

ALCOHOL WIPES- alcohol wipes cloth
GUANGZHOU XUELEI COSMETIC 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.

ALCOHOL WIPES

ACTIVE INGREDIENT

ALCOHOL (75% v/v)

PURPOSE

ANTISEPTIC

USES

HELP DECREASE BACTERIA ON THE HANDS.

WARNINGS

FOR EXTERNAL USE ONLY.

FLAMMABLE. KEEP AWAY FROM FIRE OR FLAME.

AVOID CONTACT WITH EYES, IN CASE OF CONTACT, RINSE EYES THOROUGHLY WITH WATER IMMEDIATELY.

KEEP OUT OF REACH OF CHILDREN EXCEPT UNDER ADULT SUPERVISION.

IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

IF IRRITATION DEVELOPS, DISCONTINUE USE AND CONSULT A DOCTOR.

KEEP OUT OF REACH OF CHILDREN EXCEPT UNDER ADULT SUPERVISION.

DIRECTIONS

1 □ OPEN THE BARREL CAP;

2 □ RIVE THE SEAL;

3 □ PULL OUT THE WET TISSUE TOWEL THROUGH SMALL OPENING;

4 □ COVER THE LIP;

5 □ RUB THOROUGHLY OVER ALL SURFACES OF BOTH HANDS WITH THE WET WIPES;

6 □ ALLOW TO DRY WITHOUT WIPING;

7. DISPOSE OF WIPES IN TRASH AFTER USE. DO NOT FLUSH.

OTHER INFORMATION

STORE IN ROOM TEMPERATURE. AVOID DIRECT SUNLIGHT.

