

**VITABATH BABY ECZEMA CARE MOISTURE- colloidal oatmeal cream**  
**Vitabath, 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.*

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**Vitabath Baby Eczema Care Moisture Cream**

**Active Ingredients**

Colloidal Oatmeal 1% w/w

**Purpose**

Skin protectant

**Uses**

Temporarily protects and helps relieve minor skin irritation and itching due to •Eczema •Rashes

**Warnings**

**For external use only.**

When using this product

- Avoid contact with eyes

**When using this product** do not get into eyes.

**Stop use and ask a doctor if**

- CONDITIONS WORSENS
- SYMPTOMS LAST MORE THAN 7 DAYS OR CLEAR UP AND OCCUR AGAIN WITHIN A FEW DAYS.

**KEEP OUT OF REACH OF CHILDREN.** If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

Apply as needed.

**OTHER INFORMATION:**

•Remove quality seal •Do not use if quality seal is broken •For use on mild to moderate eczema or as directed by a physician •Store at room temperature

**Inactive Ingredients**

Purified water

Glycerin

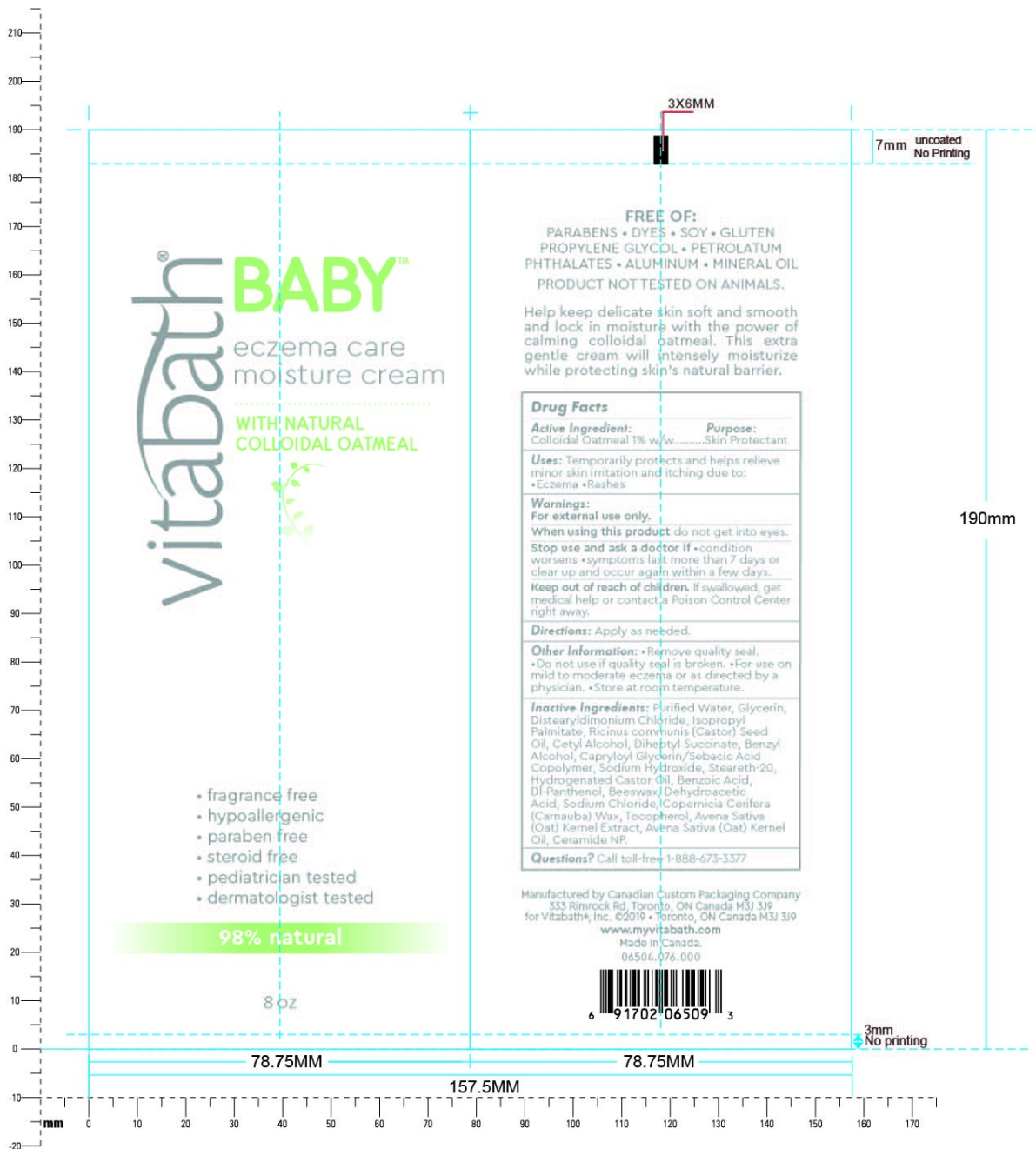
Distearyldimonium Chloride

Isopropyl Palmitate

Ricinus communis (Castor) Seed Oil

Cetyl Alcohol  
Diheptyl Succinate  
Benzyl Alcohol  
Capryloyl Glycerin/Sebacic Acid Copolymer  
Sodium Hydroxide  
Steareth-20  
Hydrogenated Castor Oil  
Benzoic Acid  
Dl-Panthenol  
Beeswax  
Dehydroacetic Acid  
Sodium Chloride  
Copernicia Cerifera (Carnauba) Wax  
Tocopherol  
Avena Sativa (Oat) Kernel Extract  
Avena Sativa (Oat) Kernel Oil  
Ceramide NP

**Questions?** Call toll-free 1-888-673-3377



## VITABATH BABY ECZEMA CARE MOISTURE

colloidal oatmeal cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73172-001
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OATMEAL (UNII: 8PI54V663Y) (OATMEAL - UNII:8PI54V663Y)	OATMEAL	1 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
<b>HYDROGENATED CASTOR OIL</b> (UNII: ZF94AP8MEY)	
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MM)	
<b>PANTHENOL</b> (UNII: WV9CM0O67Z)	
<b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>OAT</b> (UNII: Z6J799EAJK)	
<b>OAT KERNEL OIL</b> (UNII: 3UVP41R77R)	
<b>CERAMIDE NP</b> (UNII: 4370DF050B)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>DISTEARYLDIMONIUM CHLORIDE</b> (UNII: OM9573ZX3X)	
<b>ISOPROPYL PALMITATE</b> (UNII: 8CRQ2TH63M)	
<b>STEARETH-20</b> (UNII: L0Q8IK9E08)	
<b>CASTOR OIL</b> (UNII: D5340Y2I9G)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>DIHEPTYL SUCCINATE</b> (UNII: 057N7SS26Y)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>CAPRYLOYL GLYCERIN/SEBACIC ACID COPOLYMER (2000 MPA.S)</b> (UNII: N7YC58165T)	
<b>DEHYDROACETIC ACID</b> (UNII: 2KAG279R6R)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73172-001-01	226 g in 1 TUBE; Type 0: Not a Combination Product	06/11/2019	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	06/11/2019	

**Labeler** - Vitabath, Inc. (203461637)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Canadian Custom Packaging		207062514	manufacture(73172-001)

Revised: 6/2019

Vitabath, Inc.