

BREATHE HAND SANITIZER GEL- alcohol gel
Blue Cross Laboratories, 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.

Breathe Hand Sanitizer Gel

Active Ingredient(s)

Ethyl alcohol 70% Purpose: Antiseptic

Purpose

Antiseptic

Use

- to decrease bacteria on the skin that could cause disease.
- recommended for repeated use

Warnings

For external use only- hands

Flammable. Keep away from heat or flame

When using this product keep out of eyes. In case of contact with eyes, flush thoroughly with water.

avoid contact with broken skin. do not inhale or ingest.

Stop use and ask a doctor if irritation develops

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.
- for children under 6 use only under supervision
- not recommended for infants

Other information

- do not store above 105 F
- may discolor some fabrics
- harmful to wood finishes and plastics

Inactive ingredients

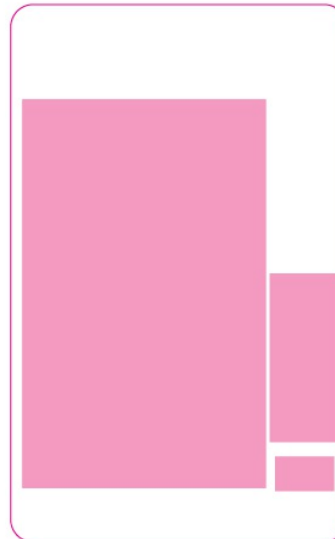
water, glycerin, fragrance, carbopol, triethanolamine

Package Label - Principal Display Panel

breathe Hand Sanitizer Gel

8 FL OZ (236 mL)

WHITE



ART #: **BLU 1089** DESIGNER: **KR** PLEASE NOTE: **BACK BLACK PLATE CHANGE**

CLIENT: **BLUE CROSS** DESCRIPTION: **SVO-US Toilet Fizzers 15CT** DATE: **OCTOBER 6, 2020** PROOF#: **1**

<p>LABEL SIZE: 3" X 1.875" DIE#: R002B COPY DIRECTION: </p>	<p>MATERIAL: CLEAR BOPP</p> <p>COATING: GLOSS LAM</p>	<p>COLOURS: ● WHITE ● BLACK ● PMS 186 ● PMS 281 ● PMS 305 (OPAQUE) ● PMS 298 (OPAQUE) <input type="checkbox"/> DIELINE (does not print)</p>	<p>THE CLIENT IS RESPONSIBLE FOR APPROVING;</p> <ol style="list-style-type: none"> ALL COPY LABEL DIMENSIONS COLOURS USED REWIND COPY DIRECTION LOCAL, PROVINCIAL OR NATIONAL REGULATIONS ASSOCIATED WITH THIS LABEL(S) 	<p>APPROVED AS IS: _____</p> <p>APPROVED WITH CHANGES INDICATED: _____</p> <p>RE-PROOF <input type="radio"/> DATE: _____</p>
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BREATHE HAND SANITIZER GEL

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:22431-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER HO M O P O L Y M E R, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
WATER (UNII: 059QF0K00R)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:22431-010-01	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/06/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/06/2020	

Labeler - Blue Cross Laboratories, Inc. (008298879)

Establishment

Name	Address	ID/FEI	Business Operations
Blue Cross Laboratories, Inc.		008298879	manufacture(22431-010)

Revised: 10/2020

Blue Cross Laboratories, Inc.