PURPLE K- hypochlorous acid spray PurpleK Co.,ltd.

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.

ACTIVE INGREDIENT

HYPOCHLOROUS ACID 0.003%

INACTIVE INGREDIENT

Water

PURPOSE

Antimicrobial

WARNINGS

For external use only.

Do not use

- for children 6 years and bolow
- on open skin wounds
- if pregnant or breast-feeding, comsult with your physician prior to use

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.

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.

Uses

Hand Sanitizer to help reduce bacteria and viruses that potentially can cause disease. For use when soap and water are not available.

Directions

- 1. Turn the spray cap to ON
- 2. Spray 3-5 times at a 20cm distance from the targeted area
- 3. Dry well after spraying
- 4. Turn the spray cap OFF after use.

Other Information

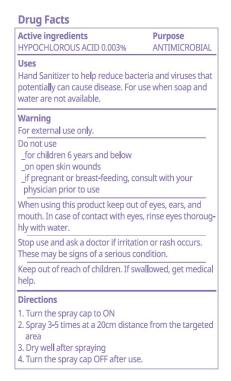
Do not adulterate or dilute. Best when stored at room temperature, below 25 degrees Celsius. Keep away from direct sunlight and heat.

Do not freeze.

Disposal & Handling: This solution is biodegradable and environmentally safe. No special disposal considerations or handling precautions required.

Shelf life: 1 year from the date of manufacture

Package Label - Purple K 120mL (NDC: 81185-010-01)





Other Information

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Disposal & Handling: This solution is biodegradable and environmentally safe. No special disposal considerations or handling precautions required.

Shelf life: 1 year from the date of manufacture

Inactive Infredient

Water

Manufactured by Purple-K co.,ltd.

- Alcohol free
- No rinsing required
- Germicidal, Bactericidal, Virucidal
- Hypochlorous acid solution



Package Label - Purple K 500mL (NDC: 81185-010-02)



Drug Facts	
Active ingredients HYPOCHLOROUS ACID 0.003%	Purpose ANTIMICROBIAL
Uses Sanitizer to help reduce bacteria and potentially can cause disease. For us are not available.	
Warning For external use only.	
Do not use _for children 6 years and below _on open skin wounds _if pregnant or breast-feeding, con: physician prior to use	sult with your
When using this product keep out of mouth. In case of contact with eyes, hly with water.	
Stop use and ask a doctor if irritation These may be signs of a serious con	or rash occurs. dition.
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Drug Facts (continued) Other Information

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Inactive Infredient

Manufactured by PurpleK Co., Ltd.

- · Alcohol free
- No rinsing required
- Germicidal, Bactericidal, Virucidal
- Hypochlorous acid solution





PURPLE K

hypochlorous acid spray

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81185-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
HYPOCHLOROUS ACID (UNII: 712K4CDC10) (HYPOCHLOROUS ACID - UNII:712K4CDC10)	HYPOCHLOROUS ACID	0.003 g in 100 mL	

Inactive Ingredients	
Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	

ı	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:81185-010- 01	120 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	11/27/2020	
	2 NDC:81185-010- 02	500 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	11/27/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		11/27/2020	

Labeler - PurpleK Co.,ltd. (694844712)

Registrant - PurpleK Co.,ltd. (694844712)

Establishment			
Name	Address	ID/FEI	Business Operations
Purple K Co.,ltd.		694844712	manufacture(81185-010)

Revised: 12/2020 PurpleK Co.,ltd.