

HAND SANITIZING WIPES- benzalkonium chloride cloth
Skaffles Group Limited Liability Company

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.

77720-003 HAND SANITIZING WIPES 0.3% BENZALKONIUM CHLORIDE

Active Ingredient

Benzalkonium Chloride 0.3%

Purpose

Antibacterial

USE

For hand washing to decrease bacteria on the skin.
Recommended for repeated use.

Warning

For external use only. Do not use if you are allergic to any of the ingredients.

Keep out of reach of children.

Directions

Directions • Adults and children 2 yrs and over,
apply to hands and allow skin to dry without wiping.

• Children under 2, ask doctor before use.

Inactive ingredients

Inactive ingredients Water, Aloe Barbadensis Leaf Juice, PEG-75 Lanolin, Quaternium-52, PEG-8 Dimethicone, Disodium Cocoamphodiacetate, Disodium EDTA, Chamomilla Recutita (Matricaria) Flower Extract, Potassium Sorbate, Phenoxyethanol, Cetylpyridinium Chloride, Sodium Benzoate, Citric Acid.

Drug Facts

Active ingredient

Benzalkonium Chloride (0.3%)

Purpose

Antibacterial

Use for hand sanitizing to decrease bacteria on the skin

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HAND SANITIZING WIPES

benzalkonium chloride cloth

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:77720-003 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------|----------------|
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y) | BENZALKONIUM CHLORIDE | 0.3 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|-----------------------------------|----------|
| WATER (UNII: 059QF0KO0R) | |
| QUATERNIUM-52 (UNII: 588EQF3H1P) | |
| PEG-75 LANOLIN (UNII: 09179OX7TB) | |

| | |
|--|--|
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P) | |
| PEG-8 DIMETHICONE (UNII: GIA7T764OD) | |
| DISODIUM CO CO AMPHODIACETATE (UNII: 18L9G3U51M) | |
| DISODIUM EDTA-COPPER (UNII: 6V475AX06U) | |
| CHAMOMILE (UNII: FGL3685T2X) | |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:77720-003-01 | 10 in 1 BAG | 06/23/2020 | |
| 1 | | 4.05 g in 1 POUCH; Type 0: Not a Combination Product | | |
| 2 | NDC:77720-003-02 | 15 in 1 BAG | 06/23/2020 | |
| 2 | | 4.05 g in 1 POUCH; Type 0: Not a Combination Product | | |
| 3 | NDC:77720-003-03 | 20 in 1 BAG | 06/23/2020 | |
| 3 | | 4.05 g in 1 POUCH; Type 0: Not a Combination Product | | |
| 4 | NDC:77720-003-04 | 25 in 1 BAG | 06/23/2020 | |
| 4 | | 4.05 g in 1 POUCH; Type 0: Not a Combination Product | | |
| 5 | NDC:77720-003-05 | 30 in 1 BAG | 06/23/2020 | |
| 5 | | 4.05 g in 1 POUCH; Type 0: Not a Combination Product | | |
| 6 | NDC:77720-003-06 | 50 in 1 BAG | 06/23/2020 | |
| 6 | | 4.05 g in 1 POUCH; Type 0: Not a Combination Product | | |
| 7 | NDC:77720-003-07 | 75 in 1 CANISTER | 06/23/2020 | |
| 7 | | 4.05 g in 1 POUCH; Type 0: Not a Combination Product | | |
| 8 | NDC:77720-003-08 | 100 in 1 BAG | 06/23/2020 | |
| 8 | | 4.05 g in 1 POUCH; Type 0: Not a Combination Product | | |
| 9 | NDC:77720-003-09 | 1 in 1 BAG | 06/23/2020 | |
| 9 | | 4.05 g in 1 POUCH; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 06/23/2020 | |

Labeler - Skaffles Group Limited Liability Company (831115642)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------------------|---------|-----------|------------------------|
| Jinhua Aidi Daily Chemical Co., Ltd | | 547506401 | manufacture(77720-003) |