

## **BABY ESSENTIALS GIFT SET- benzalkonium chloride**

**KAS Direct LLC dba BabyGanics**

*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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### **baby essentials gift set**

#### ***Drug Facts***

#### **Active ingredient**

Benzalkonium Chloride 0.1%

#### **Purpose**

Antimicrobial

#### **Uses**

- for hand sanitizing to decrease bacteria on the skin
- recommended for repeated use

#### **Warnings**

##### **For external use only**

**When using this product** avoid contact with eyes. In case of eye contact, flush eyes with water.

**Stop use and ask a doctor** if irritation or redness develops, or if condition persists for more than 72 hours.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions**

- pump a small amount of foam into palm of hand
- rub thoroughly over all surfaces of both hands
- rub hands together briskly until dry

#### **Inactive ingredients**

water, cetrimonium chloride, laurtrimonium chloride, dihydroxyethyl cocamine oxide, glycereth-17 cocoate, medium chain triglycerides, triethyl citrate, citrus reticulata (mandarin orange) peel oil, tocopherol, citrus aurantium dulcis (orange) peel oil, citrus grandis (grapefruit) peel oil

dist. by KAS direct, LLC  
Westbury, NY 11590

### **PRINCIPAL DISPLAY PANEL - Kit Package**

babyganics

baby

essentials

gift set

1- daily lotion chamomile verbena (9 FL OZ)

1- bubble bath chamomile verbena (9 FL OZ)

1- foaming shampoo+body wash chamomile verbena (7 FL OZ)

1- foaming dish & bottle soap fragrance free (3 FL OZ)

1- toy, table & highchair wipes fragrance free (25 wipes)

2- alcohol-free foaming hand sanitizer mandarin (50 ML)

Discover which ingredients are Certified Organic on bottom panel.



## BABY ESSENTIALS GIFT SET

benzalkonium chloride kit

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59062-5000
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59062-5000-1	1 in 1 PACKAGE; Type 0: Not a Combination Product	01/01/2015	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	266 mL
Part 2	1 BOTTLE	266 mL
Part 3	1 BOTTLE	207 mL
Part 4	2 BOTTLE, PUMP	100 mL
Part 5	1 PACKAGE	25
Part 6	1 BOTTLE, DISPENSING	89 mL

### Part 1 of 6

#### MOISTURIZING DAILY

lotions, oils, powders, and creams lotion

### Product Information

Route of Administration	TOPICAL
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### Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	water (UNII: 059QF0KO0R)	
INGR	CO COA BUTTER (UNII: 512OYT1CRR)	
INGR	cetyl alcohol (UNII: 936JST6JCN)	
INGR	squalene (UNII: 7QWM220FJH)	
INGR	decyl oleate (UNII: ZGR06DO97T)	
INGR	shea butter (UNII: K49155WL9Y)	
INGR	propanediol (UNII: 5965N8W85T)	
INGR	glycerin (UNII: PDC6A3C0OX)	
INGR	AVOCADO OIL (UNII: 6VNO72PFC1)	
INGR	OLIVE OIL (UNII: 6UYK2W1W1E)	

INGR	<b>canola oil</b> (UNII: 331KBJ17RK)	
INGR	<b>tocopherol</b> (UNII: R0ZB2556P8)	
INGR	<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
INGR	<b>TOMATO SEED OIL</b> (UNII: 7N87T9C06T)	
INGR	<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)	
INGR	<b>CRANBERRY SEED OIL</b> (UNII: 73KDS3BW5E)	
INGR	<b>NIGELLA SATIVA SEED</b> (UNII: 4LVZ0Z0ITT)	
INGR	<b>RASPBERRY SEED OIL</b> (UNII: 9S8867952A)	
INGR	<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
INGR	<b>POLYOXYL 20 CETOSTEARYL ETHER</b> (UNII: YRC528SWUY)	
INGR	<b>stearic acid</b> (UNII: 4ELV7Z65AP)	
INGR	<b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)	
INGR	<b>CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE</b> (UNII: 0A5MM307FC)	
INGR	<b>sodium hydroxide</b> (UNII: 55X04QC32I)	
INGR	<b>caprylyl glycol</b> (UNII: 00YIU5438U)	
INGR	<b>TRISODIUM ETHYLENEDIAMINE DISUCCINATE</b> (UNII: YA22H34H9Q)	
INGR	<b>sorbic acid</b> (UNII: X045WJ989B)	
INGR	<b>phenoxyethanol</b> (UNII: HIE492ZZ3T)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		266 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		01/01/2015	

