ANTISEPTIC HAND SANITIZER MISSONI- 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 MISSONI

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:

Drug Facts

Active ingredient

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

Ethyl alcohol 80% ...

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

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**

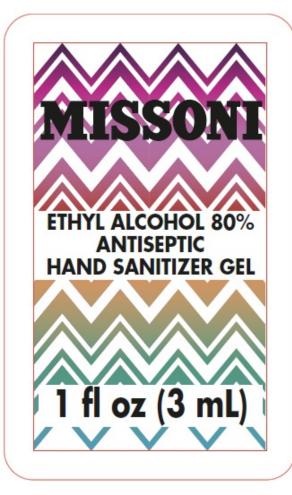
ETHYL ALCOHOL 80% ANTISEPTIC HAND SANITIZER GEL

5 – 0.1 fl oz (3 mL) Packs Net 0.51 fl oz (15 mL)





REF. 893564US



ANTISEPTIC HAND SANITIZER
ACTIVE INGREDIENT:
ETHYL ALCOHOL 80%
WARNINGS
FOR EXTERNAL LISE ONLY

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

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.

ON DE

BEST BEFORE

L:

ANTISEPTIC HAND SANITIZER MISSONI

alcohol gel

_	-			•
п	 4	+	Into	rmation
М				FILL 2 1 (1) 1

Product Type HUMAN OTC DRUG Item Code (Source) NDC:74785-001

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 HO MO POLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC) IMIDUREA (UNII: M629807ATL) PEG-12 DIMETHICONE (300 CST) (UNII: ZEL54N6W95) TROLAMINE (UNII: 903K93S3TK) WATER (UNII: 059QF0K00R)

Packaging						
# Item Code	Package Description	Marketing Start Date	Marketing End Date			
1 NDC:74785-001-00	5 in 1 BOX	07/01/2020				
1	3 mL in 1 PACKAGE; Type 0: Not a Combination Product					
Marketing Information						
Marketing Catego	ry Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph not fin	nal part333E	07/01/2020				

Labeler - V-SHAPES SRL (438846579)

Establishment						
Name	Address	ID/FEI	Business Operations			
Orlandi Inc.		079801467	pack(74785-001), label(74785-001)			

Establishment						
Name	Address	ID/FEI	Business Operations			
Accurate Labs, LLC		113427259	manufacture (74785-001)			

Revised: 7/2020 V-SHAPES SRL