANITIZER 1000 ML

Hand Sanitizer moisturizes+sanitizes+gel



#### HAND SANITIZER 2000 ML

Hand Sanitizer

moisturizes+sanitizes+gel

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

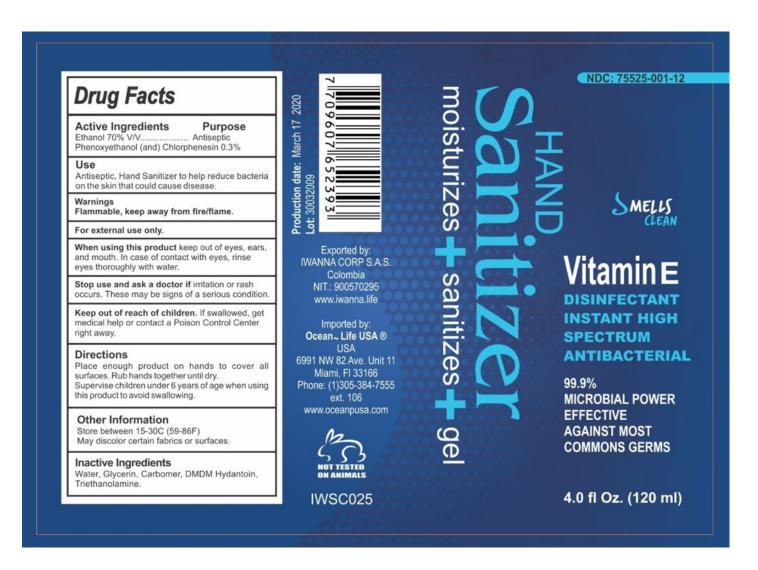


# **HAND SANITIZER 120 ML**

Hand Sanitizer

moisturizes+sanitizes+gel

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

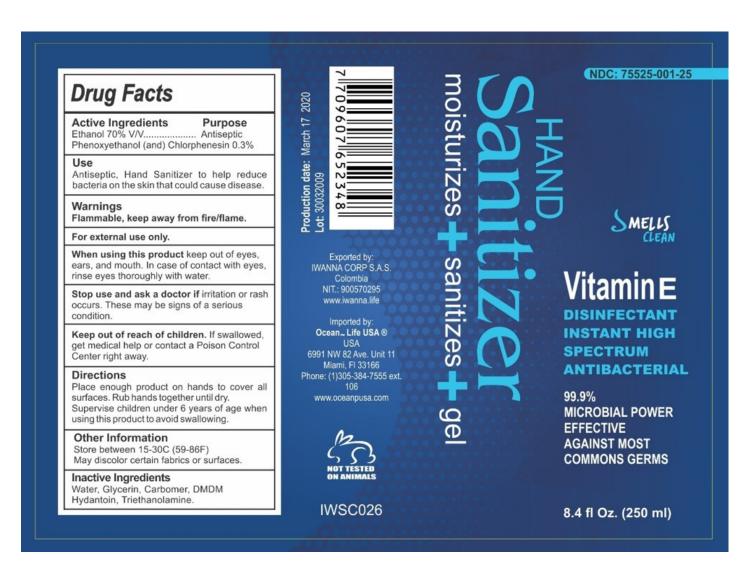


#### HAND SANITIZER 250 ML

Hand Sanitizer

moisturizes+sanitizes+gel

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



#### HAND SANITIZER 60 ML-DISPENSER

Hand Sanitizer moisturizes+sanitizes+gel 2.02 FL OZ (60 ML)

