

PUROMA- alcohol gel
ZENITH MICRO CONTROL

PUROMA Ethyl Alcohol 70% Hand Sanitizer

Active Ingredient

Alcohol 70% V/V

Purpose

Antiseptic.

Warnings

- **Flammable. Keep away from fire or flame.**
- **When using this product** do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.
- **Stop use and ask a doctor** if irritation or rash appears and lasts.

Uses

Hand Sanitizer to help reduce bacteria on skin.

Directions

- Put enough product in your palm to cover hands and rub hands together briskly until dry.
- Children under 6 years of age should be supervised when using Puroma Hand Sanitizer.

Keep out of reach of children.

If swallowed, get medical help or contact a poison control center right away.


Other information

- Store below 110°F (43°C)
- May discolor certain fabrics or surfaces

Inactive Ingredients

WATER, ISOPROPYL ALCOHOL ,GLYCERIN, ISOPROPYL MYRISTATE,ALPHA.-
TOCOPHEROL ACETATE, CARBOMER HOMOPOLYMER , CAPRYLYL
GLYCOL,AMINOMETHYLPROPANOL, ALOE VERA LEAF, PROPYLENE GLYCOL,COCO-
CAPRYLATE , FRAGRANCE.

Product label



**Ethyl Alcohol 70%
Antiseptic**

With
Moisturizers
and vitamin E

17 FL OZ (503 ml)

Drug Facts

| Active ingredient | Purpose |
|-----------------------|------------|
| Ethyl Alcohol 70% V/V | Antiseptic |

Uses

- Hand Sanitizer to help reduce bacteria on skin.
- For use when soap and water are not available.

Warnings

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

When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash appears and lasts.

Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

Directions

- Put enough product in your palm to cover hands and rub hands together briskly until dry.
- Children under 6 years of age should be supervised when using Puroma Hand Sanitizer.

Other information

- Store below 110°F (43°C).
- May discolor certain fabrics or surfaces.

inactive ingredients:

Aqua(Water), Alpha-Tocopherol Acetate, Aloe Vera Leaf, Aminomethylpropanol, Caprylyl Glycol, Carbomer Homopolymer, Coco-caprylate, Fragrance, Glycerin, Isopropyl Alcohol, Isopropyl Myristate, Propylene Glycol.

Batch No : XXXXXXXXXX

Expiry Date : XXXXXXXXXX

Made in India

Distributed by:
Infinity BioSolutions Inc.
5 Iris lane, San Carlos, CA 94070
Tel. +1-6503849546

PUROMA

alcohol gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:80948-002 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|-----------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 70 mL in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| WATER (UNII: 059QF0KO0R) | |
| ISOPROPYL ALCOHOL (UNII: ND2M416302) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC) | |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) | |
| AMINOMETHYLPROPANOL (UNII: LU49E6626Q) | |

| | |
|--|--|
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| COCO-CAPRYLATE (UNII: 4828G836N6) | |
| FRAGRANCE CLEAN ORC0600327 (UNII: 329LCV5BTF) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----|------------------|---|----------------------|--------------------|
| 1 | NDC:80948-002-01 | 30 mL in 1 BOTTLE; Type 0: Not a Combination Product | 12/20/2020 | |
| 2 | NDC:80948-002-02 | 60 mL in 1 BOTTLE; Type 0: Not a Combination Product | 12/20/2020 | |
| 3 | NDC:80948-002-03 | 50 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package | 12/20/2020 | |
| 4 | NDC:80948-002-04 | 100 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package | 12/20/2020 | |
| 5 | NDC:80948-002-05 | 120 mL in 1 BOTTLE; Type 0: Not a Combination Product | 12/20/2020 | |
| 6 | NDC:80948-002-06 | 320 mL in 1 BOTTLE; Type 0: Not a Combination Product | 12/20/2020 | |
| 7 | NDC:80948-002-07 | 503 mL in 1 BOTTLE; Type 0: Not a Combination Product | 12/20/2020 | |
| 8 | NDC:80948-002-08 | 5000 mL in 1 CAN; Type 0: Not a Combination Product | 12/20/2020 | |
| 9 | NDC:80948-002-09 | 50000 mL in 1 CAN; Type 0: Not a Combination Product | 12/20/2020 | |
| 10 | NDC:80948-002-10 | 200000 mL in 1 DRUM; Type 0: Not a Combination Product | 12/20/2020 | |
| 11 | NDC:80948-002-11 | 12 in 1 PACKAGE | 10/21/2021 | |
| 11 | | 30 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 12 | NDC:80948-002-12 | 6 in 1 PACKAGE | 10/21/2021 | |
| 12 | | 60 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 13 | NDC:80948-002-13 | 4 in 1 PACKAGE | 10/21/2021 | |
| 13 | | 237 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 14 | NDC:80948-002-14 | 237 mL in 1 BOTTLE; Type 0: Not a Combination Product | 10/21/2021 | |
| 15 | NDC:80948-002-15 | 488 mL in 1 BOTTLE; Type 0: Not a Combination Product | 10/21/2021 | |
| 16 | NDC:80948-002-16 | 2 in 1 PACKAGE | 10/21/2021 | |
| 16 | | 488 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 17 | NDC:80948-002-17 | 947 mL in 1 BOTTLE; Type 0: Not a Combination Product | 10/21/2021 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
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| OTC Monograph Drug | M003 | 12/20/2020 | |
|--------------------|------|------------|--|

Labeler - ZENITH MICRO CONTROL (915625571)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------|---------|-----------|------------------------|
| ZENITH MICRO CONTROL | | 915625571 | manufacture(80948-002) |

Revised: 12/2023

ZENITH MICRO CONTROL