## Part 2 of 6

### BUBBLE BATH

bubble bath liquid

### Product Information

<b>Route of Administration</b>	TOPICAL
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### Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	<b>water</b> (UNII: 059QF0K00R)	
INGR	<b>sodium lauroyl methyl isethionate</b> (UNII: II6VCD3S6R)	
INGR	<b>disodium cocoamphodiacetate</b> (UNII: 18L9G3U51M)	
INGR	<b>coco glucoside</b> (UNII: ICS790225B)	
INGR	<b>lauryl glucoside</b> (UNII: 76LN7P7UCU)	

INGR	<b>capryl/capramidopropyl betaine</b> (UNII: 231H3ZT9NE)	
INGR	<b>TOMATO SEED OIL</b> (UNII: 7N87T9C06T)	
INGR	<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)	
INGR	<b>CRANBERRY SEED OIL</b> (UNII: 73KDS3BW5E)	
INGR	<b>NIGELLA SATIVA SEED</b> (UNII: 4LVZ0Z0ITT)	
INGR	<b>RASPBERRY SEED OIL</b> (UNII: 9S8867952A)	
INGR	<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
INGR	<b>CALENDULA OFFICINALIS FLOWER</b> (UNII: P0M7O4Y7YD)	
INGR	<b>CHAMOMILE</b> (UNII: FGL3685T2X)	
INGR	<b>OLEA EUROPAEA LEAF</b> (UNII: MJ95C3OH47)	
INGR	<b>glycerin</b> (UNII: PDC6A3C0OX)	
INGR	<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
INGR	<b>TRISODIUM ETHYLENEDIAMINE DISUCCINATE</b> (UNII: YA22HB4H9Q)	
INGR	<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
INGR	<b>ethylhexylglycerin</b> (UNII: 147D247K3P)	
INGR	<b>sodium benzoate</b> (UNII: OJ245FE5EU)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		266 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		01/01/2015	

### Part 3 of 6

## SQUEEZE AND FOAM SHAMPOO PLUS BODY WASH

baby shampoos shampoo

### Product Information

<b>Route of Administration</b>	TOPICAL
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### Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	<b>water</b> (UNII: 059QF0KO0R)	
INGR	<b>sodium lauroyl methyl isethionate</b> (UNII: II6VCD3S6R)	
INGR	<b>CAPRYLYL/CAPRYL OLIGOGLUCOSIDE</b> (UNII: E00JL9G9K0)	
INGR	<b>propanediol</b> (UNII: 5965N8W85T)	
INGR	<b>BUTYL ACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID COPOLYMER (18000 MW)</b> (UNII: JZ1374NL9E)	
INGR	<b>sodium lauroyl oat amino acids</b> (UNII: FSW2K9B9N5)	

