## JUSTICE LETTER A BLUEBERRY SCENT ANTI-BACTERIAL HAND SANITIZERalcohol gel

Tween Brands, 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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## Justice Letter A Blueberry Scent Anti-bacterial Hand Sanitizer

## **Drug Facts**

## **Active Ingredient**

Alcohol 62%

## **Purpose**

Antiseptic

#### Use

- For hand washing to decrease bacteria on the skin.
- Recommended for repeated use.

## **Warnings**

Flammable, keep away from fire or flame.

For external use only. Do not use in the eyes or apply over large areas of the body.

In case of deep or puncture wounds, animal bites, or serious burns, consult a doctor.

Use only as directed. Do not drink. If taken internally, it will produce serious gastric disturbances

#### Stop use and ask a doctor if

irritation persists for more than 72 hours.

Supervise children in the use of this product.

#### Other Information

- Store beow  $105\,^{0}$ F ( $40.5\,^{0}$ C)
- May discolor some fabrics.

#### Keep out of reach of children.

If swallowed get medical help or contact a Poison Control Center right away.

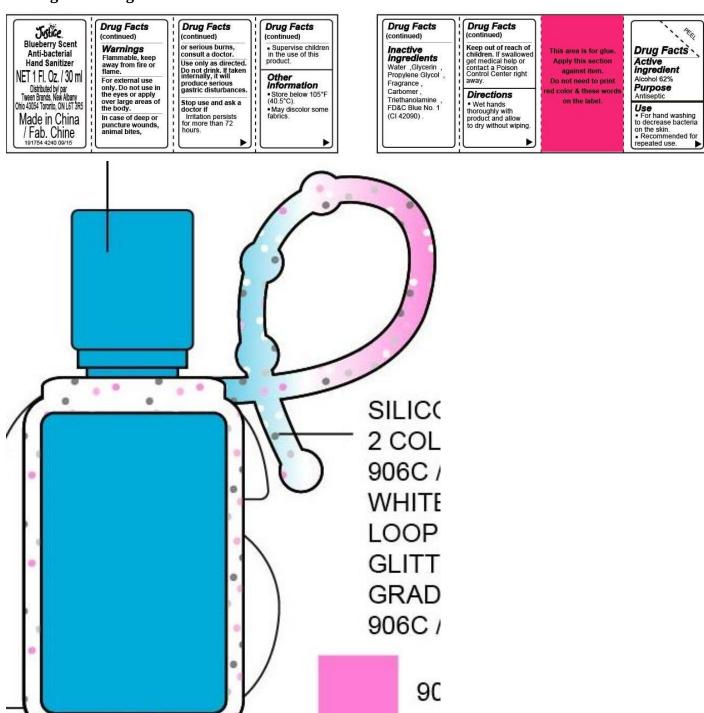
#### Directions

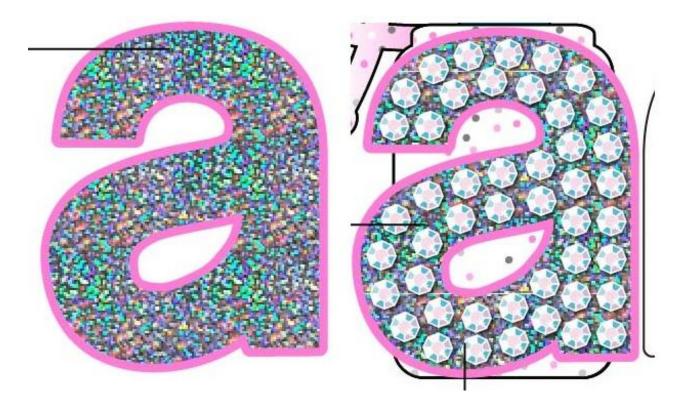
• Wet hands thoroughly with product and allow to dry without wiping.

#### **Inactive Ingredients**

Water, Glycerin, Propylene Glycol, Fragrance, Carbomer, Triethanolamine, FD&C Blue No. 1 (CI 42090)

# **Package Labeling:**





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alcohol gel

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60637-033		
Route of Administration	TOPICAL				

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	620 mg in 1 mL	

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
GLYCERIN (UNII: PDC6A3C0OX)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
TROLAMINE (UNII: 903K93S3TK)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			

P	Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date	
1	NDC:60637-033-30	1 in 1 CARTON	09/29/2015		
1		30 mL in 1 BOTTLE; 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	part333E	09/29/2015		

Labeler - Tween Brands, Inc. (965758188)

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