

HAND SANITIZER VANILLA SCENT- alcohol gel
Michaels Stores Procurement Company

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.

Hand Sanitizer Vanilla Scent

Active Ingredient

Ethyl 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. In case of contact with eyes, rinse thoroughly with water.
- 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.
- **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.
- Supervise children in the use of this product.

Other information

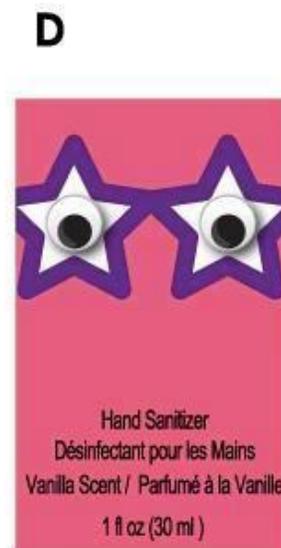
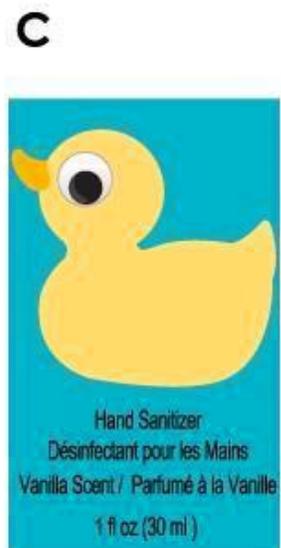
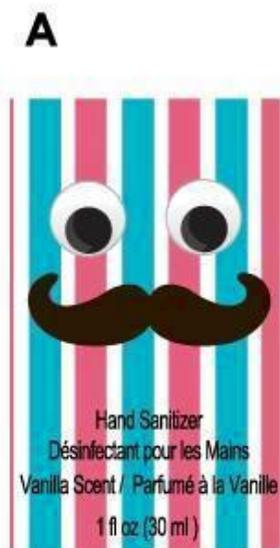
- Store below 105 degrees F (40.5 degrees C).
- May discolor some fabrics.

Inactive Ingredients

- carbomer, DandC red n 33, FDandC blue n 1, FDandC yellow n 5, fragrance, glycerin, propylene glycol, triethanolamine, water

Product Labeling

<p>Drug Facts (continued)</p> <p>Warnings Flammable, keep away from fire or flame.</p> <p>For external use only</p> <p>When using this product</p> <ul style="list-style-type: none"> Do not use in the eyes. In case of contact with eyes, rinse thoroughly with water. 	<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> Use only as directed. Do not drink. If taken internally, it will produce serious gastric disturbances. <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> Irritation persists for more than 72 hours. 	<p>Drug Facts (continued)</p> <p>Keep out of reach 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>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. 	<p>Drug Facts (continued)</p> <p>Inactive ingredients carbomer, D&C red. 33, FD&C blue. 1, FD&C yellow. 5, fragrance, glycerin, propylene glycol, triethanolamine, water</p>	<p style="text-align: right;">PEEL DECOLLER DESPEGAR</p> <p>Drug Facts</p> <p>Active ingredient Ethyl 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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Size: 2.5X4.2cm

HAND SANITIZER VANILLA SCENT

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60675-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60675-004-00	30 mL in 1 BOTTLE		
2	NDC:60675-004-01	30 mL in 1 BOTTLE		
3	NDC:60675-004-02	30 mL in 1 BOTTLE		
4	NDC:60675-004-03	30 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	09/24/2014	

Labeler - Michaels Stores Procurement Company (030791425)

Establishment

Name	Address	ID/FEI	Business Operations
Huizhou Yiyani Cosmetic Limited		421321809	manufacture(60675-004)

Revised: 9/2014

Michaels Stores Procurement Company