FROSTED BERRIES AND CREAM SANITIZER PEN - alcohol liquid Zhejiang Blue Dream Cosmetics Co., Ltd.

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.

DRUG FACT

Active Ingredient Ethyl Alcohol 62%

Purpose Antiseptic

Uses:

To decrease bacteria on skin that could cause disease

Recommended for repeated use

Warnings:

For external use only

Flammable. Keep away from heat and flame.

When using this product

- Keep out of eyes. In case of contact with eyes, flush thoroughly with water
- Avoid contact with broken skin
- Do not inhale or ingest

Stop use and ask a doctor if skin irritation develops

Keep out of reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

Directions:

- Wet hands thoroughly with product and allow to dry without wiping
- For children under 6, use only under adult supervision.
- Not recommended for infants

Other Information

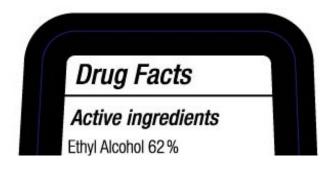
- Do not store above 105F
- May discolor some fabrics
- Harmful to wood finishes and plastics

Inactive Ingredients:

Water, Glycerin, Triethanolamine, Carbomer, Fragrance, PEG-40 Hydrogenated Castor Oil, DMDM Hydantoin, Hydrogenated Jojoba Oil, FDA and C Blue No. 1, FD and C Red No. 40, FD and C Yellow No. 5



label



Purpose

Antiseptic

Uses

- To decrease bacteria on the skin that could cause disease.
- Recommended for repeated use.

Warnings

For external use only.

Flammable. Keep away from heat and flame.

When using this product • Keep out of eyes. In case of contact with eyes, flush thoroughly with water. • Avoid contact with broken skin. • Do not inhale or ingest.

Stop use and ask a doctor if skin irritation develops.

Keep out of reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

Directions

- Wet hands thoroughly with product and allow to dry without wiping.
- For childeren under 6, use only under adult supervision.
- Not recommended for infants.

Other information

- Do not store above 105°F.
- May discolor some fabrics.
- Harmful to wood finishes and plastics.

Inactive ingredients

Ingredients / Ingrédients: Water (Aqua), Glycerin, Triethanolamine, Carbomer, Fragrance (Parfum), PEG-40 Hydrogenated Castor Oil, DMDM Hydatoin, Hydrogenated Joboja Oil, FD&C Red No.40, FD&C Yellow 5, FD&C Blue No.1

Formulated Exclusively and Distributed By:
Enchanté Accessories, Inc.,
New York, NY 10016
Not Tested On Animals. For Adult Use Only.
Designed in the USA. Made in China.

3FL.OZ/90ML

FROSTED BERRIES AND CREAM SANITIZER PEN

alcohol liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:34460-6005

Route of Administration TOPICAL

Active Ingredient/Active Moiety

,		
Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 g in 100 g

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)	35.16 g in 100 g	
GLYCERIN (UNII: PDC6A3C0OX)	2.0 g in 100 g	
TROLAMINE (UNII: 9O3K93S3TK)	0.2 g in 100 g	
CARBOMER HOMOPOLYMER TYPE A (UNII: F68 VH75CJC)	0.2 g in 100 g	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	0.1 g in 100 g	
DMDM HYDANTO IN (UNII: BYR0546 TOW)	0.2 g in 100 g	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	0.003 g in 100 g	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	0.002 g in 100 g	
FD&C RED NO. 40 (UNII: WZB9127XOA)	0.005 g in 100 g	

Ш	Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
П	1 NDC:34460-6005-1	10 g in 1 BOTTLE			
ľ	2 NDC:34460-6005-2	90 g in 1 BOTTLE			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333	08/07/2010		

Labeler - Zhejiang Blue Dream Cosmetics Co., Ltd. (529047234)

$\pmb{Registrant - \text{ Zhejiang Blue Dream Cosmetics Co., Ltd. (529047234)}}$

Establishment			
Name	Address	ID/FEI	Business Operations
Zhejiang Blue Dream Cosmetics Co., Ltd.		529047234	manufacture

Zhejiang Blue Dream Cosmetics Co., Ltd.

Revised: 7/2010