

ANTIBACTERIAL WIPES- benzalkonium chloride cloth On The Spot Products, LLC

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.

Antibacterial Wipes

Active Ingredient(s)

Benzalkonium Chloride%. Purpose: Antibacterial

Purpose

Antibacterial

Use

Antibacterial wet wipes to help reduce bacteria on the skin.

Warnings

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

When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash appears and lasts.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

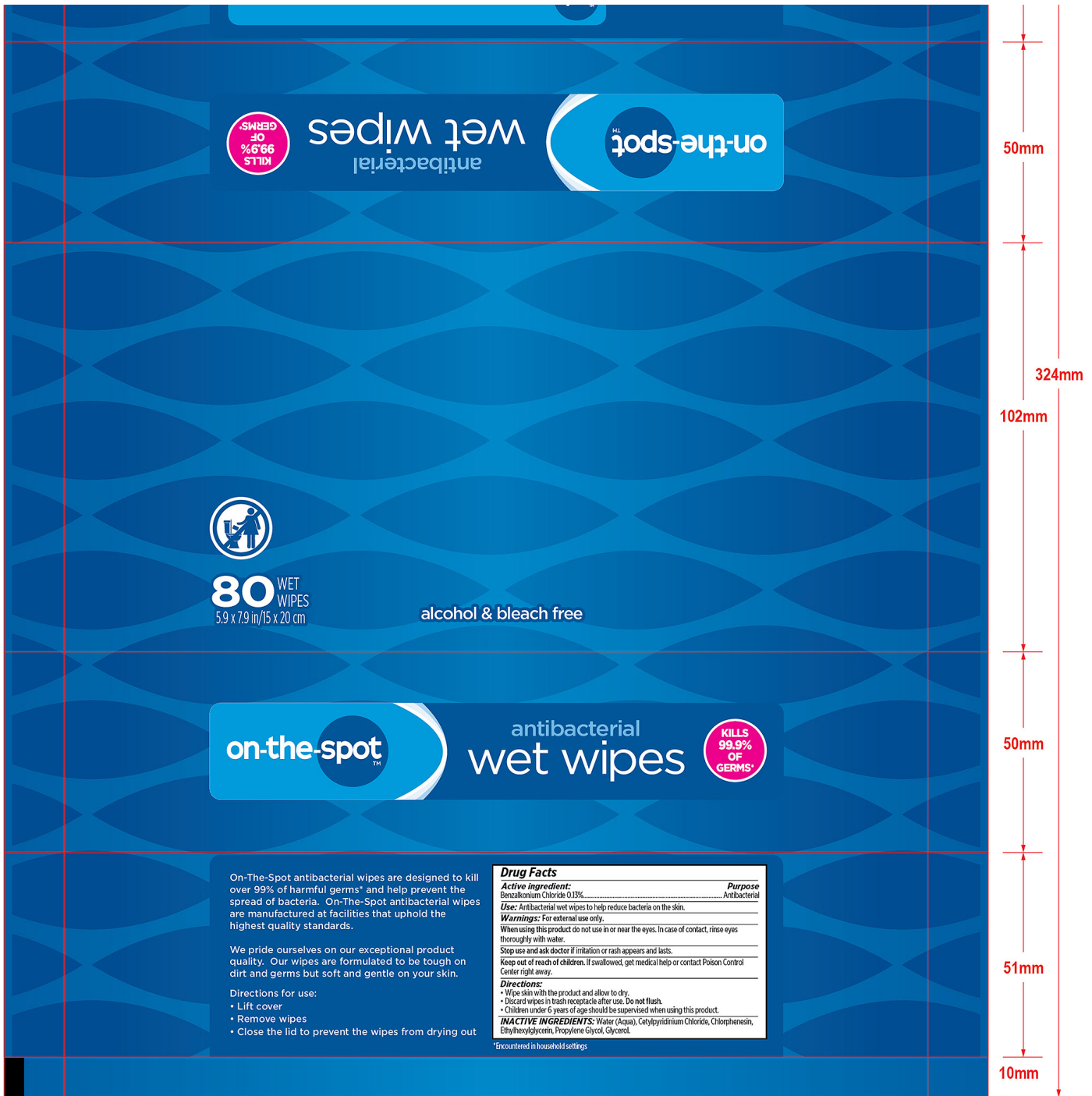
- Wipe skin with the product and allow to dry.
- Discard wipes in trash receptacle after use. Do not flush.
- Children under 6 years of age should be supervised when using this product.

Inactive ingredients

Package Label - Principal Display Panel

80 pcs label





ANTIBACTERIAL WIPES

benzalkonium chloride cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77490-013(NDC:52489-002)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	0.0002 mL in 1 mL
CHLORPHENESIN (UNII: I670DAL4SZ)	0.0002 mL in 1 mL
PROPYLENE GLYCOL, (S)- (UNII: 942194N4TD)	0.0002 mL in 1 mL
GLYCEROL FORMAL (UNII: 3L7GR2604E)	0.0002 mL in 1 mL
WATER (UNII: 059QF0K00R)	0.9941 mL in 1 mL
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	0.0002 mL in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77490-013-80	360 mL in 1 PACKAGE; Type 0: Not a Combination Product	05/27/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/27/2020	

Labeler - On The Spot Products, LLC (117497833)

Registrant - On The Spot Products, LLC (117497833)

Establishment

Name	Address	ID/FEI	Business Operations
On The Spot Products, LLC		117497833	relabel(77490-013)