

## **AVEENO BABY BATHTIME SOLUTIONS MOMMY AND ME GIFT SET-**

**dimethicone**

**Johnson & Johnson Consumer 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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**Aveeno® baby bathtime solutions mommy & me gift set AVEENO® Baby Daily Moisture Lotion**

### **Drug Facts**

#### **Active ingredient**

Dimethicone 1.2%

#### **Purpose**

Skin protectant

#### **Uses**

- Helps prevent and temporarily protects chafed, chapped or cracked skin

#### **Warnings**

**For external use only.**

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

- Do not get into eyes

#### **Stop use and ask a doctor if**

- Condition worsens
- Symptoms last more than 7 days or clear up and occur again within a few days

#### **Do not use on**

- Deep or puncture wounds
- Animal bites
- Serious burns

**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**

- To open, twist off cap and remove quality seal. Do not use if quality seal is broken.
- Store at room temperature.

## **Inactive ingredients**

Water, Glycerin, Distearylidimonium Chloride, Petrolatum, Isopropyl Palmitate, Cetyl Alcohol, Avena Sativa (Oat) Kernel Flour, Benzyl Alcohol, Sodium Chloride, Allantoin

## **Questions?**

**866-428-3366**; Outside US dial collect **215-273-8755** [www.aveeno.com](http://www.aveeno.com)

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**JOHNSON & JOHNSON**

**CONSUMER INC.**

Skillman, NJ 08558

## **PRINCIPAL DISPLAY PANEL - Kit Container**

RECOMMENDED BY  
PEDIATRICIANS  
& DERMATOLOGISTS

**Aveeno** ®

baby

**bathtime**

**solutions**

**mommy & me**

**gift set**

**for BABY:** Daily Moisture Wash & Shampoo 8 fl oz  
(236 mL), Daily Moisture Lotion 8 oz (227 g),  
CALMING COMFORT ® Bath 8 fl oz (236mL)

**for MOM:** Stress Relief Body Wash 12 fl oz (354 mL)



# Aveeno<sup>®</sup> baby

## bathtime solutions

### mommy & me gift set

**for BABY:** Daily Moisture Wash & Shampoo 8 fl oz (236 mL), Daily Moisture Lotion 8 oz (227 g), CALMING COMFORT<sup>™</sup> Bath 8 fl oz (236 mL)

**for MOM:** Stress Relief Body Wash 12 fl oz (354 mL)

#### AVEENO<sup>®</sup> Baby Daily Moisture Lotion 8 oz (227 g)

<b>Drug Facts</b>	
<b>Active ingredient</b>	<b>Purpose</b>
Dimethicone 1.2%	Skin protectant
<b>Uses</b> - Helps prevent and temporarily protects chafed, chapped, or cracked skin.	
<b>Warnings</b> For external use only.	
<b>When using this product</b> - Do not get into eyes.	
<b>Stop use and ask a doctor if</b> - Condition worsens - Symptoms last more than 7 days or clear up and occur again within a few days.	
<b>Do not use on</b> - Deep or puncture wounds - Animal bites - Serious burns	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> - Apply as needed.	
<b>Other information</b> - To open, twist off cap and remove quality seal. Do not use if quality seal is broken. - Store at room temperature.	
<b>Inactive ingredients</b> Water, Glycerin, Distearaldimonium Chloride, Petrolatum, Isopropyl Palmitate, Cetyl Alcohol, Avena Sativa (Oat) Kernel Flour, Benzyl Alcohol, Sodium Chloride, Allantoin	

#### AVEENO<sup>®</sup> Baby Daily Moisture Wash & Shampoo 8 fl oz (236 mL)

**DIRECTIONS:** Dispense onto a wet washcloth or hand and apply to hair and body. Lather and rinse.

**SAFETY TIP:** Keep out of reach of children. Do not use if quality seal is broken or missing.

**Ingredients** Water, Cocamidopropyl Betaine, Sodium Lauroamphoacetate, Glycerin, Coco-Glucoside, Sodium Chloride, Citric Acid, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Sodium Benzoate, Glyceryl Oleate, Fragrance, Sodium Hydroxide, Polyquaternium-10, Guar Hydroxypropyltrimonium Chloride, Avena Sativa (Oat) Kernel Extract

Made in Canada

#### AVEENO<sup>®</sup> Baby CALMING COMFORT<sup>™</sup> Bath 8 fl oz (236 mL)

**DIRECTIONS:** Dispense directly into bath water. Or dispense onto a wet washcloth or hand and apply to hair and body. Lather and rinse.

