CLEANSING DISINFECTION WIPES- cleansing disinfection wipes cloth Guangdong Bolicen Bio-Technology 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.

CLEANSING&DISINFECTION WIPES

Active Ingredient(s)

Alcohol 10% w/w

Benzalkonium Chlorid 0. 1%w/w

Poly(hexamethylenebiguanide)hydro-chloride 0.05%w/w

Didecyl Dimethylammonium Chloride 0.3%w/w

Purpose

Antiseptic

Use

USE FOR HAND AND SKIN SURFACE DISINFECTING AND CLEANSING

Warnings

For external use only. Keep away from sunlight, store in a cool, dry place

Do not use

In children less than 2 months of age On open skin wounds

When using this product keep out of eyes and sore or broken skin, If contact with eyes occurs, rinse thoroughly with water.top use and ask a doctor if irritation or rash occurs, These may be signs of a serious condition Keep out of reach of children. Get medical help or contact a Poison Control Center right away if needed

Stop use and ask a doctor if imitation or rash occurs, These may be signs of a serious condition

Keep out of reach of children. Get medical help or contact a Poison Control Center right away if needed

Directions

Open lid, For first time user, remove tamper evident seal, Pullout wipes as needed. Close the lid after use each time top revent moisture loss

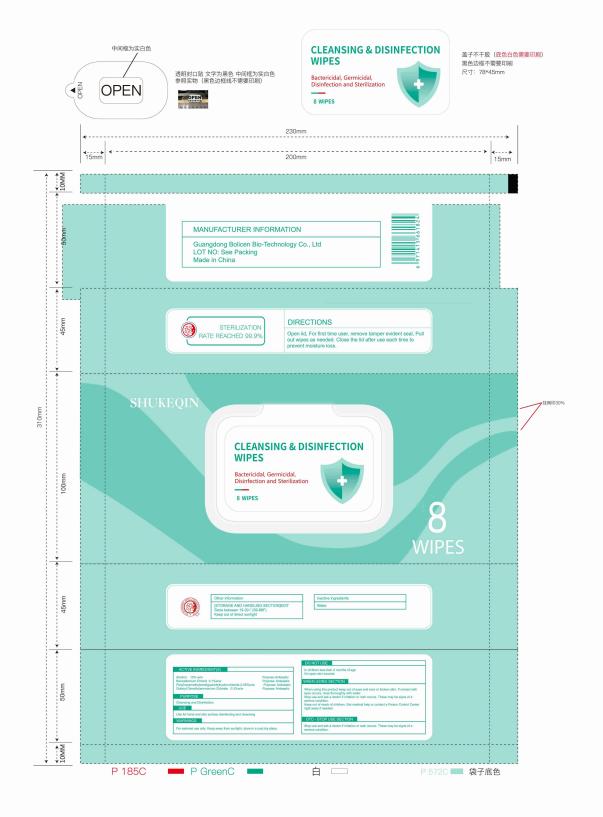
Other information

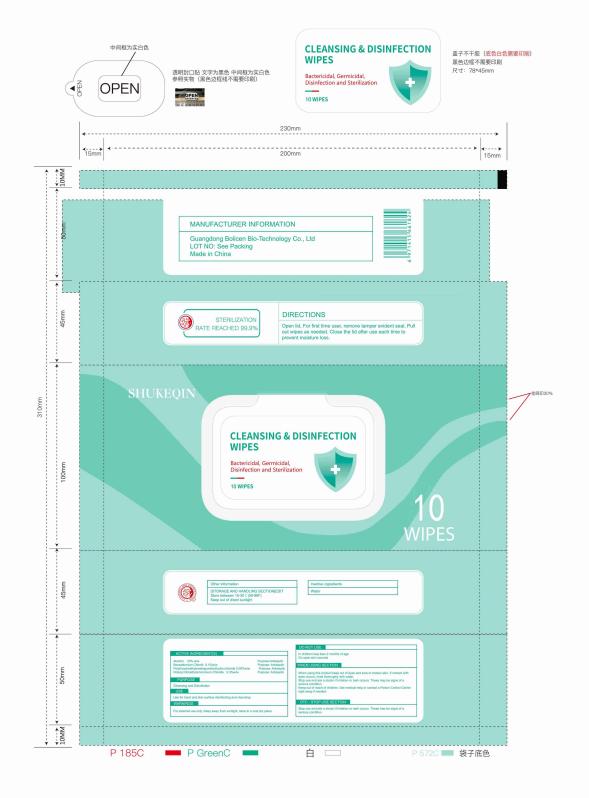
Do not store above 40 $^{\circ}$ C. May discolor some fabrics and surfaces Store between15-30 $^{\circ}$ C

