**4154 FIRST AID KIT- 4154 first aid kit**
**4139 FIRST AID KIT- 4139 first aid kit**
**4313 FIRST AID KIT- 4313 first aid kit**
**Honeywell Safety Products USA, INC**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.*

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**4139, 4154, 4313 First Aid Kit (BZK wipes, FABC, ASA, ammonia- SF00004159, 68P25BR, SF00004513)**

**First Aid Burn Cream**
***Active ingredient***

Benzalkonium chloride o.13%

Lidocaine HCl 0.5%

**First Aid Burn Cream**
***Purpose***

First aid antiseptic

External analgesic

**First Aid Burn Cream**
***Uses***

- prevent skin infection
- for temporary relief of pain associated with minor burns

**First Aid Burn Cream**
***Warnings***

**For external use only**

**Do not use**

- in or near the eyes
- if you are allergic to any of the ingredients
- in large areas of the body, particularly over raw surfaces or blistered areas
- for more than 10 days

**Ask a doctor before use if you have**

- deep or puncture wounds
- animal bites
- serious burns

**Stop use and ask a doctor if**

- condition worsens
- symptoms persist for more than 7 days or clear up and occurs again within a few days

**First Aid Burn Cream**

***Directions***

- **adults and children 2 years of age and older:**
- clean the affected area
- apply a small amount of this product (equal to the surface area of the tip of a finger) onto affected area 1 to 3 times daily
- may be covered with a sterile bandage
- children under 2 years of age: consult a doctor

**First Aid Burn Cream**
***Other information***

- tamper evident sealed packets
- do not use if packet is opened or torn

**First Aid Burn Cream**
***Inactive ingredients***

aloe barbadensis juice, cetyl alcohol, diazolidinyl urea, edetate disodium, glycerin, glyceryl stearate SE, methylparaben, mineral oil, PEG-100, propylene glycol, propylparaben, stearic acid, trolamine, water

**First Aid Burn Cream**
***Questions***

1-800-430-5490

**Aspirin**
***Active ingredient (in each tablet)***

Aspirin 325 mg (NSAID)* *nonsteroidal anti-inflammatory drug

**Aspirin**
***Purpose***

Pain reliever/fever reducer

**Aspirin**
***Uses***

temporarily reduces fever and relieves minor aches and pains associated with:

- a cold
- headache
- toothache
- muscular aches
- backache
- minor pain of arthritis
- premenstrual and menstrual periods

**Aspirin**
***Warnings***

**Reye's syndrome**: Children and teenagers who have or are recovering from chicken pox or flu-like

symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

**Allergy alert:** Aspirin may cause a severe allergic reaction which may include:

- hives
- facial swelling
- asthma (wheezing)
- shock

**Stomach bleeding warning:** This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:are:

- age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

**Do not use**

- if you are allergic to aspirin or any other pain reliever/fever reducer

**Ask a doctor before use if**

- stomach bleeding warning applies to you
- you have a history of stomach problems such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis or kidney disease
- you are taking a diuretic
- you have asthma

**Ask a doctor or pharmacist before use if you are**

- taking a prescription drug for diabetes, gout or arthritis

**Stop use and ask a doctor if**

- you experience any of the following signs of stomach bleeding:
- feel faint
- vomit blood
- have bloody or black stools
- have stomach pain that does not get better
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present in the painful area
- ringing in the ears or loss of hearing occurs
- any new symptoms appear

**If pregnant or breast-feeding,**

**If pregnant or breat-feeding,** ask a health professional before use. It is especially important not to use aspirin during the last three months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

**Keep out of reach of children.**

- In case of overdose, get medical help or contact Poison Control Center right away.

