

**JUSTICE VANILLA SCENT ANTI-BACTERIAL HAND SANITIZER - ethyl alcohol liquid
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.

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.

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.

Other information

- Store below 105F(40.5C) ■ May discolor some fabrics

Inactive ingredients

Water, Glycerin, Propylene Glycol, Fragrance, Carbomer, Triethanolamine, FD&C Yellow No.5,FD&C Blue No.1

INSIDE

<p>Justice Vanilla Scent Anti-bacterial Hand Sanitizer NET 1 Fl. Oz. / 30 ml Distributed by/ par Tween Brands, New Albany Ohio 43054 Toronto, ON L6T 3R5 Made in China / Fab. Chine 191153 3604 03/15</p>	<p>Drug Facts (continued)</p> <p>Warnings Flammable, keep away from fire or flame.</p> <p>For external use only. Do not use in the eyes or apply over large areas of the body.</p> <p>In case of deep or puncture wounds, animal bites,</p>	<p>Drug Facts (continued)</p> <p>or serious burns, consult a doctor.</p> <p>Use only as directed. Do not drink. If taken internally, it will produce serious gastric disturbances.</p> <p>Stop use and ask a doctor if Irritation persists for more than 72 hours.</p>	<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> Supervise children in the use of this product. <p>Other information</p> <ul style="list-style-type: none"> Store below 105°F (40.5°C). May discolor some fabrics.
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OUTSIDE

<p>Drug Facts (continued)</p> <p>Inactive ingredients Water, Glycerin, Propylene Glycol, Fragrance, Carbomer, Triethanolamine, FD&C Yellow No. 5, FD&C Blue No. 1</p>	<p>Drug Facts (continued)</p> <p>Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <ul style="list-style-type: none"> Wet hands thoroughly with product and allow to dry without wiping. 	<p>This area is for glue. Apply this section against item. Do not need to print red color & these words on the label.</p>	<p>Drug Facts</p> <p>Active ingredient Alcohol 62%</p> <p>Purpose Antiseptic</p> <p>Use</p> <ul style="list-style-type: none"> For hand washing to decrease bacteria on the skin. Recommended for repeated use.
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ethyl alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60637-021
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TROLAMINE (UNII: 9O3K93S3TK)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60637-021-30	30 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	01/27/2015	

Labeler - Tween Brands Inc (965758188)

Revised: 1/2015

Tween Brands Inc