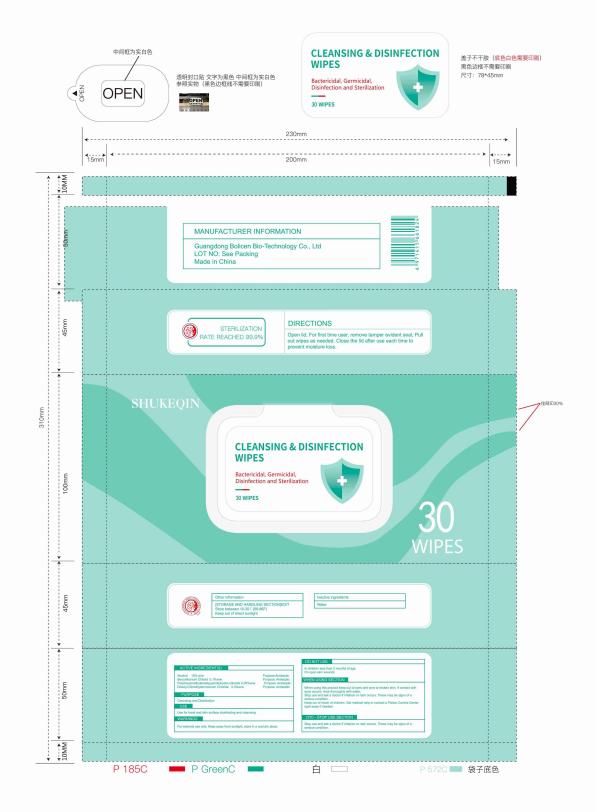
Inactive ingredients

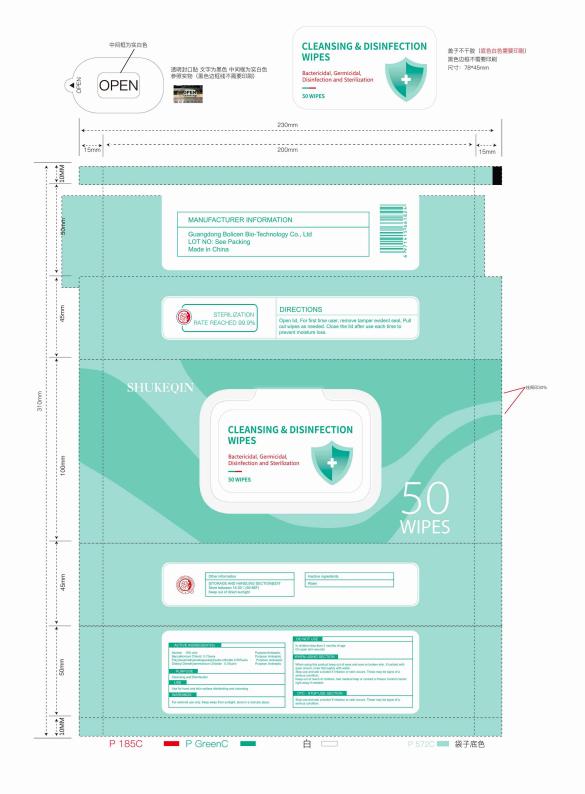
Water

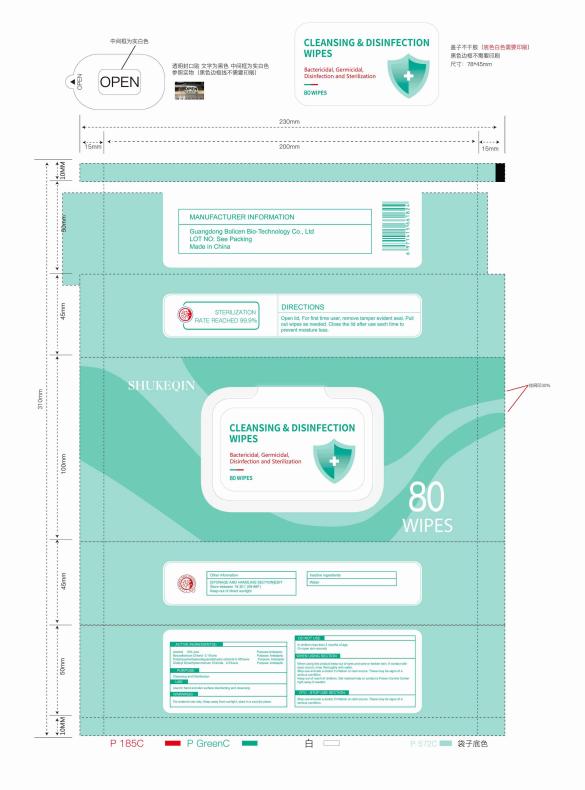
Package Label - Principal Display Panel

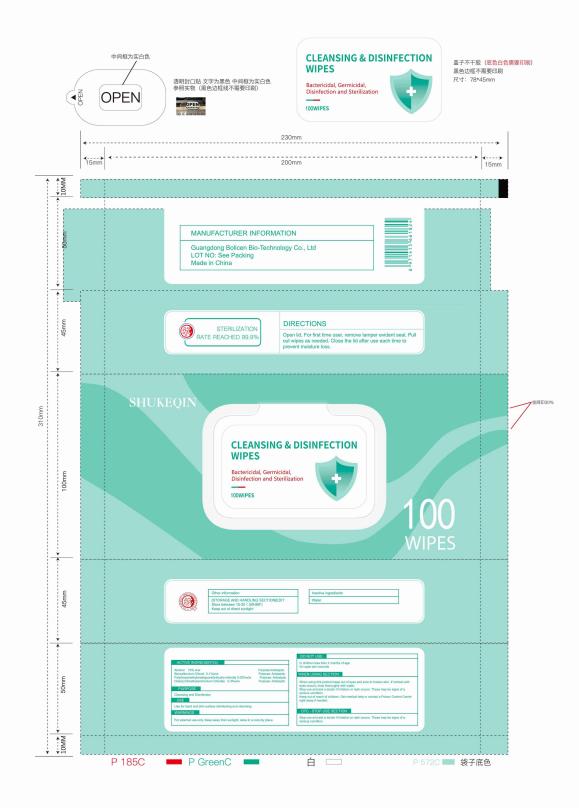












CLEANSING DISINFECTION WIPES

cleansing disinfection wipes cloth

Product Information

| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:78293-008 |
|-------------------------|----------------|--------------------|---------------|
| Route of Administration | TOPICAL | | |

| Active Ingredient/Active Moiety | | | |
|---|-----------------------------|----------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKO NIUM - UNII:7N6 JUD5X6 Y) | BENZALKONIUM CHLORIDE | 0.1 in 100 | |
| POLIHEXANIDE (UNII: 322U039GMF) (POLIHEXANIDE - UNII:322U039GMF) | POLIHEXANIDE | 0.05 in 100 | |
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 10 in 100 | |
| DIDECYLDIMONIUM CHLORIDE (UNII: JXN40 O9 Y9 B) (DIDECYLDIMONIUM - UNII:Z7F472XQPA) | DIDECYLDIMONIUM CHLORIDE | 0.3 in 100 | |

| Inactive Ingredients | | |
|--------------------------|-----------------|----------|
| | Ingredient Name | Strength |
| WATER (UNII: 059QF0KO0R) | | |