**Aspirin**
***Directions***
- drink a full glass of water with each dose
- adults and children 12 years of age and older: take 1 or 2 tablets every 4 hours while symptoms last, not more than 12 tablets in 24 hours
- children under 12 years of age: consult a doctor

**Aspirin**
***Other information***
- store at room temperature 15° - 30°C (59° - 86°F)
- TAMPER EVIDIENT PACKETS
- DO NOT USE IF OPEN OR TORN

**Aspirin**
***Inactive ingredients***

corn starch, croscarmellose sodium*, hypromellose*, microcrystalline cellulose*, mineral oil*, polyethylene glycol*, povidone, propylene glycol, silicon dioxide, stearic acid*, titanium dioxide*

*may contain these ingredients

**Aspirin**
***Questions or Comments***

1-800-430-5490

**BZK**
***Active ingredient***

Benzalkonium chloride 0.13% w/v

**BZK**
***Purpose***

First aid antiseptic

**BZK**
***Uses***

Antiseptic cleansing of face, hands, and body without soap and water

**BZK**
***Warnings***

For external use only

**Do not use**
- in the eyes or over large areas of the body
- on mucous membranes

- on irritated skin
- in case of deep puncture wounds, animal bites or serious burns, consult a doctor
- longer than 1 week unless directed by a doctor

**Keep out of reach of children**

If swallowed, get medical help or contact a Poison Control Center right away.

**Stop use and ask a doctor if**
- irritation, redness or other symptoms develop
- the condition persists or gets worse

**BZK**
***Directions***
- tear open packet and use as a washcloth

**BZK**
***Other information***
- store at room temperature 15 $^{0}$ to 30 $^{0}$ C (59 $^{0}$ - 86 $^{0}$ F)
- do not reuse towelette

**BZK**
***Inactive ingredients***

water

**BZK**
***Questions***

1-800-430-5490

**Ammonia**
**Active ingredient**

Ammonia 15%

**Ammonia**
**Purpose**

Respiratory stimulant

**Ammonia**
***Uses***
- to prevent or treat fainting

**Ammonia**
***Warnings***

**For external use only**

**Do not use**
- if you have breathing problems such as asthma or emphysema

**Stop use and ask a doctor if**

- condition persists

**Keep out of reach of children**

- If swallowed get medical help or contact a Poison Control Center immidiately

**Ammonia**

***Directions***

- hold inhalant away from face and crush ampoule between thumb and forefinger at position indicated on sleeve.
- hold near nostrils for inhalation of volatile vapo

**Ammonia**

***Other information***

- store at room temperature away from light

**Ammonioa**

***Inactive ingredients***

alcohol USP, FD&C red #40, lavender oil, lemon oil fcc, nutmeg oil, purified water

**Ammonia**

***Questions or Comments?***

1-800-430-5490

**4139**

**SF00004159 kit contents**

1 3/4X3 PLAS SING 50/BOX

1 GAUZE BANDAGE, 4" X 6 YD

1 INSTANT COLD PACK 4" X 6"

1 ANTIMCRBL ANTSPTC TWLETTS

1 ADHESIVE TAPE W/P 1/2"X 5 YD

1 FIRST AID GUIDE ASHI

2 GAUZE CLEAN-WRAP BDGE N/S 2"

1 ABD COMBINE PAD 5" X 9"

1 FIRST AID CREAM 0.9 GRM PKT 20

1 SCISSOR BDGE 4" RED PLS HDL

1 KIT TWEEZER 3 1/2" SLANTED

1 # 25 EMPTY NO LOGO BLANK

LBL STOCK 6-3/8"X4"

LBL STOCK 4"X2-7/8"

