

HAND SANITIZER BIRTHDAY CAKE- alcohol gel
JFL ENTERPRISES, INC

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.

ANTIBACTERIAL HAND GEL Dippin Dots Birthday Cake

Active ingredient

Alcohol 62%

Purpose

Antiseptic Hand Sanitizer

Use

Decrease bacteria on hands

Warnings

External Use Only. DO NOT EAT.

Keep out of reach of children

if swallowed get medical help or contact a Poison Control Center right away.

Flammable: Keep away from flame or high heat

Directions

Rub hands thoroughly with product and allow to dry.

Inactive Ingredient

Carbomer, Glycerin, Jojoba Particles, Chocolate & Cream Extract, Pigment Red GB106-30-40, Blue 318C Propylene Glycol, Triethanolamine, Water.

Stop and Ask a doctor if

Irritation or redness develop.

HAND SANITIZER (ALCOHOL) GEL

DO NOT EAT**Drug Facts**

Active Ingredient	Purpose
Ethyl Alcohol 62%.....	Antiseptic

Use Decreases bacteria on hands**Warnings** For external use only, **DO NOT EAT.**

<p>■ Flammable: Keep away from flame or high heat</p>
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When using this product keep out of eyes. In case of contact flush eyes with water.**Stop and ask a doctor** if irritation or redness develop.**Keep out of reach of Children.** If swallowed get medical help or contact a Poison Control Center right away.**Directions:** Rub hands thoroughly with product and allow to dry.Dippin' Dots® is used under license to
JFL Enterprises, Inc.PEEL UP
TO SEE
ADDITIONAL
DRUG
FACTS**Exp:****Inactive Ingredients:**

Water: 27.35%, Glycerin: 3.5%,
Propylene Glycol: 3%, Carbomer: 2.5%,
Triethanolamine: 0.5%,
Chocolate & Cream Extract: 0.5%,
Jojoba Particles: 0.6%,
Pigment: GB106-3040 red,
318C blue: 0.05%

NOT TESTED ON ANIMALS**DO NOT EAT**

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Made in China

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HAND SANITIZER BIRTHDAY CAKE

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71246-4013
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER HOMO POLYMER TYPE B (ALLYL SUCROSE CROSSLINKED) (UNII: Z135WT9208)	
TRIETHANOLAMINE 2-CYCLOHEXYL-4,6-DINITROPHENOLATE (UNII: N2TK31JIAH)	

PIGMENT RED 1 (UNII: D54Q24K2EI)	
JOJOBA ACID (UNII: MO7HV04S9Y)	
PIGMENT BLUE 1 (UNII: 4SBE571RQF)	
CHOCOLATE BROWN HT FREE ACID (UNII: RH77QMZ6Y1)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71246-4013-1	40 mL in 1 POUCH; Type 0: Not a Combination Product	02/02/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part333A	02/01/2017	

Labeler - JFL ENTERPRISES, INC (010967011)

Establishment

Name	Address	ID/FEI	Business Operations
NingBo Huize Commodity Co.,Ltd.		544434795	manufacture(71246-4013)

Revised: 1/2018

JFL ENTERPRISES, INC