

**ANTIBACTERIAL WET WIPES- benzethonium chloride cloth**  
**YOYO LIP GLOSS, INC**

*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.*

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This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

**Active Ingredient(s)**

Alcohol 80% v/v. Purpose: Antiseptic

**Purpose**

Antiseptic, Hand Sanitizer

**Use**

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

**Warnings**

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

**Do not use**

- in children less than 2 months of age
- on open skin wounds

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.

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away.

## Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

## Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

## Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

## Package Label - Principal Display Panel

210mm

25mm

185mm

10mm

13mm

46mm

92mm

46mm

13mm

**WARNING!**  
TO AVOID DANGER OF SUFFOCATION, KEEP THIS PLASTIC BAG AWAY FROM BABIES AND CHILDREN. DO NOT USE THIS BAG IN CRIBS, BEDS, CARRIAGES OR PLAYPENS. THIS BAG IS NOT A TOY.

**AVERTISSEMENT!**  
AFIN D'ÉVITER LE DANGER D'ASPHYXIE, VEUILLEZ CONSERVER CE SAC EN PLASTIQUE À DISTANCE DES BÉBÉS ET DES ENFANTS. N'UTILISEZ PAS CE SAC DANS LES BERCEAUX, LES LITS, LES LANDAUS OU PARCS POUR BÉBÉS. CE SAC N'EST PAS UN JOUET.

**DIRECTIONS / CONSEILS:**  
PEEL BACK THE LABEL AND USE AS REQUIRED. RESEAL LABEL AFTER USE TO KEEP WIPES MOIST. ÉPILCHER L'ÉTIQUETTE ET UTILISER SELON LES BESOINS. REFERMER L'ÉTIQUETTE APRÈS UTILISATION POUR GARDER LES LINGETTES HUMIDES.

FABRIQUÉ POUR MANUFACTURED FOR  
YOYO LIP GLOSS, INC  
ASTORIA, NY 11103  
1-800-YOYO-LIP  
(1-800-969-6547)

**Word Party**

**ANTIBACTERIAL WET WIPES**  
**LINGETTES HUMIDES ANTIBACTÉRIENNES**  
FRAGRANCE FREE  
SANS PARFUM

Poids Net 16 Lingettes Net Wt. 16 Wipes

**Drug Facts**  
**Active Ingredients** Purpose  
Benzalkonium Chloride 0.1% Antibacterial  
Use decreases bacteria on skin

**Warnings**  
**For external use only**  
Do not use if you are allergic to any of the ingredients  
When using this product, do not get into eyes. If contact occurs, rinse thoroughly with water.  
Stop use and ask a doctor if irritation or rash develops and continues for more than 72 hours.  
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**  
**Adults and children 2 years & older:**  
• Apply to hands.  
• Allow to dry without wiping.  
**Children under 2 years:**  
• Ask a doctor before use.

**Inactive ingredients:**  
Aqua, Propylene Glycol, Glycerin, Phenoxyethanol, Polyaminopropyl Biguanide Sulfate, Hydroxypropylmethylolium Honey, Sodium Citrate

**Faits sur les drogues**  
**Objetif des ingrédients actifs** Purpose  
Chlorure de benzalkonium 0,1% Antibactérien  
L'utilisation diminue les bactéries sur la peau

**Avvertissements**  
**Pour usage externe uniquement**  
Ne pas utiliser si vous êtes allergique à l'un des ingrédients  
Lors de l'utilisation de ce produit, éviter tout contact avec les yeux. En cas de contact, rincer abondamment à l'eau.  
Cessez l'utilisation et demandez à un médecin si une irritation ou une éruption cutanée se développe et persiste pendant plus de 72 heures.  
Tenir hors de contact avec les enfants. En cas d'ingestion, consulter un médecin ou un centre antipoison immédiatement.

**Instructions**  
**Adultes et enfants de 2 ans et plus :**  
• Appliquer aux mains  
• Laisser sécher sans essuyer  
**Les enfants de moins de 2 ans :**  
• Consulter un médecin avant utilisation

**Ingrédients inactifs:**  
Aqua, Propylène Glycol, Glycérine, Phénoxyéthanol, Polyaminopropyl Biguanide Sulfate, Hydroxypropylmethylolium Honey, Sodium Citrate

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# ANTIBACTERIAL WET WIPES

benzethonium chloride cloth

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70611-005
Route of Administration	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZETHONIUM CHLORIDE (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP)	BENZETHONIUM CHLORIDE	0.1 g in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS TRISODIUM CITRATE (UNII: RS7A450LGA)	
POLYAMINOPROPYL BIGUANIDE (UNII: DT9D8Z79ET)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
HONEY (UNII: Y9H1V576FH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70611-005-01	16 in 1 POUCH	05/11/2020	
1		16 mL in 1 APPLICATOR; Type 0: Not a Combination Product		
2	NDC:70611-005-02	72 in 1 POUCH	03/30/2020	
2		72 mL in 1 APPLICATOR; 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	03/30/2020	

**Labeler** - YOYO LIP GLOSS, INC (828881792)

## Establishment

Name	Address	ID/FEI	Business Operations
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Revised: 5/2020

YOYO LIP GLOSS, INC