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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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

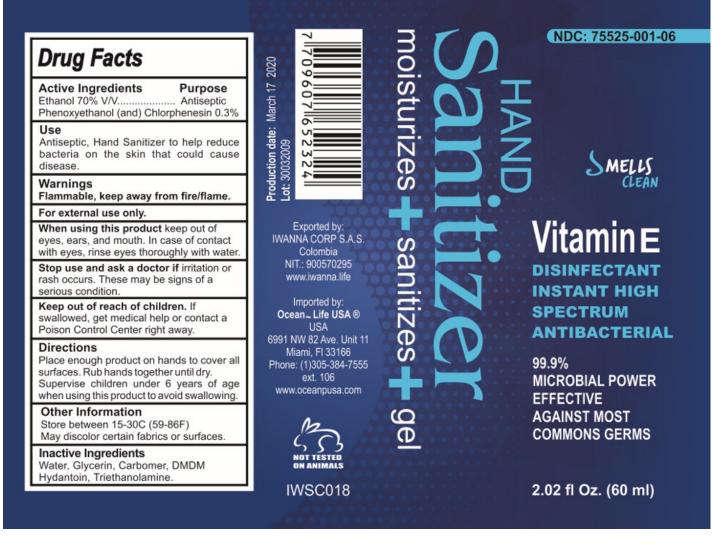


HAND SANITIZER 60 ML

Hand Sanitizer

moisturizes+sanitizes+gel

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

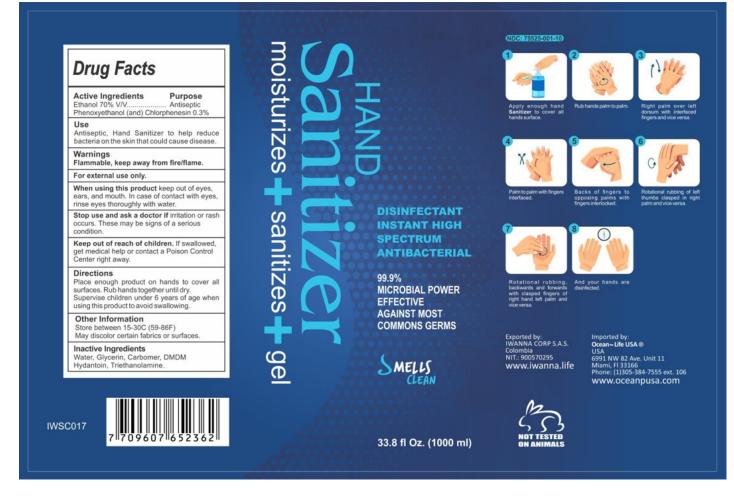


HAND SANITIZER 1000 ML

Hand Sanitizer

moisturizes+sanitizes+gel

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

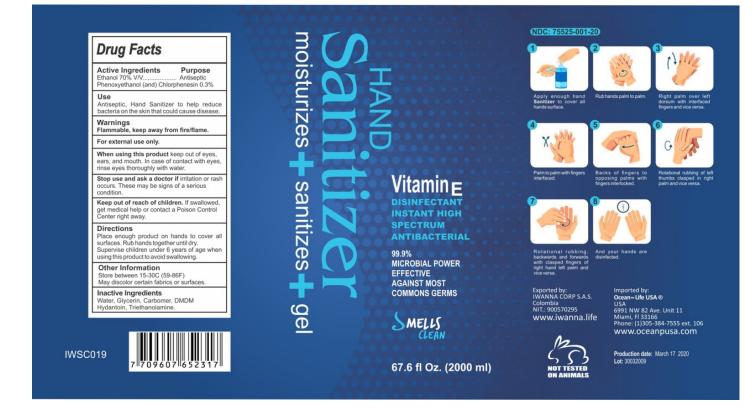


HAND SANITIZER 2000 ML

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

Drug Facts	2020	Br	
Active Ingredients Purpose Ethanol 70% V/V Antiseptic Phenoxyethanol (and) Chlorphenesin 0.3%	March 17 2	moisturizes	́т
Use Antiseptic, Hand Sanitizer to help reduce bacteria on the skin that could cause disease.			A
Warnings Flammable, keep away from fire/flame.	Production da	Ze	SMELLS
For external use only.	Lot:	S S	U CLEAN
When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	Exported by: IWANNA CORP S.A.S.	+ =	Vitamin E
Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.	Colombia NIT.: 900570295 www.iwanna.life	sa	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	Imported by: Ocean~ Life USA ®	sanitiz	INSTANT HIGH SPECTRUM
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.	USA 6991 NW 82 Ave. Unit 11 Miami, Fl 33166 Phone: (1)305-384-7555 ext. 106	zes	ANTIBACTERIA 99.9% MICROBIAL POWER
Other Information Store between 15-30C (59-86F) May discolor certain fabrics or surfaces.	www.oceanpusa.com	9¢	EFFECTIVE AGAINST MOST COMMONS GERMS
Inactive Ingredients Water, Glycerin, Carbomer, DMDM Hydantoin, Triethanolamine.	C, S S NOT TESTED ON ANIMALS	<u>e</u>	
in some section.	IWSC025		4.0 fl Oz. (120 ml

