

**ANTISEPTIC HAND SANITIZER VERSACE- alcohol gel
V-SHAPES SRL**

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.

Antiseptic Hand sanitizer VERSACE

Drug Facts

Active ingredient

Ethyl alcohol 80%

Purpose

Antiseptic

Use

For hand washing to decrease bacteria on the skin

Warnings

For external use only

Flammable, keep away from fire or flame.

Do not use

in the eyes

Stop use and ask a doctor if

- irritation and redness develop
- condition 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

Inactive ingredients

Carbomer, imidazolidinyl urea, PEG-12 dimethicone, propylene chlorhexidine gluconate, triethanolamine, water.

Questions?

1-(888) 408-1694

Package Labeling:

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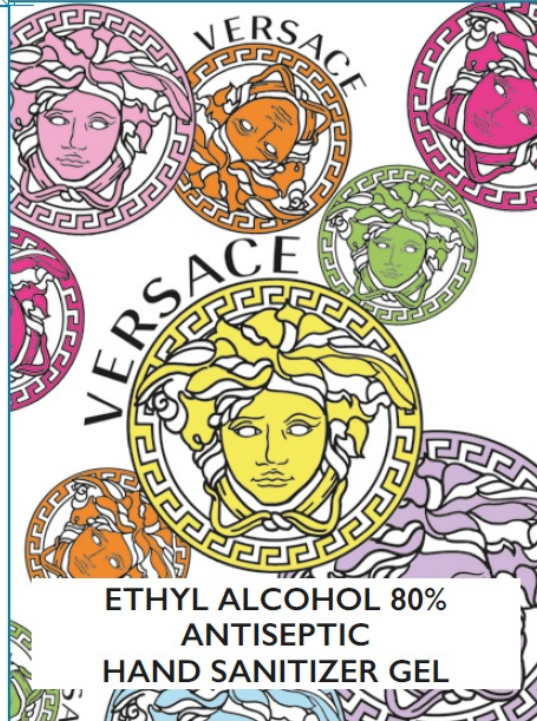
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Questions? 1-(888) 408-1694

THIS UNIT NOT LABELED FOR RETAIL SALE
MANUFACTURED FOR V-SHAPES S.R.L
VIA PERSICETANA, 20B - 40012
CALDERARA DI RENO (BO) - ITALY MADE IN USA

DISTRIBUTED BY: EUROITALIA USA INC 595 MADISON AVENUE - NEW YORK, N.Y.

VERSACE



ETHYL ALCOHOL 80%
ANTISEPTIC
HAND SANITIZER GEL

5 - 0.1 fl oz (3 mL) Packs
Net 0.5 l fl oz (15 mL)

REF. 793564US





ANTISEPTIC HAND SANITIZER

**ACTIVE INGREDIENT:
ETHYL ALCOHOL 80%**

WARNINGS

FOR EXTERNAL USE ONLY.

FLAMMABLE, KEEP AWAY FROM FIRE OR FLAME.

DO NOT USE IN THE EYES.

STOP USE AND ASK A DOCTOR IF:

1. IRRITATION AND REDNESS DEVELOP
2. CONDITION 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.

TO REPORT A SERIOUS ADVERSE EVENT, CONTACT

+1 (888) 408-1694

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L:

ANTISEPTIC HAND SANITIZER VERSACE

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74785-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.8 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
IMIDUREA (UNII: M629807ATL)	
PEG-12 DIMETHICONE (300 CST) (UNII: ZEL54N6W95)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74785-003-00	5 in 1 BOX	07/01/2020	
1		3 mL in 1 PACKAGE; 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	07/01/2020	

Labeler - V-SHAPES SRL (438846579)**Establishment**

Name	Address	ID/FEI	Business Operations
Orlandi Inc.		079801467	pack(74785-003) , label(74785-003)

Establishment

Name	Address	ID/FEI	Business Operations
Accurate Labs, LLC		113427259	manufacture(74785-003)

Revised: 7/2020

V-SHAPES SRL