## ALCOHOL- alcohol spray Hello Bello

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.

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#### **DRUG FACTS**

## **ACTIVE INGREDIENT(S)**

Alcohol 80% v/v.

#### **PURPOSE**

Antiseptic

## USE(S):

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 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:**

glycerin, hydrogen peroxide, purified water USP

## Principal Display Panel - 59 mL Bottle Label

**Non-sterile Solution** 

hello bello™

Alcohol Antiseptic 80 Topical Solution

Hand Sanitizer Spray

2 fl. oz. (59 ml) e



Principal Display Panel - 59 mL Bottle Label

hello bello™

Apple Blossom

## Hand Sanitizer Spray

2.0 fl. oz. (59 ml) e



## **ALCOHOL**

alcohol spray

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73418-042
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	Strength		
Alcohol (UNII: 3K9958V90M) (Alcohol - UNII:3K9958V90M)	Alcohol	80 mL in 100 mL		

Inactive Ingredients			
Ingredient Name	Strength		
Glycerin (UNII: PDC6A3C0OX)			
Hydrogen Peroxide (UNII: BBX060AN9V)			

Water (UNII: 059QF0KO0R)

ı	P	ackaging			
	#	Item Code Package Description		Marketing Start Date	Marketing End Date
l	1	NDC:73418-042- 01	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	04/01/2020		

## **ALCOHOL**

alcohol spray

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73418-043	
Doube of Administration	TORICAL			

l	Active Ingredient/Active Moiety		
l	Ingredient Name	Basis of Strength	Strength
l	Alcohol (UNII: 3K9958V90M) (Alcohol - UNII:3K9958V90M)	Alcohol	62.5 mL in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
Water (UNII: 059QF0KO0R)		
Glycerin (UNII: PDC6A3C0OX)		
Polysorbate 20 (UNII: 7T1F30V5YH)		
Panthenol (UNII: W9CM0O67Z)		
Allantoin (UNII: 344S277G0Z)		
Avocado (UNII: SDS87L369F)		
Calendula Officinalis Flower (UNII: P0M7O4Y7YD)		
Cucumber (UNII: YY7C30VXJT)		

Pa	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:73418-043- 01	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2020	

Marketing Ir	nformation		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	02/01/2020	

# Labeler - Hello Bello (081135707)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Unconditional Love		081135707	MANUFACTURE(73418-042, 73418-043)

Revised: 2/2021 Hello Bello