

**HAND SANITIZER- hypochlorous acid solution**  
**THAI WACOAL PUBLIC COMPANY LIMITED**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).*

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**Active Ingredient(s)**

Hypochlorous Acid 95% v/v.

**Purpose**

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

**Do not use**

- in children less than 2 months of age
- on open skin wounds

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)
- Avoid freezing and excessive heat above 40C (104F)

**Inactive ingredients**

Water, Sodium Chloride, Seawater, Colloidal Gold

**Package Label - Principal Display Panel**

50mL NDC:79841 -001-05

ENFANT  
**cleanze**  
 Natural Water  
 Cleaning Spray

100% Natural  
 Hypochlorous Acid  
 Non-toxic



PRODUCT OF THAILAND  
 50 ml.

ผ่านการทดสอบและทดสอบ  
 ทางการแพทย์ที่ DermScan Asia  
 Dermatology tested  
 Non-irritating

EC050DP1WH

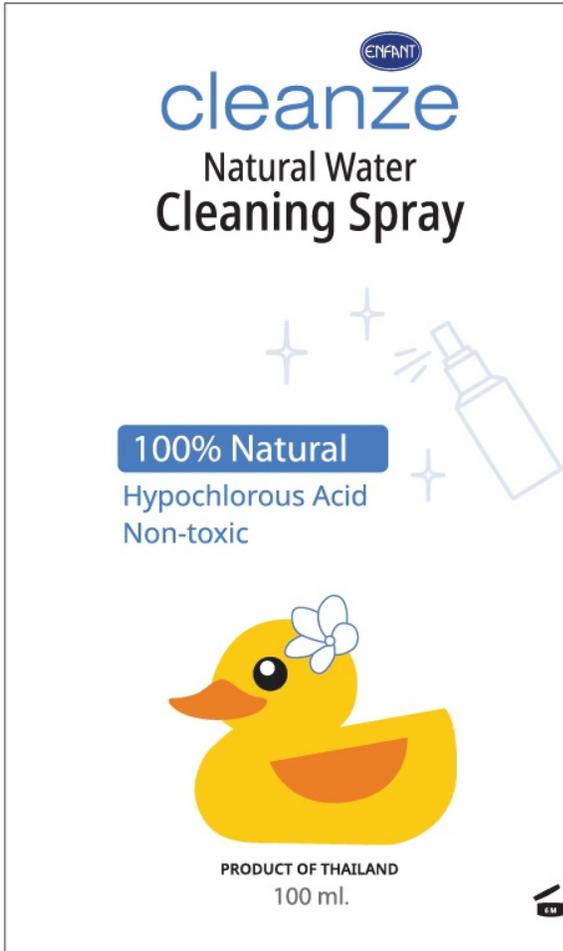


ENFANT  
**cleanze**  
 Natural Water  
 Cleaning Spray

Drug Facts	
<b>Active Ingredients</b>	<b>Purpose</b>
Hypochlorous Acid 95%	Antiseptic
<b>Uses:</b> Hand sanitizer to help reduce bacteria that potentially can cause disease	
<b>Warnings</b>	
For external use only. Flammable. Keep away from heat or flame	
<b>Do not use</b>	
<ul style="list-style-type: none"> <li>In children less than 2 months of age</li> <li>on open skin wounds</li> </ul>	
<b>When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water</b>	
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<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>Place enough product on hands to cover all surfaces.</li> <li>Rub hands together until dry.</li> <li>Supervise children under 6 years of age when using this product to avoid swallowing.</li> </ul>	
<b>Other information</b>	
<ul style="list-style-type: none"> <li>Store between 15-90C (59-86F)</li> <li>Avoid freezing and excessive heat above 40C (104F)</li> </ul>	
<b>Inactive ingredients</b>	
Water, Sodium Chloride, Sea Water, Colloidal Gold	
<b>Questions or comments</b>	
FDA MedWatch Number : 1-888-463-6332 <a href="http://www.us.enfantcleanze.com">www.us.enfantcleanze.com</a>	
<b>Manufacturer by Ireal Plus (Thailand) Co., Ltd.</b>	
38 Moo 9, Hual Phra, Don Tum, Nakhon Pathom 73150 THAILAND	
<b>Production controlled and distributed by</b>	
Thai Wacoal Public Company Limited 132 Soi Charoenrat 7, Bangkok, Bangkoklaem, Bangkok 10120, Thailand	

[www.enfantcleanze.com](http://www.enfantcleanze.com)  
 50 ml (1.7oz)

