## ATTITUDE DIAPER CREAM ZINC UNSCENTED- zinc oxide stick 9055-7588 Quebec Inc. (Attitude)

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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# ATTITUDE Baby Leaves Diaper Cream - Zinc - Unscented DRUG FACTS

Zinc oxide (15%)

Skin protectant - Diaper rash treatment

Helps prevent diaper rash.

Protects chafed irritated skin due to diaper rash.

Helps protect from wetness that causes diaper rash.

Temporarily protects and helps relieve minor skin irritation due to diaper rash.

Helps treat/heal diaper rash.

## Allergens: almond

For external use only.

**When using** this product avoid contact with eyes. If contact occurs, rinse thoroughly with water.

Stop use and consult a doctor if symptoms worsen or last for more than 7 days.

**Keep out of reach of children.** If swallowed, call a poison control centre or get edical help right away.

Change wet and soiled diapers promptly, cleanser the diaper area, and allow to dry. Push on the bottom to release the product. Heat the product for a few seconds on your hands and apply on baby's bottom. Apply product liberally as often as necessary, with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged. If necessary, after use, wipe off the excess on the tube contour before closing it.

Store at temperatures below 90 F (32 C).

Cocos Nucifera (Coconut) Oil, Ricinus Communis (Castor) Seed Oil, Polyhydroxystearic Acid, Caprylic/Capric Triglyceride, Helianthus Annuus (Sunflower) Seed Wax, Vitis Vinifera (Grape) Seed Oil, C10-18 Triglycerides, Behenyl Behenate, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Glyceryl Behenate, Euphorbia Cerifera (Candelilla) Wax, Vaccinium Myrtillus (Blueberry) Leaf Extract.

#### **ATTITUDETM**

natural care

baby leavesTM

diaper cream - zinc

protects & nourishes

Unscented

EWG VerifiedTM

Vegan

Stick 30g /1 oz.

NPN 80119243

dermatologically tested

plastic free

Uses / Usages: Helps prevent diaper rash. Protects chafed irritated skin due to diaper rash. Helps protect from wetness that causes diaper rash. Temporarily protects and helps relieve minor skin irritation due to diaper rash. Helps treat/ heal diaper rash. Aide à prévenir l'érythème fessier. Protège la peau l'égèrement irritée en raison d'un érythème fessier. Aide à protéger contre la moiteur qui cause l'érythème fessier. Protège et aide à soulager temporairement les irritations mineures causées par l'érythème fessier. Aide à traiter/ soigner l'érythème fessier.

Inactive ingredients / Ingrédients inactifs: Cocos Nucífera (Cocontt) Oil, Ricinus Communis (Castor) Seed Oil, Polyhydroxystearic Acid, Caprylic/Capric Triglyceride, Helianthus Annuus (Sunflower) Seed Wax, Vitis Vinifera (Grape) Seed Oil, C10-18 Triglycerides, Behenyl Behenate, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Glyceryl Behenate, Euphorbia Cerifera (Candelilla) Wax, Vaccinium Myrtillus (Blueberry), Leaf Extract.

\*Standard ISO 16128



#### DRUG FACTS / INFO-MEDICAMENT

Active ingredient / Ingrédient actif : Zinc oxide (15%) / Oxyde de zinc (15%) Purpose / Utilisation: Skin protectant - Diaper rash treament / Traitement de l'érythème fessier

Allergènes/Allergens: Amande ■ Almond

Warnings / Attention: For external use only. When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water. Stop use and consult a doctor if symptoms worsen or last for more than 7 days. Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away. Pour usage externe seulement. Lorsque vous utilisez ce produit éviter tout contact avec les yeux. Le cas échéant, bien rincer avec de l'eau. Cessez d'utiliser et consultez un médecin si les symptômes s'aggravent ou durent plus de 7 jours. Garder hors de la portée des enfants. En cas d'ingestion, appeler immédiatement un centre antipoison ou obtenir une assistance médicale.

Other Information / Autre information: Store at temperatures below 90°F (32°C). ■ Entreposer à une température inférieure à 32°C.

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#### Directions / Mode d'emploi:

Change wet and soiled diapers promptly, cleanse the diaper area, and allow to dry. Push on the bottom to release the product. Heat the product for a few seconds on your hands and apply on baby's bottom. Apply product liberally as often as necessary, with each diaper change, especially at bedfirne or anytime when exposure to wet diapers may be prolonged. If necessary, after use, wipe off the excess on the tube contour before

closing it. ■ Changez rapidement la couche humide et souillée, nettoyez la zone et laissez sécher. Pousser sur le fond pour faire sortir le produit. Réchauffer le produit quelques secondes sur la peau et étendre sur les fesses de bébé. Appliquez généreusement le produit aussi souvent que nécessaire, à chaque changement de couche, surtout au coucher ou à tout moment où l'exposition aux couches mouillées peut être prolongée. Si nécessaire, a parès utilisation, bien essuyer les surplus sur le contour du tube avant de le fermer.

## ATTITUDE



# baby leaves

diaper cream - zinc protects & nourishes UNSCENTED

crème de change - zinc protège et nourrit SANS ODEUR

STICK • BÂTON 30g / 1 oz.

NPN: 80119243

DERMATOLOGICALLY TESTED
TESTÉ DERMATOLOGIQUEMENT

100% NATURAL ORIGIN\* 100% D'ORIGINE NATURELLE\*

> PLASTIC FREE SANS PLASTIQUE

## ATTITUDE DIAPER CREAM ZINC UNSCENTED

zinc oxide stick

### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:61649-260

Route of Administration TOPICAL

## **Active Ingredient/Active Moiety**

Ingredient Name Basis of Strength Strength

ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	15 g in 100 g
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Inactive Ingredients		
Ingredient Name	Strength	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)		
GLYCERYL MONOBEHENATE (UNII: A626UU0W2A)		
CANDELILLA WAX (UNII: WL0328HX19)		
GRAPE SEED OIL (UNII: 930MLC8XGG)		
BEHENYL BEHENATE (UNII: K8NU647RJ0)		
ALMOND OIL (UNII: 66YXD4DKO9)		
COCONUT OIL (UNII: Q9L0O73W7L)		
CASTOR OIL (UNII: D5340Y2I9G)		
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)		
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)		
C10-18 TRIGLYCERIDES (UNII: 43AGM4PHPI)		
VACCINIUM MYRTILLUS LEAF (UNII: Y4U5910U70)		

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:61649-260- 01	30 g in 1 TUBE; Type 0: Not a Combination Product	07/24/2023	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M016	07/24/2023	

## **Labeler -** 9055-7588 Quebec Inc. (Attitude) (201137051)

Establishment			
Name	Address	ID/FEI	Business Operations
9055-7588 Quebec Inc dba Attitude		204307099	analysis(61649-260), label(61649-260), manufacture(61649-260), pack(61649-260)

Revised: 7/2023 9055-7588 Quebec Inc. (Attitude)