## ZONE DEFENSE HAND SANITIZER- alcohol liquid Baer Enterprises, LLC

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.

-----

- a. Alcohol (ethanol) (80%, volume/volume (v/v)
- b. Glycol (4% v/v)
- c. Fragrance
- d. Sterile distilled water or boiled cold water.

#### **Active Ingredient(s)**

Alcohol 80% v/v. Purpose: Antiseptic

#### **Purpose**

Antiseptic, Hand Sanitizer

#### Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

#### Warnings

For external use only. Flammable. Keep away from heat or flame

#### Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

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

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

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

#### **Directions**

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

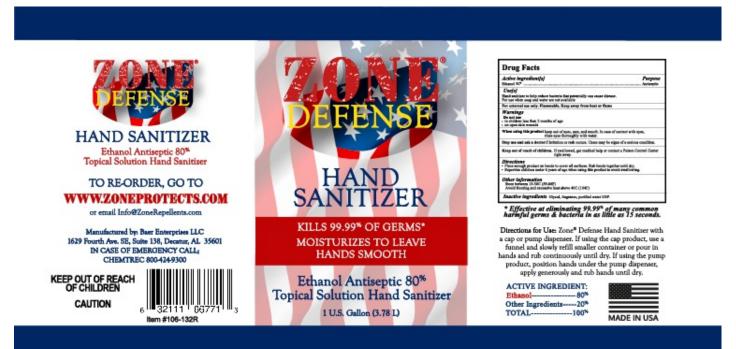
#### Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

#### **Inactive ingredients**

glycol, fragrance, purified water USP

#### Package Label - Principal Display Panel



3780 mL NDC: 73829-106-32

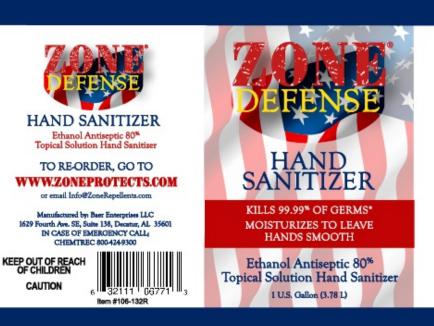
#### **ZONE DEFENSE HAND SANITIZER**

alcohol liquid				
<b>Product Information</b>				
Product Type	HUMAN OTC DRUG	Item	Code (Source)	NDC:73829-106
Route of Administration	TOPICAL			
Active Ingredient/Active	Mojety			
Active Ingredient/Active Moiety				
Ingredient Name			<b>Basis of Strength</b>	Strength
ALCOHOL (UNII: 3K9958V90M) (ALC	COHOL - UNII:3K9958V90M)		ALCOHOL	3024 mL in 3780 mL

Inactive Ingredients				
Ingredient Name	Strength			
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	151.2 mL in 3780 mL			
O-ETHYLVANILLIN (UNII: HB4H48MKNI)	2.268 mL in 3780 mL			
WATER (UNII: 059QF0KO0R)				

Product Characteristics			
Color	Score		
Shape	Size		
Flavor	Imprint Code		
Contains			

ı	Packaging				
	# Item Co	le Package Description	Marketing Start Date	Marketing End Date	
	1 NDC:73829 106-32	3780 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020		





\* Effective at eliminating 99.99% of many common harmful germs & bacteria in as little as 15 seconds.

Directions for Use: Zone® Defense Hand Sanitiser with a cap or pump dispenser. If using the cap product, use a funnel and slowly refill smaller container or pour in hands and rub concinuously until dry. If using the pump product, position bands under the pump dispenser, apply generously and rub hands until dry.

ACTIVE INGREDIENT:
Ethanol 80<sup>N</sup>
Other Ingredients 20<sup>N</sup>
TOTAL 100<sup>N</sup>



# Marketing InformationMarketing CategoryApplication Number or Monograph CitationMarketing Start DateMarketing End DateOTC monograph not finalpart333A03/30/2020

### Registrant - Baer Enterprises, LLC (189728590)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Baer Enterprises, LLC		189728590	manufacture(73829-106)	

Revised: 1/2022 Baer Enterprises, LLC