100 mL NDC:79841 -001-10

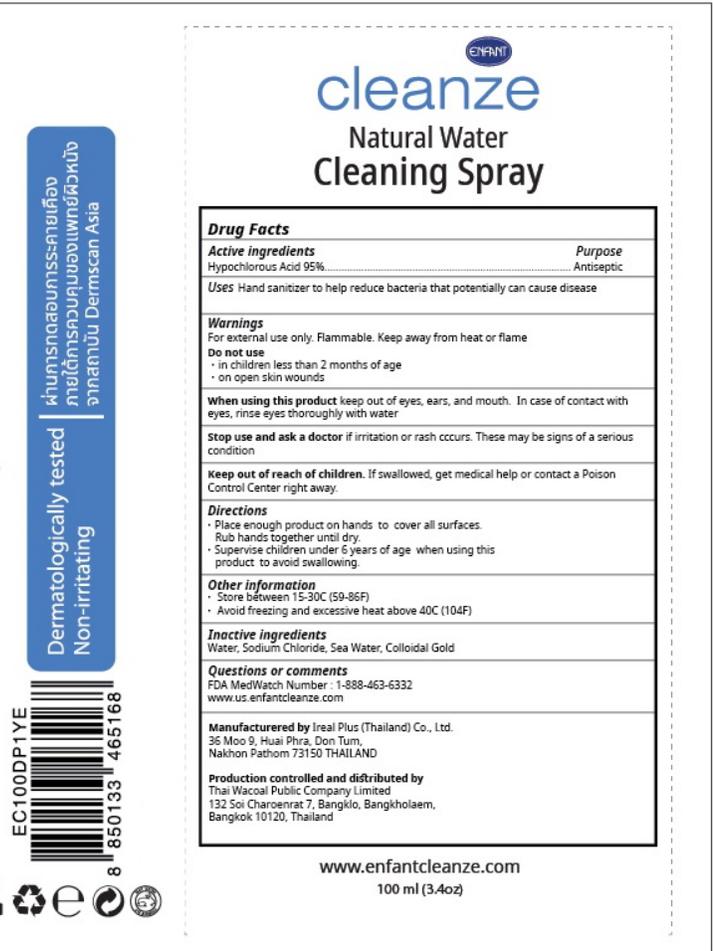


**cleanze**  
Natural Water  
Cleaning Spray

100% Natural  
Hypochlorous Acid  
Non-toxic



PRODUCT OF THAILAND  
100 ml.



**cleanze**  
Natural Water  
Cleaning Spray

Drug Facts	Purpose
<b>Active ingredients</b> Hypochlorous Acid 95%	Antiseptic
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<b>Other information</b> - Store between 15-30C (59-86F) - Avoid freezing and excessive heat above 40C (104F)	
<b>Inactive ingredients</b> Water, Sodium Chloride, Sea Water, Colloidal Gold	
<b>Questions or comments</b> FDA MedWatch Number: 1-888-463-6332 www.us.enfantcleanze.com	
<b>Manufacturer</b> by Ireal Plus (Thailand) Co., Ltd. 36 Moo 9, Huai Phra, Don Tum, Nakhon Pathom 73150 THAILAND	
<b>Production controlled and distributed by</b> Thai Wacoal Public Company Limited 132 Soi Charoenrat 7, Bangkok, Bangkoklaem, Bangkok 10120, Thailand	

www.enfantcleanze.com  
100 ml (3.4oz)

450 mL NDC:79841 -001-45

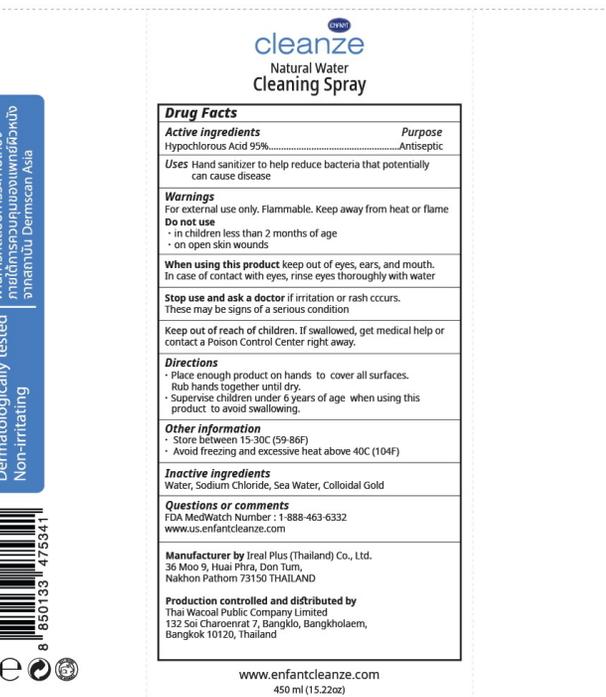


**cleanze**  
Natural Water  
Cleaning Spray

100% Natural  
Hypochlorous Acid  
Non-toxic



PRODUCT OF THAILAND  
450 ml.



**cleanze**  
Natural Water  
Cleaning Spray

Drug Facts	Purpose
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www.enfantcleanze.com  
450 ml (15.22oz)

115mm

# HAND SANITIZER

hypochlorous acid solution

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:79841-001
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYPOCHLOROUS ACID (UNII: 712K4CDC10) (HYPOCHLOROUS ACID - UNII:712K4CDC10)	HYPOCHLOROUS ACID	95 mg in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
GOLD (UNII: 79 Y1949PYO)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
MERCURY (UNII: FXS1BY2PGL)	
WATER (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79841-001-05	50 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/31/2020	
2	NDC:79841-001-10	100 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/31/2020	
3	NDC:79841-001-45	450 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/31/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		07/31/2020	

**Labeler** - THAI WACOAL PUBLIC COMPANY LIMITED (659934301)

## Establishment

Name	Address	ID/FEI	Business Operations
IREAL PLUS (THAILAND) COMPANY LIMITED		671902247	manufacture(79841-001)