INGR	<b>glycerin</b> (UNII: PDC6A3C0OX)	
INGR	<b>ethylhexylglycerin</b> (UNII: 147D247K3P)	
INGR	<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
INGR	<b>trisodium ethylenediamine disuccinate</b> (UNII: YA22H34H9Q)	
INGR	<b>dehydroacetic acid</b> (UNII: 2KAG279R6R)	
INGR	<b>TOMATO SEED OIL</b> (UNII: 7N87T9C06T)	
INGR	<b>SUNFLOWER OIL</b> (UNII: 3W1JG795Y)	
INGR	<b>CRANBERRY SEED OIL</b> (UNII: 73KDS3BW5E)	
INGR	<b>NIGELLA SATIVA SEED</b> (UNII: 4LVZ0Z0ITT)	
INGR	<b>RASPBERRY SEED OIL</b> (UNII: 9S8867952A)	
INGR	<b>PHENOXYETHANOL</b> (UNII: HE492ZZ3T)	
INGR	<b>sodium hydroxide</b> (UNII: 55X04QC32I)	
INGR	<b>PHYTATE SODIUM</b> (UNII: 88496G1ERL)	
INGR	<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
INGR	<b>CUCUMBER</b> (UNII: YY7C30VXJT)	
INGR	<b>CHAMOMILE</b> (UNII: FGL3685T2X)	
INGR	<b>AVOCADO</b> (UNII: SDS87L369F)	
INGR	<b>tocopherol</b> (UNII: R0ZB2556P8)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		207 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		01/01/2015	

### Part 4 of 6

## BABYGANICS ALCOHOL-FREE FOAMING HAND SANITIZER MANDARIN

benzalkonium chloride liquid

### Product Information

<b>Route of Administration</b>	TOPICAL
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### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.1 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>water</b> (UNII: 059QF0KO0R)	
<b>cetrimonium chloride</b> (UNII: UC9PE95IBP)	
<b>laurtrimonium chloride</b> (UNII: A81MSI0FIC)	
<b>dihydroxyethyl cocamine oxide</b> (UNII: 8AR51R3BL5)	
<b>glycereth-17 cocoate</b> (UNII: 3057VPT0KC)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>triethyl citrate</b> (UNII: 8Z96QXD6UM)	
<b>TANGERINE</b> (UNII: KH3E3096OO)	
<b>tocopherol</b> (UNII: R0ZB2556P8)	
<b>ORANGE OIL</b> (UNII: AKN3KSD11B)	
<b>CITRUS MAXIMA FRUIT RIND OIL</b> (UNII: 8U3877WD44)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59062-4000-5	50 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	08/15/2013	

### Part 5 of 6

### TOY, TABLE AND HIGHCHAIR WIPES

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

### Product Information

<b>Route of Administration</b>	TOPICAL
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### Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	<b>water</b> (UNII: 059QF0KO0R)	
INGR	<b>glycerin</b> (UNII: PDC6A3C0OX)	
INGR	<b>decyl glucoside</b> (UNII: Z17H97EA6Y)	
INGR	<b>malic acid</b> (UNII: 817L1N4CKP)	
INGR	<b>potassium sorbate</b> (UNII: 1VPU26JZZ4)	
INGR	<b>gluconolactone</b> (UNII: WQ29KQ9POT)	
INGR	<b>sodium benzoate</b> (UNII: OJ245FE5EU)	
INGR	<b>DIRECT BLACK 19</b> (UNII: B91N7SNH1C)	



**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		25 in 1 PACKAGE; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		01/01/2015	

**Part 6 of 6****FOAMING DISH AND BOTTLE SOAP**

bath soaps and detergents liquid

**Product Information**

Route of Administration TOPICAL

**Other Ingredients**

Ingredient Kind	Ingredient Name	Quantity
INGR	water (UNII: 059QF0KO0R)	
INGR	cocamidopropyl hydroxysultaine (UNII: 62V75NI93W)	
INGR	lauramine oxide (UNII: 4F6FC4MI8W)	
INGR	decyl glucoside (UNII: Z17H97EA6Y)	
INGR	sodium lauroyl sarcosinate (UNII: 632GS99618)	
INGR	glycerin (UNII: PDC6A3C0OX)	
INGR	methylisothiazolinone (UNII: 229D0E1QFA)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		89 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		01/01/2015	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333E	01/01/2015	

**Labeler** - KAS Direct LLC dba BabyGanics (002764605)

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KAS Direct LLC dba BabyGanics