### SMELLS CLEAN- antibacterial liquid hand soap liquid 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 SOAP

# Hand Antibacterial Soap

This is a Liquid Hand Soap Active Ingredient POLYAMINOPROPYL BIGUANIDE

# **ACTIVE INGREDIENTS**

BENZALKONIUM CHLORIDE 0.3%

Purpose: Antibacterial

# PURPOSE

Purpose: Antibacterial

# INDICATIONS AND USAGE

1.Wet your Hands

- 2. Apply enough soap to cover all hands surface
- 3. Rub hands palm to palm
- 4. Right hand over left dorsum with interfaced fingers and vice versa
- 5. Palm to palm with fingers interfaced
- 6. Backs on fingers to opposing palms with fingers interlocked
- 7. Rotational rubbing of left thumbs clasped in right palm and vice versa
- 8. Rotational rubbing of left thumbs clasped in right palm and vice versa
- 9. Wet and rinse your hands
- 10. And your hands are desinfected

# WARNINGS

For external use only

When using this product avoid contact with eyes. In case of eye contact, flush with water

Stop use and ask a doctor if irritation or redness develops

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

# WHEN USING

When using this product avoid contact with eyes. In case of eye contact, flush with water

# **STOP USING**

Stop use and ask a doctor if irritation or redness develops

# DOSAGE AND ADMINISTRATION

Apply on Hands Rub vigorously for at least 15 seconds Rinse and dry

# **KEEP OUT OF REACH OF CHILDREN**

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

#### STORAGE AND HANDLING

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

#### **INACTIVE INGREDIENT**

Sodium Laureth Sulfate, Cocamidopropyl Betaine, Cocamide DEA, Cocamidopropylamine Oxyde, Citric Acid, Sodium Chloride, Glycerin, DMDM Hydantoin.

#### Package Label Principal Display

Hand Soap Antibacterial High Spectrum Instant Antibacterial Desinfectant **Hand Soap 500 ml- Dispensing** Hand Soap moisturizes+sanitizes

16.9 fl. oz (500 mL) NDC: 75525-002-50



# Hand Soap 500 ml- Pump

Hand Soap

moisturizes+sanitizes

# 16.9 fl. oz (500 mL) NDC: 75525-002-51



# Hand Soap 1000 ml- Dispenser

Hand Soap moisturizes+sanitizes 33.8 fl. oz (1000 mL) NDC: 75525-002-10



# Hand Soap 1000 ml- Pump

Hand Soap

moisturizes+sanitizes

33.8 fl. oz (1000 mL) NDC: 75525-002-11



## Hand Soap 2000 ml- Dispenser

Hand Soap

moisturizes+sanitizes

67.6 fl. oz (2000 mL) NDC: 75525-002-20



#### Hand Soap 2000 ml- Pump

Hand Soap

moisturizes+sanitizes

67.6 fl. oz (2000 mL) NDC: 75525-002-21



# **SMELLS CLEAN**

**SODIUM CHLORIDE** (UNII: 451W47IQ8X)

**DMDM HYDANTO IN** (UNII: BYR0546TOW)

COCAMIDO PRO PYLAMINE O XIDE (UNII: M4SL82J7HK)

CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)

GLYCERIN (UNII: PDC6A3C0OX)

antibacterial liquid hand soap liquid						
Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source) NDC:75525-002			25-002	
Route of Administration	TOPICAL					
Active Ingredient/Active Moi	ety					
Ingredient Name			<b>Basis of Strength</b>		Strength	
		BENZALKONIUM CHLORIDE		0.3 g in 100 mL		
Inactive Ingredients						
Ingredient Name				Strength		
COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)				2 mL in 100 mL		
COCO DIETHANOLAMIDE (UNII: 92005F972D)				0.5 mL in 100 mL		
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)			10 mL in 100 mL			
WATER (UNII: 059QF0KO0R)						

1 mL in 100 mL

 $1\,mL$  in 100 mL

1 mL in 100 mL 0.18 mL in 100 mL

0.1 mL in 100 mL

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:75525-002- 50	500 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	04/01/2020		
2	NDC:75525-002- 10	1000 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	04/01/2020		
3	NDC:75525-002- 51	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/01/2020		
4	NDC:75525-002- 11	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/01/2020		
5	NDC:75525-002- 20	2000 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	04/01/2020		
6	NDC:75525-002- 21	2000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/01/2020		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333A	04/01/2020			

# **Registrant** - MASTER CUSTOMS BROKER (054631555)

Establishment					
Name	Address	ID/FEI	<b>Business Operations</b>		
IWANNA CORP SAS		883223177	manufacture(75525-002)		

Revised: 12/2020

IWANNA CORP SAS