HAND SANITIZER 250 ML

Hand Sanitizer

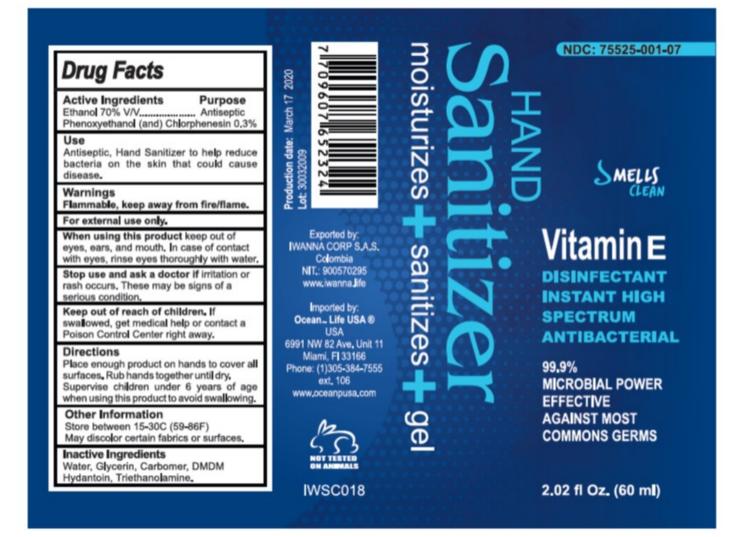
moisturizes+sanitizes+gel

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

Drug Facts	2020 6 0 4	T	NDC: 75525-
Active Ingredients Purpose Ethanol 70% V/V Antiseptic Phenoxyethanol (and) Chlorphenesin 0.3%		San	Ϋ́
Use Antiseptic, Hand Sanitizer to help reduce bacteria on the skin that could cause disease.	Production date: March 17 Lot: 30032009		Z
Warnings Flammable, keep away from fire/flame.	Production dat	es E	
For external use only.			SMEL
When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	Exported by: IWANNA CORP S.A.S. Colombia	ss S	
Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.	NIT.: 900570295 www.iwanna.life Imported by:	niti N	Vitamin
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	Ocean_Life USA ® USA 6991 NW 82 Ave. Unit 11 Miami, Fl 33166	Sanitizes	INSTANT HIG SPECTRUM
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.	Phone: (1)305-384-7555 ext. 106 www.oceanpusa.com	+ g	99.9% MICROBIAL POW EFFECTIVE
Other Information Store between 15-30C (59-86F) May discolor certain fabrics or surfaces.	53	<u>e</u>	AGAINST MOST COMMONS GERM
Inactive Ingredients Water, Glycerin, Carbomer, DMDM Hydantoin, Triethanolamine.	IWSC026		

HAND SANITIZER 60 ML-DISPENSER

Hand Sanitizer moisturizes+sanitizes+gel 2.02 FL OZ (60 ML) NDC:75525-001-07



HAND SANITIZER SMELLS CLEAN

ethanol gel

Product Information						
Product Type	HUMAN OTC DRUG	UMAN OTC DRUG Item Code (Source)			NDC:75525-001	
Route of Administration	TOPICAL					
Active Ingredient/Active Moi	ety					
Ingred	В	asis of St	rength	Strength		
ALCOHOL (UNII: 3K9958V90M) (ALC	ALC	ALCOHOL		70 mL in 100 mL		
Inactive Ingredients						
J	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: 059QF0KO0R)				27.8 mL	in 100 mL	

.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	0.009 g in 100 mL
PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.143 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

Packaging					
#	Item Code		Package Description	Marketing Start Date	Marketing End Date
1	NDC:75525-001- 06	60 mI	in 1 BOTTLE, SPRAY; Type 0: Not a Combination Prod	uct 03/30/2020	
2	NDC:75525-001- 50	500 m	L in 1 BOTTLE, PUMP; Type 0: Not a Combination Prod	uct 03/30/2020	
3	NDC:75525-001- 10	1000 Produ	mL in 1 BOTTLE, PUMP; Type 0: Not a Combination ct	03/30/2020	
4	NDC:75525-001- 20	2000 Pro du	mL in 1 BOTTLE, PUMP; Type 0: Not a Combination ct	03/30/2020	
5	NDC:75525-001- 25	250 m Produ	L in 1 BOTTLE, DISPENSING; Type 0: Not a Combinatio ct	on 03/30/2020	
6	NDC:75525-001- 12	120 m Produ	L in 1 BOTTLE, DISPENSING; Type 0: Not a Combinatio ct	ⁿ 03/30/2020	
7	NDC:75525-001- 07	60 mI Produ	L in 1 BOTTLE, DISPENSING; Type 0: Not a Combination ct	n 03/30/2020	
Marketing Information					
	Marketing Categ	gory	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		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