1 LBL STOCK 3"x1-7/8"

1 PR LRG NITRILE GLVES ZIP BAG

1 TRI BNDG NON WOVEN 40"X40"X56"

5 GAUZE PADS 3"X3" 12PLY

5 GAUZE PADS 4"X4" 12PLY

6 ASPIRIN BULK 2/PK

3 AMMONIA INHALANT, BULK

**4154**
**68P25BR Kit Contents**

1 3/4X3 PLAS SING 50/BOX

1 GAUZE BANDAGE, 4" X 6 YD

1 INSTANT COLD PACK 4" X 6"

1 ANTIMCRBL ANTSPTC TWLETTS

1 ADHESIVE TAPE W/P 1/2"X 5 YD

1 FIRST AID GUIDE ASHI

2 GAUZE CLEAN-WRAP BDGE N/S 2"

1 ABD COMBINE PAD 5" X 9"

1 FIRST AID CREAM 0.9 GRM PKT 20

1 SCISSOR BDGE 4" RED PLS HDL

1 KIT TWEEZER 3 1/2" SLANTED

LBL STOCK 6-3/8"X4"

LBL STOCK 4"X2-7/8"

1 LBL STOCK 3"x1-7/8"

1 PR LRG NITRILE GLVES ZIP BAG

1 KIT, PP 16 UNIT FA

1 TRI BNDG NON WOVEN 40"X40"X56"

5 GAUZE PADS 3"X3" 12PLY

5 GAUZE PADS 4"X4" 12PLY

6 ASPIRIN BULK 2/PK

3 AMMONIA INHALANT, BULK

**4313**
**SF00004513 kit contents**

1 3/4X3 PLAS SING 50/BOX

1 GAUZE BANDAGE, 4" X 6 YD

1 NSTANT COLD PACK 4" X 6"

1 ANTIMCRBL ANTSPTC TWLETTS

1 ADHESIVE TAPE W/P 1/2"X 5 YD

1 FIRST AID GUIDE ASHI

2 GAUZE CLEAN-WRAP BDGE N/S 2"

1 ABD COMBINE PAD 5" X 9"

1 FIRST AID CREAM 0.9 GRM PKT 20

1 SCISSOR BDGE 4" RED PLS HDL

1 KIT TWEEZER 3 1/2" SLANTED

1 # 25 EMPTY NO LOGO BLANK

LBL STOCK 6-3/8"X4"

LBL STOCK 4"X2-7/8"

