INSANITIZE- hand sanitizer liquid
JOKER AG

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.

InSanitize

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
b. Water
c. Carbomer Homopolymer
d. Glycerin
e. Aloe Vera Leaf
f. Propylene Glycol
g. Tert-butyl alcohol
h. Denatonium benzoate
i. Triisopropanolamine
j. 3,5,5-TRIMETHYLHEXANAL

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Alcohol 72% 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)

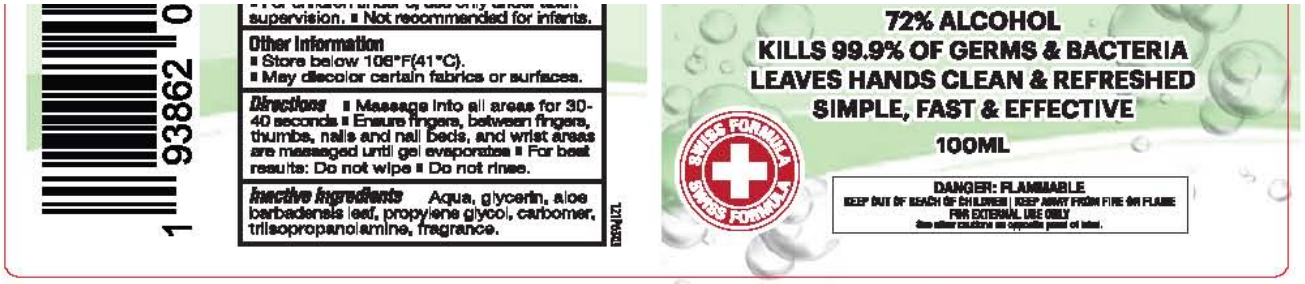
Inactive ingredients

Water
Carbomer Homopolymer
Glycerin
Aloe Vera Leaf
Propylene Glycol
Tert-butyl alcohol
Denatonium benzoate
Triisopropanolamine
3,5,5-TRIMETHYLHEXANAL

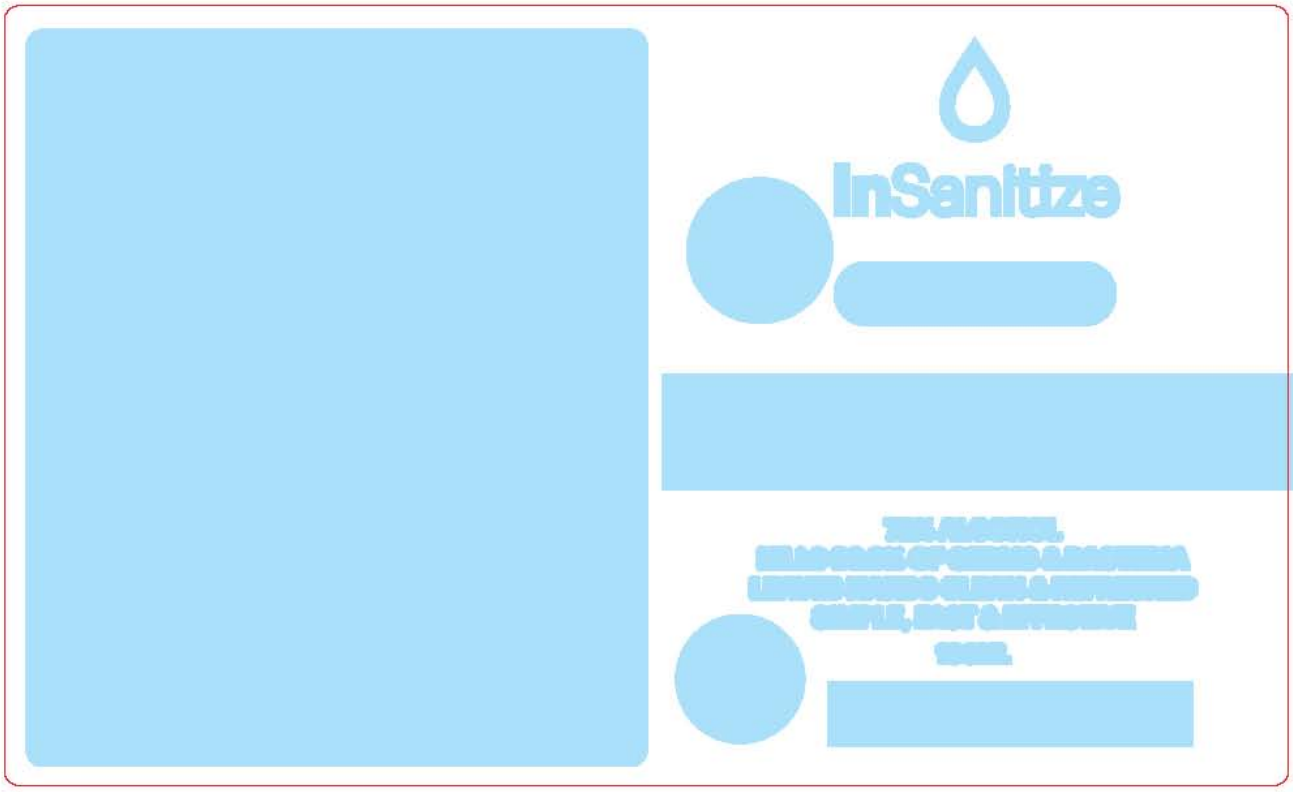
Package Label - Principal Display Panel

InSanitize Power Gel_Liquid Sanitizer 100ml
Label: 125 x 76 mm
Rev: 3 (May 20, 2020)

CMYK



Spot Opaque White



Opaque white base

INSANITIZE

hand sanitizer liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:75757-301
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	72 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	
3,5,5-TRIMETHYLHEXANAL (UNII: U62H30BXPJ)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)	
TRIISOPROPANOLAMINE (UNII: W9EN9DLM98)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75757-301-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:75757-301-02	43 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:75757-301-03	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:75757-301-04	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
5	NDC:75757-301-05	220 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
6	NDC:75757-301-06	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
7	NDC:75757-301-07	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
8	NDC:75757-301-08	995 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
9	NDC:75757-301-09	1890 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
10	NDC:75757-301-10	2000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
11	NDC:75757-301-11	5000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
12	NDC:75757-301-12	10000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
13	NDC:75757-301-13	15000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - JOKER AG (480850932)

Establishment

Name	Address	ID/FEI	Business Operations
Guangzhou Berfly Cosmetic Co., Ltd		553098664	manufacture(75757-301)