UNITED SPIRIT OF AMERICA HAND SANITIZER- ethyl alcohol gel
Prime Enterprises

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.

Warrior Waterless Anti-Bacterial Hand Sanitizer

Active Ingredient

Ethyl Alcohol 70% v/v

Purpose

Antiseptic

Use

For hand washing, to decrease bacteria on the skin.

Warnings

For external use only.

Flammable: Do not while smoking or near heat of flame

When using this product avoid contact with eyes. If product gets into eyes, rinse with water to remove. Avoid contact with broken skin. Do not inhale or ingest.

Stop use and ask a doctor if rash or irritation develops and lasts.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

- Wet hands thoroughly with product and allow drying without wiping.
- Use only under adult supervision for children under 6
- Not recommended for infants

Other information

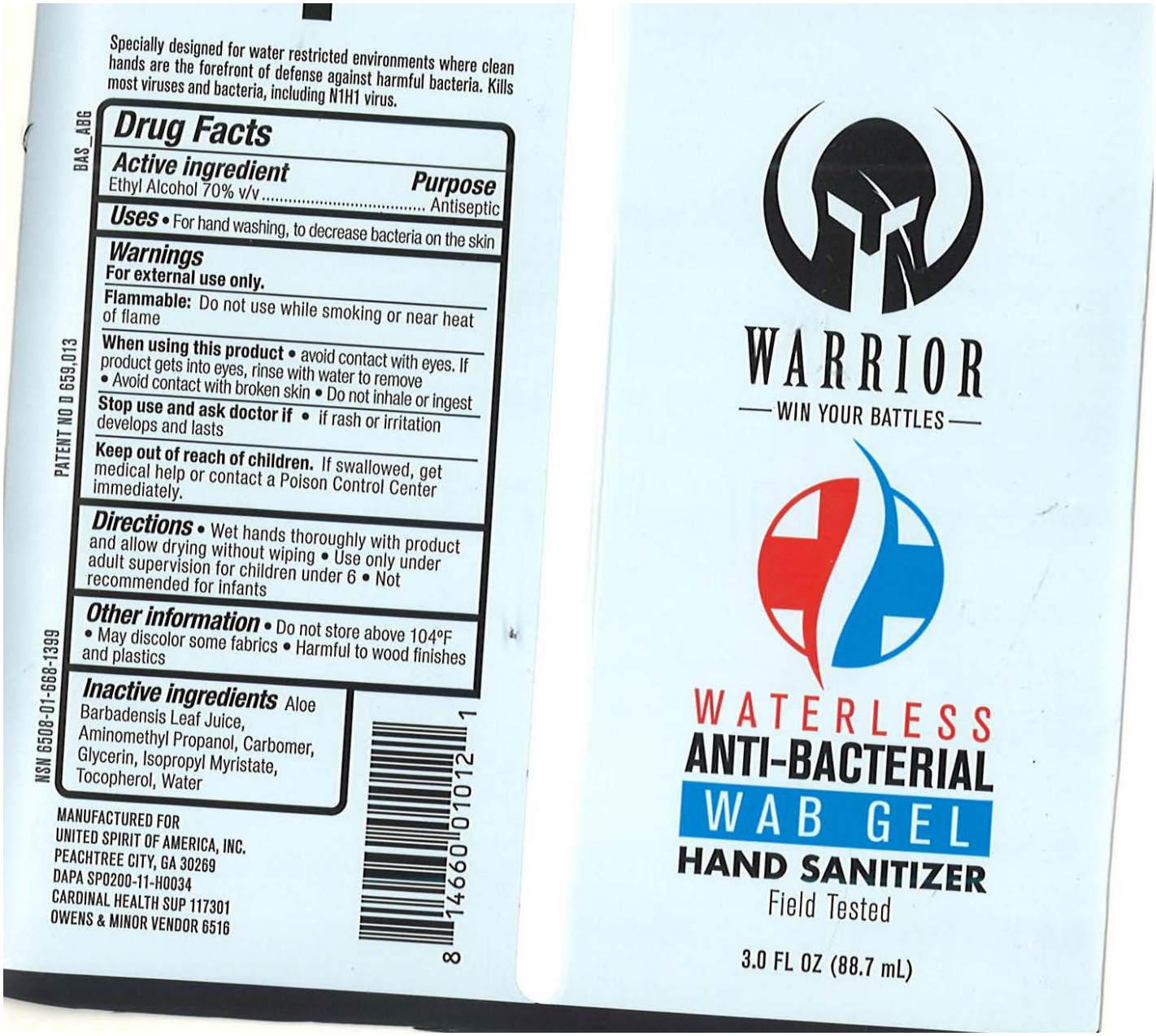
- Do not store above 104 F.
- May discolor some fabrics

- Harmful to wood finishes and plastics

Inactive ingredients

Aloe Barbadensis Leaf Juice, Aminomethyl Propanol, Carbomer, Glycerin, Isopropyl Myristate, Tocopherol, Water

Warrior Waterless Anti-Bacterial Hand Sanitizer



UNITED SPIRIT OF AMERICA HAND SANITIZER

ethyl alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58443-0523

Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	606.2 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
TOCOPHEROL (UNII: R0ZB2556P8)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
CARBOMER 934 (UNII: Z135WT9208)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	

Product Characteristics

Color	white (clear)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0523-3	88.7 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/13/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/13/2019	

Labeler - Prime Enterprises (101946028)

Registrant - Prime Enterprises (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises		101946028	manufacture(58443-0523) , analysis(58443-0523) , label(58443-0523) , pack(58443-0523)