1 LBL STOCK 3"x1-7/8"

1 PR LRG NITRILE GLVES ZIP BAG

1 TRI BNDG NON WOVEN 40"X40"X56"

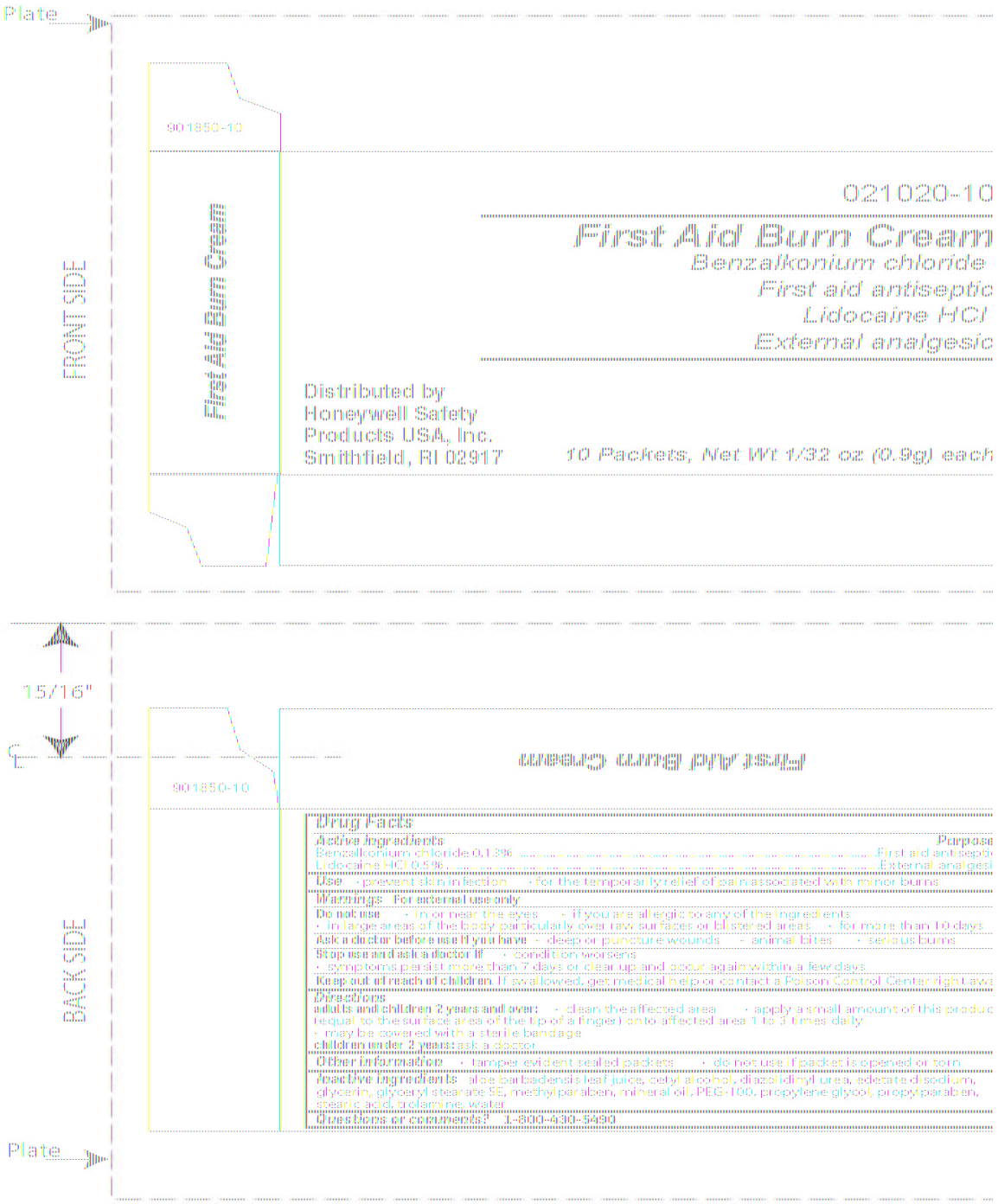
5 GAUZE PADS 3"X3" 12PLY

5 GAUZE PADS 4"X4" 12PLY

6 ASPIRIN BULK 2/PK

3 AMMONIA INHALANT, BULK

**First Aid Burn Cream**
**Principal Display Panel**


796353-10 Rev. A Unit Carton Printing Plate for "B" size
Plate
901850-10
First Aid Burn Cream
021020-10
First Aid Burn Cream
Benzalkonium chloride
First aid antiseptic
Lidocaine HCl
External analgesic
Distributed by
Honeywell Safety
Products USA, Inc.
Smithfield, RI 02917
10 Packets, Net Wt 1/32 oz (0.9g) each
3.250"
15/16"
901850-10
Drug Facts
Active Ingredients
Purpose
Benzalkonium chloride 0.13%
First aid antiseptic
Lidocaine HCl 0.5%
External analgesi
Use • prevent skin infection • for the temporary relief of pain associated with minor burns
Warnings For external use only
Do not use • in or near the eyes • if you are allergic to any of the ingredients
• in large areas of the body particularly over raw surfaces or blistered areas • for more than 10 days
Ask a doctor before use if you have • deep or puncture wounds • animal bites • serious burns
Stop use and ask a doctor if • condition worsens
• symptoms persist 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 awa
Directions
adults and children 2 years and over: • clean the affected area • apply a small amount of this produc
(equal to the surface area of the tip of a finger) onto affected area 1 to 3 times daily
• may be covered with a sterile bandage
children under 2 years: ask a doctor
Other information • tamper evident sealed packets • do not use if packet is opened or torn
Inactive ingredients aloe barbadensis leaf juice, cetyl alcohol, diazolidinyl urea, edetate disodium,
glycerin, glyceryl stearate SE, methylparaben, mineral oil, PEG-100, propylene glycol, propylparaben,
stearic acid, trolamine, water
Questions or comments? 1-800-430-3490
Plate