**SAFETY WARNING:** Keep this product out of reach of children. Do not use if quality seal is broken or missing. Do not use without consulting a doctor if child has asthma or allergies or if there is a family history of either. Serious breathing problems could occur.

**Ingredients** Water, Cocamidopropyl Betaine, Sodium Lauroamphoacetate, Glycerin, Coco-Glucoside, Sodium Chloride, Hydroxypropyl Starch Phosphate, Citric Acid, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Fragrance, Sodium Benzoate, Glyceryl Oleate, Polyquaternium-7, Sodium Hydroxide, Avena Sativa (Oat) Kernel Extract

Made in Canada

#### AVEENO<sup>®</sup> Stress Relief Body Wash 12 fl oz (354 mL)

**DIRECTIONS:** Shake well before use. Squeeze body wash onto a wet pouf, washcloth or hands. Work into a rich, creamy lather, then rinse.

**FOR SHAVING:** Apply by hand as a rich shaving wash for silky legs.

**Ingredients** Water, Glycerin, Cocamidopropyl Betaine, Sodium Laureth Sulfate, Avena Sativa (Oat) Kernel Flour, Citric Acid, Sodium Chloride, Sodium Benzoate, Guar Hydroxypropyltrimonium Chloride, Fragrance, Glycol Distearate, Polyquaternium-10, Tetrasodium EDTA, Myristyl Alcohol, Sodium Hydroxide

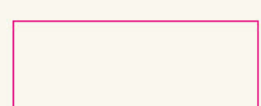
Made in Canada

PAPER BASKET: Made in China. Keep basket dry and away from moisture.

**SAFETY TIP:** This is not a toy. Keep out of reach of children. Do not use if quality seals are broken or missing. Discard all packaging materials immediately after opening.

Questions? **866-428-3366**; Outside US dial collect **215-273-8755** [www.aveeno.com](http://www.aveeno.com)

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CONSUMER INC.**  
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**AVEENO<sup>®</sup> Stress Relief Body Wash**

is clinically shown to help calm and relax you in the shower while cleansing and moisturizing your skin

AVEENO<sup>®</sup> is a Pediatrician and Dermatologist recommended brand

for mom

**AVEENO<sup>®</sup> Baby Daily Moisture Wash & Shampoo**

gently cleanses and nourishes baby's hair and sensitive skin

**AVEENO<sup>®</sup> Baby Daily Moisture Lotion** protects and moisturizes baby's sensitive skin for 24hrs

**AVEENO<sup>®</sup> Baby CALMING COMFORT<sup>™</sup> Bath** gently cleanses baby's delicate skin and helps calm baby before bedtime

for baby

Your Gift Set Includes:

**AVEENO® baby bathtime solutions mommy & me gift set**

includes products to help take care of your new baby's delicate skin with a stress relief body wash for you! AVEENO® Baby uses high quality, natural oats, and carefully harvests their moisturizing and soothing properties. These AVEENO® Baby products are pH-balanced. All AVEENO® Baby products are free of soap, parabens, phthalates, and phenoxethanol.

