

**GENTLE BEAST ANTISEPTIC WIPES- isopropyl alcohol swab**  
**AJ 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.*

-----  
**AJ Co., Ltd. - Gentle Beast Antiseptic Wipes**

Isopropyl Alcohol

Butylene Glycol, Cetylpyridinium chloride, Citric Acid, Glycerin, Polysorbate 20, Sodium Benzoate, Water

Decrease bacteria on skin. For use when soap and water are not available.

keep out of reach of the children

- Discard after single use and do not flush in the toilet.
- Reseal back after use to avoid evaporation of alcohol
- Supervise children under 6 years of age when using this product to avoid swallowing.

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.

for external use only

## GENTLE BEAST ANTISEPTIC WIPES

isopropyl alcohol swab

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:75356-0008
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of	Strength
-----------------	----------	----------

Ingredient Name	Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CETYLPIRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
WATER (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75356-0008-1	337 g in 1 PACKET; Type 0: Not a Combination Product	03/01/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/01/2021	

**Labeler** - AJ Co., Ltd. (631079605)

**Registrant** - AJ Co., Ltd. (631079605)

### Establishment

Name	Address	ID/FEI	Business Operations
AJ Co., Ltd.		631079605	manufacture(75356-0008) , label(75356-0008) , pack(75356-0008)

Revised: 3/2021

AJ Co., Ltd.