**Aspirin**

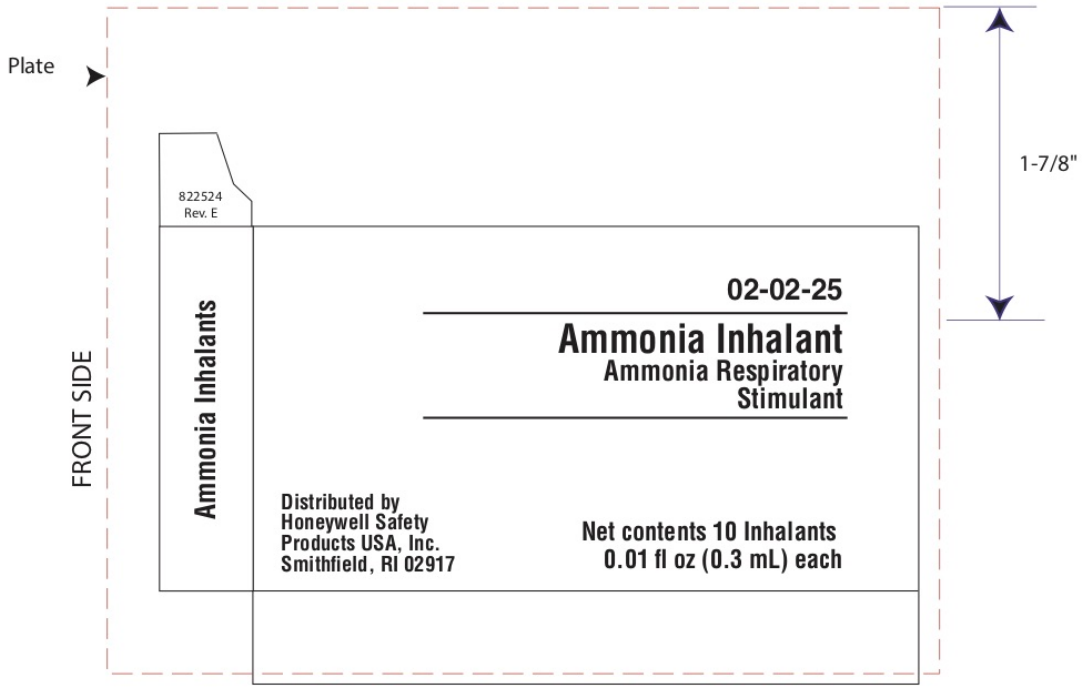
## *Principal Display Panel*

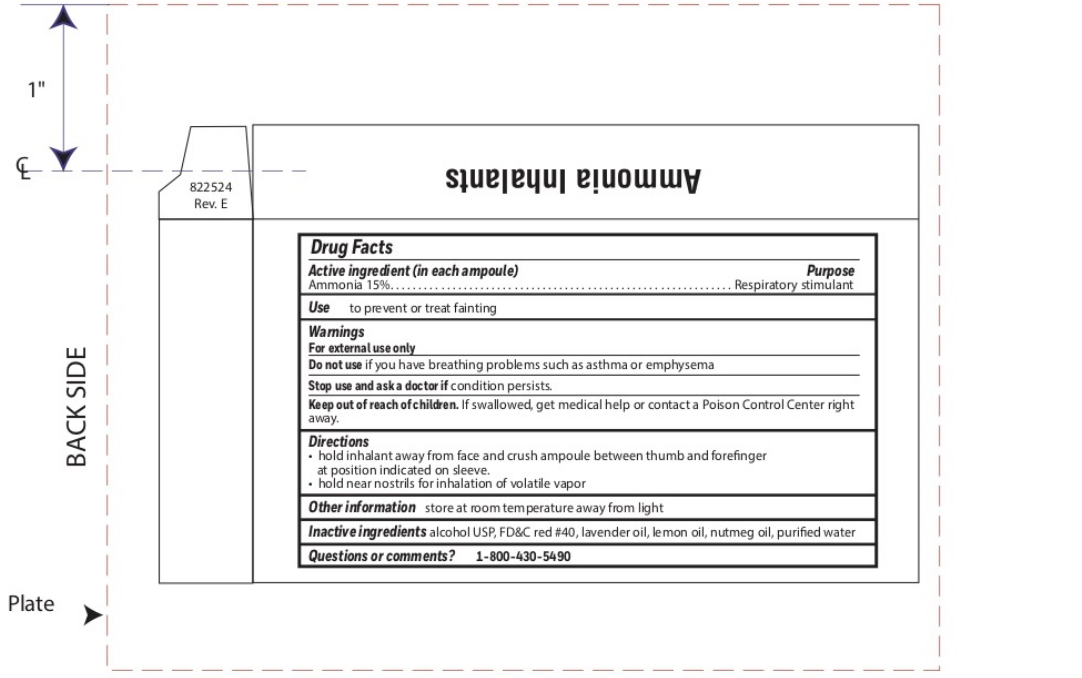

**BZK**

## *Principal Display Panel*


**Ammonia**
***Principal Display Panel***

796006 Rev. E Unit Carton Printing Plate for "A" size carton.




796006 Rev. E (page 3 of 3)

**4139 Kit Label**

**SF00004159**

First Aid

BELFOR

Distributed by Honeywell Safety Products USA, Inc Smithfield, RI 02917

**4154 Kit Label**
**68P25BR**

BRONER
GLOVE AND SAFETY
1-800-521-1318

First Aid

Distributed by Honeywell Safety Products USA, Inc. Smithfield, RI 02917

**4313 Kit Label**
**SF00004513**

#25 MT KIT STEEL 10.5" x 7.5"
PRINTED PANTONE gray 423, blue 654, orange 172

ACTUAL LOGO SIZE: 7.9" x 3.15"


This drawing has been submitted for your approval.

☐ Needs changes ☐ Approved

(A digital signature or response via email are both accepted as an approval to this form. Please indicate any changes back to your Swift Representative)

Name _____ Signature _____ Date _____

# 4154 FIRST AID KIT

4154 first aid kit kit

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:0498-4154 |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:0498-4154-01 | 1 in 1 KIT; Type 0: Not a Combination Product | 10/18/2018 | |

| Quantity of Parts | | |
|---|---|---|
| **Part #** | **Package Quantity** | **Total Product Quantity** |
| **Part 1** | 20 PACKET | 18 g |
| **Part 2** | 1 PACKET | 1.4 mL |