NDC:75525-001-07

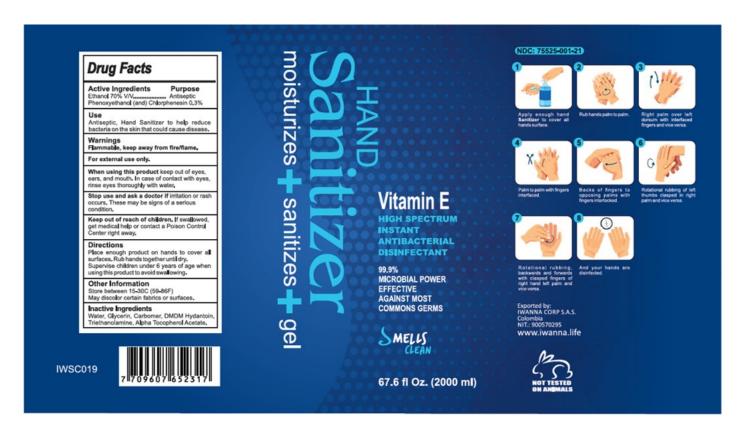


#### HAND SANITIZER 2000 ML DISP

Hand Sanitizer

moisturizes+sanitizes+gel

67.6 fl. oz (2000 mL) NDC: 75525-001-21

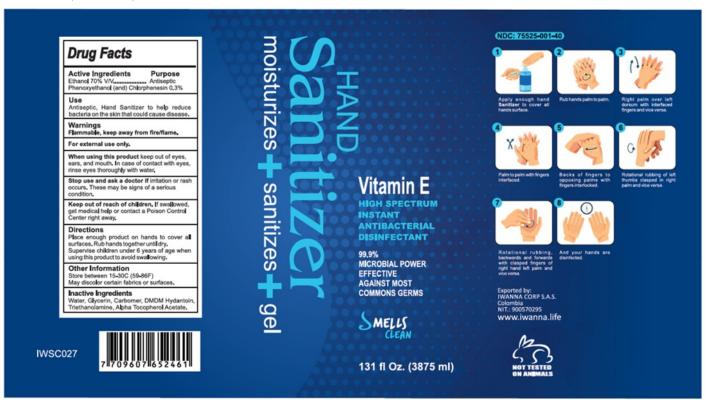


#### HAND SANITIZER 3875 ML DISP

Hand Sanitizer

moisturizes+sanitizes+gel

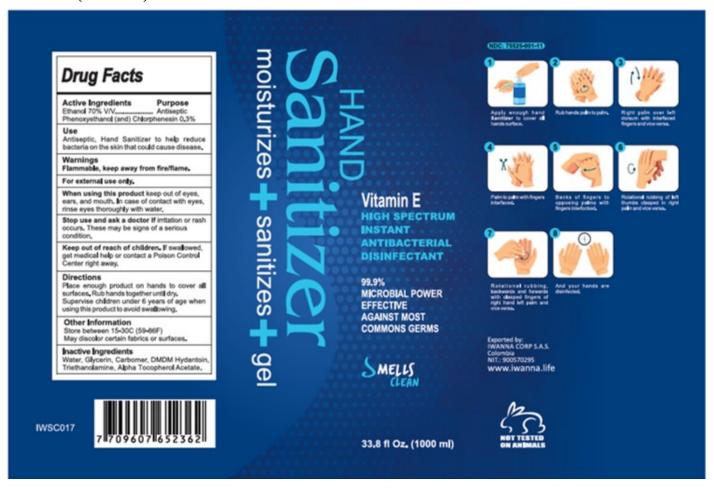
131 fl. oz (3875 mL) NDC: 75525-001-40



#### HAND SANITIZER 1000 ML DISP

Hand Sanitizer

33.8 fl. oz (1000 mL) NDC: 75525-001-11

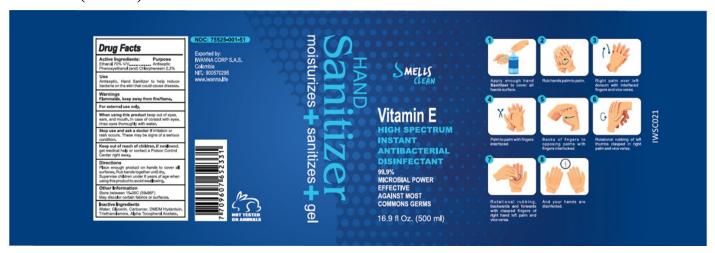


#### HAND SANITIZER 500 ML DISP

Hand Sanitizer

moisturizes+sanitizes+gel

16.9 fl. oz (500 mL) NDC: 75525-001-51



#### 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	<b>Basis of Strength</b>	Strength	
CHLORPHENES IN (UNII: 1670 DAL4SZ) (CHLORPHENES IN - UNII:1670 DAL4SZ)	CHLORPHENESIN	0.143 g in 100 mL	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL	
PHENOXYETHANOL (UNII: HIE492ZZ3T) (PHENOXYETHANOL - UNII:HIE492ZZ3T)	PHENOXYETHANOL	0.143 g in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
CARBOMER 940 (UNII: 4Q93RCW27E)	0.2685 g in 100 mL		
GLYCERIN (UNII: PDC6A3C0OX)	0.95 g in 100 mL		
WATER (UNII: 059QF0KO0R)	27.8 mL in 100 mL		
.ALPHATO COPHERO L ACETATE (UNII: 9E8 X80 D2L0)	0.009 g in 100 mL		
TROLAMINE (UNII: 903K93S3TK)	0.479 g in 100 mL		
DMDM HYDANTO IN (UNII: BYR0546 TOW)	0.095 g in 100 mL		

Pá	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	
8	NDC:75525-001- 51	500 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	06/30/2020	
9	NDC:75525-001- 11	1000 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	06/30/2020	
10	NDC:75525-001- 21	2000 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	06/30/2020	
11	NDC:75525-001- 40	3875 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	06/30/2020	

Marketing Inform	nation		
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: 12/2020 IWANNA CORP SAS