## AVEENO BABY BATHTIME SOLUTIONS MOMMY AND ME GIFT SET

dimethicone kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69968-0692
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69968-0692-9	1 in 1 CONTAINER	09/07/2020	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
<b>Part 1</b>	1 TUBE	227 g
<b>Part 2</b>	1 BOTTLE	236 mL
<b>Part 3</b>	1 BOTTLE	236 mL
<b>Part 4</b>	1 BOTTLE	354 mL

## Part 1 of 4

### AVEENO BABY DAILY MOISTURE

dimethicone lotion

### Product Information

<b>Item Code (Source)</b>	NDC:69968-0679
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<b>Route of Administration</b>	TOPICAL
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### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	12 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
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<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>DISTEARYLDIMONIUM CHLORIDE</b> (UNII: OM9573ZX3X)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	
<b>ISOPROPYL PALMITATE</b> (UNII: 8CRQ2TH63M)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>OAT</b> (UNII: Z6J799EAJK)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>ALLANTOIN</b> (UNII: 344S277G0Z)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69968-0679-8	227 g in 1 TUBE; 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	08/01/2001	

## Part 2 of 4

### AVEENO BABY DAILY MOISTURE WASH AND SHAMPOO

baby shampoos liquid

## Product Information

Route of Administration TOPICAL

## Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	<b>WATER</b> (UNII: 059QF0KO0R)	
INGR	<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3O11KX)	
INGR	<b>SODIUM LAUROAMPHOACETATE</b> (UNII: SLK428451L)	
INGR	<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
INGR	<b>COCO GLUCOSIDE</b> (UNII: ICS790225B)	
INGR	<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
INGR	<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
INGR	<b>CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED)</b> (UNII: 59TL3WG5CO)	
INGR	<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	

INGR	<b>GLYCERYL OLEATE</b> (UNII: 4PC054V79P)	
INGR	<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
INGR	<b>GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE (1.7 SUBSTITUENTS PER SACCHARIDE)</b> (UNII: B16G315W7A)	
INGR	<b>OAT</b> (UNII: Z6J799EAJK)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		236 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
Cosmetic		07/06/2020	

### Part 3 of 4

## AVEENO BABY CALMING COMFORT BATH

baby shampoos liquid

### Product Information

**Route of Administration** TOPICAL

### Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
INGR	<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
INGR	<b>CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED)</b> (UNII: 59TL3WG5CO)	
INGR	<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
INGR	<b>GLYCERYL OLEATE</b> (UNII: 4PC054V79P)	
INGR	<b>POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600000 MW)</b> (UNII: 0L414VCS5Y)	
INGR	<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
INGR	<b>OAT</b> (UNII: Z6J799EAJK)	
INGR	<b>WATER</b> (UNII: 059QF0KO0R)	
INGR	<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3011KX)	
INGR	<b>SODIUM LAUROAMPHOACETATE</b> (UNII: SLK428451L)	
INGR	<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
INGR	<b>COCO GLUCOSIDE</b> (UNII: ICS790225B)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		236 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
Cosmetic		06/01/2020	

## Part 4 of 4

### AVEENO STRESS RELIEF BODY WASH

cleansing (cold creams, cleansing lotions, liquids, and pads) liquid

## Product Information

Route of Administration TOPICAL

## Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	<b>WATER</b> (UNII: 059QF0KO0R)	
INGR	<b>GLYCERIN</b> (UNII: PDC6A3C00X)	
INGR	<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3011KX)	
INGR	<b>SODIUM LAURETH-3 SULFATE</b> (UNII: BPV390UAP0)	
INGR	<b>OATMEAL</b> (UNII: 8PI54V663Y)	
INGR	<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
INGR	<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
INGR	<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
INGR	<b>GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE (1.7 SUBSTITUENTS PER SACCHARIDE)</b> (UNII: B16G315W7A)	
INGR	<b>GLYCOL DISTEARATE</b> (UNII: 13W7MDN21W)	
INGR	<b>EDETATE SODIUM</b> (UNII: MP1J8420LU)	
INGR	<b>MYRISTYL ALCOHOL</b> (UNII: V42034O9PU)	
INGR	<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		354 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
Cosmetic		01/31/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	09/07/2020	

**Labeler** - Johnson & Johnson Consumer Inc. (118772437)

Revised: 1/2023

Johnson & Johnson Consumer Inc.