# PURE CLEAN PREMIUM HAND SANITIZER- hand sanitizer gel WOMANSWORLD Co., Ltd.

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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# **Active Ingredient**

Alcohol 75% v/v

# **Purpose**

Antiseptic

# Use

• Hand sanitizer to help reduce bacteria that potentially can cause disease.

# **Warnings**

For external use only. Flammable. Keep away from heat or flame.

**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. These may be signs of 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 your palm to thoroughly cover your hands.
- Rub hands together briskly until dry.
- Supervise children when using this product to avoid swallowing.

## Other Information

- Store between 15-30 °C (59-86°F).
- Avoid freezing and excessive heat above 104°F(40°C).
- May discolor certain fabrics or surface.

# **Inactive Ingredients**

Water, Butylene Glycol, Glycerin, Aloe Vera Leaf, Sodium Hyaluronate, 1,2-Hexanediol

# Package Label - Principal Display Panel

# **Pure Clean** Premium Hand Sanitizer Sanitizer is quick and effective at killing 99.9% of all germs **75**% alcoho gel type Contains moisturizer to soothe the skin 100mL (3.38 FL OZ) NDC 77708-002-20

# **Drug Facts**

# Active ingredients

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## Inactive ingredients

Water, Butylene Glycol, Glycerin, Carbomer, Triethanolamine, Aloe Vera Leaf, Sodium Hyaluronate, 1,2-Hexanediol



Manufactured by: ICOMAX Co., Ltd. 87, Gajangsaneopseobuk-ro., Osan, 18102, Korea, South (KOR)
Distributed by: WOMANSWORLD
Co., Ltd. 733, Hyeeum-ro, Gwangtanmyeon, Paju-si, Gyeonggi-do, Korea, South (KOR) http://womansworld.co.kr

# PURE CLEAN PREMIUM HAND SANITIZER

hand sanitizer gel

# **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:77708-002

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	
TROLAMINE (UNII: 903K93S3TK)	0.2 mL in 100 mL	
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	0.5 mL in 100 mL	
WATER (UNII: 059QF0KO0R)	21.28988 mL in 100 mL	
GLYCERIN (UNII: PDC6A3C0OX)	1 mL in 100 mL	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	2 mL in 100 mL	
HYALURO NATE SO DIUM (UNII: YSE9 PPT4TH)	0.0001 mL in 100 mL	
1,2-HEXANEDIO L (UNII: TR0 46 Y3K1G)	0.00022 mL in 100 mL	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.0098 mL in 100 mL	

Packaging				
ı	# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
ı	1 NDC:77708-002-20	100 mL in 1 TUBE; Type 0: Not a Combination Product	05/19/2020	

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333A	05/19/2020			

# Labeler - WOMANSWORLD Co., Ltd. (688320057)

# Registrant - WOMANSWORLD Co., Ltd. (688320057)

Establishment				
Name	Address	ID/FEI	Business Operations	
ICOMAX Co., Ltd.		694834031	manufacture (77708-002)	

Revised: 5/2020 WOMANSWORLD Co., Ltd.