

## **LITTLE ONES BABY FRESH SANITIZER- ethyl alcohol liquid**

**Kmart Corporation**

*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**

Ethyl Alcohol 65%

#### **Purpose**

Antiseptic

#### **Uses**

to help decrease bacteria on the skin.

#### **Warnings**

For external use only.

- Flammable
- Keep away from source of heat or fire.

#### **When using this product**

avoid contact with eyes. If contact occurs, rinse thoroughly with water.

Stop use and ask a doctor if irritation or redness develops and lasts.

*Keep out of reach of children.*

In case of accidental ingestion, get medical help or contact a Poison Control Center immediately. 1-800-222-1222

#### **Directions**

- put enough product in your palm to cover hands and rub hands together until dry
- children under 6 years should be supervised when using this product.

#### **Other information**

- store at a temperature below 110°F (43°C)
- may discolor certain fabrics or surfaces

#### **Inactive ingredients**

Water (Aqua), Fragrance (Parfum), Carbomer, Aminomethyl Propanol, Tocopheryl Acetate, Isopropyl Alcohol, Isopropyl Myristate, Aloe Barbadosensis Leaf Juice, Glycerin, Red 33 (CI 17200).

#### **Questions or comments?**

1-800-842-7886

**Label Copy**



**LITTLE ONES BABY FRESH SANITIZER**

ethyl alcohol liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49738-413
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	650 mg in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBOMER 934 (UNII: Z135WT9208)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

glycerin (UNII: PDC6A3C0OX)

D&C RED NO. 33 (UNII: 9DBA0SBB0L)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49738-413-03	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/22/2017	
2	NDC:49738-413-07	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/22/2017	
3	NDC:49738-413-33	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/22/2017	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/22/2017	

**Labeler** - Kmart Corporation (008965873)

**Registrant** - Apollo Health and Beauty Care Inc. (201901209)

### Establishment

Name	Address	ID/FEI	Business Operations
Apollo Health and Beauty Care Inc.		201901209	manufacture(49738-413)

Revised: 5/2017

Kmart Corporation