#### **BOOGIE BOTTOMS- dimethicone and zinc oxide spray Nehemiah Manufacturing Company LLC**

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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#### **Boogie Bottoms**<sup>TM</sup>

#### Drug Facts

Active ingredients	Purpose
Zinc Oxide 25%	Skin Protectant
Dimethicone 20%	Skin Protectant

#### Uses

- Helps treat and prevent diaper rash
- Protects chafed skin due to diaper rash and helps seal out wetness.

#### Warnings

- For external use only.
- When using this product do not get into eyes. If contact occurs, rinse eyes thoroughly with water.
- **Stop use and ask doctor if** condition worsens or symptoms last more than 7 days or clear up and occur again within a few days.

### • Keep out of reach of children.

- Lock when not in use.
- If swallowed, get medical help or contact a poison control center immediately.

#### Directions

- Change wet and soiled diapers promptly.
- Cleanse diaper area and allow to dry.
- Shake bottle well before use. Unlock to spray.
- Re-lock when not in use.
- Spray 4-6 inches from skin. No rub-in is required.
- Apply liberally as often as necessary, with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged.

### **Other Information**

Store at 59° F - 87° F

#### **Inactive ingredients**

Cyclomethicone, Hexamethyldisiloxane, Lanolin, Light Mineral Oil, Microcrystalline Wax, Vitamin A Palmitate, Vitamin D3, White Petrolatum

#### Questions?

1.877.469.8877 - MADE IN USA

Distributed by Nehemiah Manufacturing Co, 1907 South St, Cincinnati, OH U.S.A. 45204

#### **PRINCIPAL DISPLAY PANEL - 49 ML Bottle Label**

**NEW!** NDC 75957-003-01

#### Boogie BOTTOMS<sup>TM</sup>

No-Rub **Diaper Rash Spray** Skin Protectant

#### SHAKE WELL

Treats & Prevents diaper rash

Spray-on application

Fast & Easy to use

25% Zinc Oxide

Free from: fragrances • dyes • parabens

NET 1.7 FL OZ (49ML)



### **BOOGIE BOTTOMS**

<b>BOOGIE BOT</b> ' limethicone and zinc							
	onde oprag						
Product Informat	ion						
Product Type		HUMAN OTC DRUG	Ite m Co	Item Code (Source)		NDC:75957-003	
Route of Administra	tion	TOPICAL					
Active Ingredient	Active Moi	ety					
-	Ingre	dient Name		Ва	asis of Streng	th S	trength
Dimethicone (UNII: 92	RU3N3Y1O) (Dir	nethicone - UNII:92RU3N3Y	/10)	Dime	ethic one	200 m	g in 1 mL
Zinc Oxide (UNII: SOIZ	2LOH54Z) (Zinc	Oxide - UNII:SOI2LOH54Z)		Zinc	Oxide	200 m	g in 1 mL
Inactive Ingredie	nts	Ingredient Name				Str	ength
CYCLOMETHICONE (	UNII: NMQ3479	94Z)					
HEXAMETHYLDISILO	XANE (UNII: D7	'M4659BPU)					
LANOLIN (UNII: 7EV65EAW6H)							
MINERAL OIL (UNII: T	5L8T28FGP)						
MICROCRYSTALLINI	E WAX (UNII: XO	DF597Q3KY)					
PETROLATUM (UNII:							
VITAMIN A PALMITA							
CHOLECALCIFEROL							
ALPHATOCOPHER		QWA1RIO01)					
CORN OIL (UNII: 8470	G5/WFM)						
Product Characte	ristics						
Color	٢	WHITE	Score				
Shape			Size				
Flavor		J	Imprint Code				
Contains							
Packaging							
# Item Code		Package Description			ng Start Date	Marketin	g End Da
1 NDC:75957-003-01	49 mL in 1 BOT	TLE; Type 0: Not a Combin	ation Product	06/01/201	.8		

#	f Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75957-003-01	49 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2018	
2	NDC:75957-003-02	3 in 1 CELLO PACK	06/01/2018	
2	NDC:75957-003-01	49 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:75957-003-03	4 in 1 CELLO PACK	06/01/2018	
3	NDC:75957-003-01	49 mL in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:75957-003-04	1 in 1 BOX	06/01/2018	
4	NDC:75957-003-01	49 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC MONOGRAPH FINAL	part347	06/01/2018			

# Labeler - Nehemiah Manufacturing Company LLC (831701466)

## Establishment

Name	Address	ID/FEI	Business Operations
Trividia Manufacturing Solutions, Inc.		018927392	MANUFACTURE(75957-003), LABEL(75957-003), PACK(75957-003)

Revised: 3/2019

Nehemiah Manufacturing Company LLC