SHELF LIFE: 2 YEARS

INACTIVE INGREDIENTS

WATER (AQUA), TERT-BUTYL ALCOHOL, DENATONIUM BENZOATE

1 WIPES, NDC: 74658-013-01

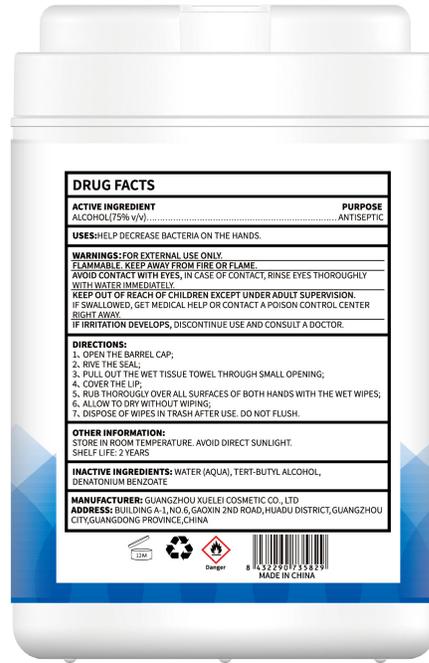




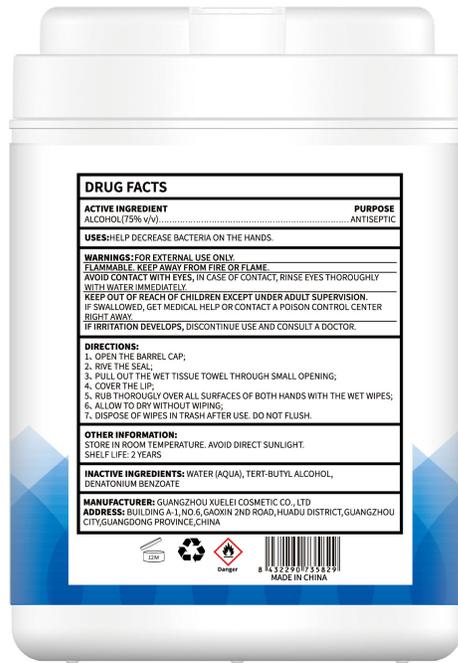
75 WIPES, NDC: 74658-013-02



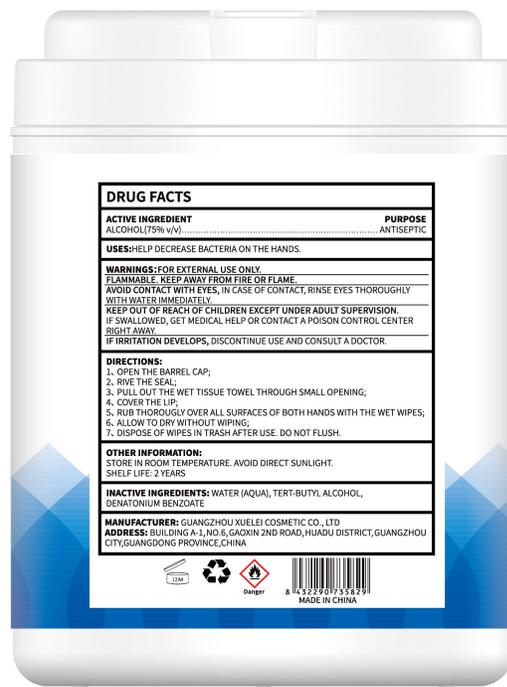
80 WIPES, NDC: 74658-013-03



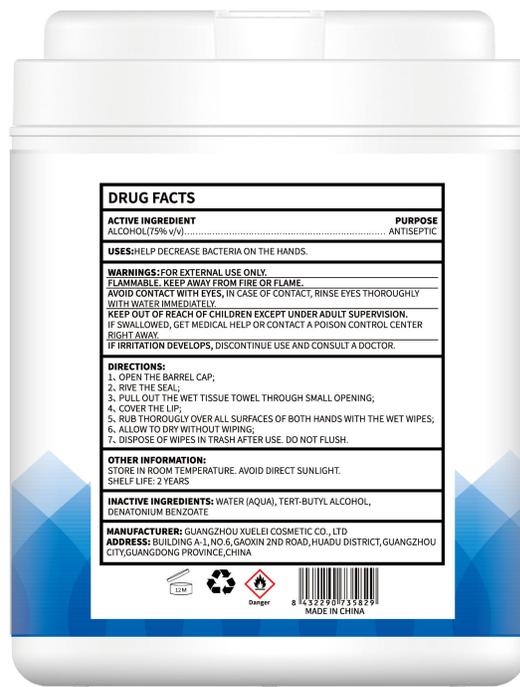
100 WIPES, NDC: 74658-013-04



120 WIPES, NDC: 74658-013-05



130 WIPES, NDC: 74658-013-06



150 WIPES, NDC: 74658-013-07



180 WIPES, NDC: 74658-013-08



200 WIPES, NDC: 74658-013-09



ALCOHOL WIPES

alcohol wipes cloth

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:74658-013 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|-----------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 75 mL in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| TERT-BUTYL ALCOHOL (UNII: MD83SFE959) | |
| WATER (UNII: 059QF0KO0R) | |
| DENATONIUM BENZOATE ANHYDROUS (UNII: M5BA6GAF1O) | |

| Packaging | | | | |
|------------------|------------------|--|-----------------------------|---------------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:74658-013-01 | 1 in 1 BAG | 10/10/2020 | |
| 1 | | 4.3 mL in 1 PATCH; Type 0: Not a Combination Product | | |
| 2 | NDC:74658-013-02 | 75 in 1 BOTTLE | 10/10/2020 | |
| 2 | | 4.3 mL in 1 PATCH; Type 0: Not a Combination Product | | |
| 3 | NDC:74658-013-03 | 80 in 1 BOTTLE | 10/10/2020 | |
| 3 | | 4.3 mL in 1 PATCH; Type 0: Not a Combination Product | | |
| 4 | NDC:74658-013-04 | 100 in 1 BOTTLE | 10/10/2020 | |
| 4 | | 4.3 mL in 1 PATCH; Type 0: Not a Combination Product | | |
| 5 | NDC:74658-013-05 | 120 in 1 BOTTLE | 10/10/2020 | |
| 5 | | 4.3 mL in 1 PATCH; Type 0: Not a Combination Product | | |
| 6 | NDC:74658-013-06 | 130 in 1 BOTTLE | 10/10/2020 | |
| 6 | | 4.3 mL in 1 PATCH; Type 0: Not a Combination Product | | |
| 7 | NDC:74658-013-07 | 150 in 1 BOTTLE | 10/10/2020 | |
| 7 | | 4.3 mL in 1 PATCH; Type 0: Not a Combination Product | | |
| 8 | NDC:74658-013-08 | 180 in 1 BOTTLE | 10/10/2020 | |
| 8 | | 4.3 mL in 1 PATCH; Type 0: Not a Combination Product | | |
| 9 | NDC:74658-013-09 | 200 in 1 BOTTLE | 10/10/2020 | |
| 9 | | 4.3 mL in 1 PATCH; 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 | 10/10/2020 | |

Labeler - GUANGZHOU XUELEI COSMETIC CO.,LTD. (526885026)

Registrant - GUANGZHOU XUELEI COSMETIC CO.,LTD. (526885026)

| Establishment | | | |
|----------------------|----------------|---------------|----------------------------|
| Name | Address | ID/FEI | Business Operations |
| | | | |

GUANGZHOU XUELEI COSMETIC
CO.,LTD.

526885026

manufacture(74658-013) , label(74658-013) ,
pack(74658-013)

Revised: 11/2021

GUANGZHOU XUELEI COSMETIC CO.,LTD.