| **Part 3** | 6 PACKET | 12 |

| | | |
|---|---|---|
| **Part 4** | 3 AMPULE | 0.9 mL |

## Part 1 of 4

## FIRST AID BURN

benzalkonium chloride, lidocaine hydrochloride cream

| Product Information | |
|---|---|
| **Item Code (Source)** | NDC:0498-0903 |
| **Route of Administration** | TOPICAL |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **BENZALKONIUM CHLORIDE** (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y) | BENZALKONIUM CHLORIDE | 0.13 g in 100 g |
| **LIDOCAINE HYDROCHLORIDE** (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987) | LIDOCAINE HYDROCHLORIDE | 0.5 g in 100 g |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **ALOE VERA LEAF** (UNII: ZY81Z83H0X) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **STEARIC ACID** (UNII: 4ELV7Z65AP) | |
| **METHYLPARABEN** (UNII: A2I8C7HI9T) | |
| **CETYL ALCOHOL** (UNII: 936JST6JCN) | |
| **GLYCERYL MONOSTEARATE** (UNII: 230OU9XXE4) | |
| **PEG-100 STEARATE** (UNII: YD01N1999R) | |
| **LIGHT MINERAL OIL** (UNII: N6K5787QVP) | |
| **EDETATE DISODIUM** (UNII: 7FLD91C86K) | |
| **TROLAMINE** (UNII: 9O3K93S3TK) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **PROPYLPARABEN** (UNII: Z8IX2SC1OH) | |
| **DIAZOLIDINYL UREA** (UNII: H5RIZ3MPW4) | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | | 0.9 g in 1 PACKET; 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 | part333A | 12/20/2017 | |