| P | Packaging | | | | |
|---|------------------|---|-----------------------------|--------------------|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 | NDC:78293-008-01 | 8 in 1 BAG; Type 0: Not a Combination Product | 07/12/2020 | | |
| 2 | NDC:78293-008-02 | 10 in 1 BAG; Type 0: Not a Combination Product | 07/12/2020 | | |
| 3 | NDC:78293-008-03 | 30 in 1 BAG; Type 0: Not a Combination Product | 07/12/2020 | | |
| 4 | NDC:78293-008-04 | 50 in 1 BAG; Type 0: Not a Combination Product | 07/12/2020 | | |
| 5 | NDC:78293-008-05 | 80 in 1 BAG; Type 0: Not a Combination Product | 07/12/2020 | | |
| 6 | NDC:78293-008-06 | 100 in 1 BAG; Type 0: Not a Combination Product | 07/12/2020 | | |

| Marketing Information | | | | |
|-------------------------|--|----------------------|--------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph not final | part333A | 07/12/2020 | | |
| | | | | |

Labeler - Guangdong Bolicen Bio-Technology Co., Ltd. (554525110)

| Establishment | | | | |
|--|---------|-----------|----------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Guangdong Bolicen Bio-Technology Co., Ltd. | | 554525110 | manufacture(78293-008) | |

Revised: 7/2020