## Part 2 of 4

## ANTISEPTIC TOWELETTE

benzalkonium chloride liquid

| Product Information | |
|---|---|
| **Item Code (Source)** | NDC:0498-0501 |
| **Route of Administration** | TOPICAL |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **BENZALKONIUM CHLORIDE** (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y) | BENZALKONIUM CHLORIDE | 1.3 mg in 1 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **WATER** (UNII: 059QF0KO0R) | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:0498-0501-00 | 1.4 mL in 1 PACKET; 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 | 09/18/2018 | |

## Part 3 of 4

## ASPIRIN

aspirin tablet

| Product Information | |
|---|---|
| **Item Code (Source)** | NDC:0498-0114 |
| **Route of Administration** | ORAL |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **ASPIRIN** (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E) | ASPIRIN | 325 mg |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **CELLULOSE, MICROCRYSTALLINE** (UNII: OP1R32D61U) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WJQ0SDW1A) | |
| **STEARIC ACID** (UNII: 4ELV7Z65AP) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **POVIDONE** (UNII: FZ989GH94E) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **CROSCARMELLOSE SODIUM** (UNII: M28OL1HH48) | |
| **HYPROMELLOSE 2208 (100 MPA.S)** (UNII: B1QE5P712K) | |
| **MINERAL OIL** (UNII: T5L8T28FGP) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | white | **Score** | 2 pieces |
| **Shape** | ROUND | **Size** | 10mm |
| **Flavor** | | **Imprint Code** | FR21 |
| **Contains** | | | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:0498-0114-01 | 2 in 1 PACKET; 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 | part343 | 09/18/2018 | |

## Part 4 of 4

## AMMONIA INHALENT

ammonia inhalent inhalant

| Product Information | |
|---|---|
| **Item Code (Source)** | NDC:0498-3334 |
| **Route of Administration** | RESPIRATORY (INHALATION) |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **AMMONIA** (UNII: 5138Q19F1X) (AMMONIA - UNII:5138Q19F1X) | AMMONIA | 0.045 g in 0.3 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **ALCOHOL** (UNII: 3K9958V90M) | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:0498-3334-00 | 0.3 mL in 1 AMPULE; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| unapproved drug other | | 09/18/2018 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| unapproved drug other | | 10/18/2018 | |

# 4139 FIRST AID KIT

4139 first aid kit kit

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:0498-4139 |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:0498-4139-01 | 1 in 1 KIT; Type 0: Not a Combination Product | 10/18/2018 | |

| Quantity of Parts | | |
|---|---|---|
| **Part #** | **Package Quantity** | **Total Product Quantity** |
| **Part 1** | 20 PACKET | 18 g |
| **Part 2** | 1 PACKET | 1.4 mL |
| **Part 3** | 6 PACKET | 12 |
| **Part 4** | 3 AMPULE | 0.9 mL |

## Part 1 of 4

# FIRST AID BURN

benzalkonium chloride, lidocaine hydrochloride cream

| Product Information | |
|---|---|
| **Item Code (Source)** | NDC:0498-0903 |
| **Route of Administration** | TOPICAL |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **BENZALKONIUM CHLORIDE** (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y) | BENZALKONIUM CHLORIDE | 0.13 g in 100 g |
| **LIDOCAINE HYDROCHLORIDE** (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987) | LIDOCAINE HYDROCHLORIDE | 0.5 g in 100 g |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **ALOE VERA LEAF** (UNII: ZY81Z83H0X) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **STEARIC ACID** (UNII: 4ELV7Z65AP) | |
| **METHYLPARABEN** (UNII: A2I8C7HI9T) | |
| **CETYL ALCOHOL** (UNII: 936JST6JCN) | |
| **GLYCERYL MONOSTEARATE** (UNII: 230OU9XXE4) | |
| **PEG-100 STEARATE** (UNII: YD01N1999R) | |
| **LIGHT MINERAL OIL** (UNII: N6K5787QVP) | |
| **EDETATE DISODIUM** (UNII: 7FLD91C86K) | |
| **TROLAMINE** (UNII: 9O3K93S3TK) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **PROPYLPARABEN** (UNII: Z8IX2SC1OH) | |
| **DIAZOLIDINYL UREA** (UNII: H5RIZ3MPW4) | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | | 0.9 g in 1 PACKET; 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 | part333A | 12/20/2017 | |

## Part 2 of 4

## ANTISEPTIC TOWELETTE

benzalkonium chloride liquid

| Product Information | |
|---|---|
| **Item Code (Source)** | NDC:0498-0501 |
| **Route of Administration** | TOPICAL |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **BENZALKONIUM CHLORIDE** (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y) | BENZALKONIUM CHLORIDE | 1.3 mg in 1 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **WATER** (UNII: 059QF0KO0R) | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:0498-0501-00 | 1.4 mL in 1 PACKET; 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 | 09/18/2018 | |

## Part 3 of 4

## ASPIRIN

aspirin tablet

| Product Information | |
|---|---|
| **Item Code (Source)** | NDC:0498-0114 |
| **Route of Administration** | ORAL |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |

| | | |
|---|---|---|
| **ASPIRIN** (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E) | ASPIRIN | 325 mg |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **CELLULOSE, MICROCRYSTALLINE** (UNII: OP1R32D61U) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WJQ0SDW1A) | |
| **STEARIC ACID** (UNII: 4ELV7Z65AP) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **POVIDONE** (UNII: FZ989GH94E) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **CROSCARMELLOSE SODIUM** (UNII: M28OL1HH48) | |
| **HYPROMELLOSE 2208 (100 MPA.S)** (UNII: B1QE5P712K) | |
| **MINERAL OIL** (UNII: T5L8T28FGP) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | white | **Score** | 2 pieces |
| **Shape** | ROUND | **Size** | 10mm |
| **Flavor** | | **Imprint Code** | FR21 |
| **Contains** | | | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:0498-0114-01 | 2 in 1 PACKET; 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 | part343 | 09/18/2018 | |

## Part 4 of 4

## AMMONIA INHALENT

ammonia inhalent inhalant

| Product Information | |
|---|---|
| **Item Code (Source)** | NDC:0498-3334 |
| **Route of Administration** | RESPIRATORY (INHALATION) |

**Active Ingredient/Active Moiety**

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **AMMONIA** (UNII: 5138Q19F1X) (AMMONIA - UNII:5138Q19F1X) | AMMONIA | 0.045 g in 0.3 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **ALCOHOL** (UNII: 3K9958V90M) | |

**Packaging**

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:0498-3334-00 | 0.3 mL in 1 AMPULE; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| unapproved drug other | | 09/18/2018 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| unapproved drug other | | 10/18/2018 | |

# 4313 FIRST AID KIT

4313 first aid kit kit

**Product Information**

| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0498-4313 |
|---|---|---|---|

**Packaging**

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:0498-4313-01 | 1 in 1 KIT; Type 0: Not a Combination Product | 10/18/2018 | |

**Quantity of Parts**

| Part # | Package Quantity | Total Product Quantity |
|---|---|---|
| **Part 1** | 20 PACKET | 18 g |
| **Part 2** | 1 PACKET | 1.4 mL |
| **Part 3** | 6 PACKET | 12 |
| **Part 4** | 3 AMPULE | 0.9 mL |

## Part 1 of 4

# FIRST AID BURN

benzalkonium chloride, lidocaine hydrochloride cream

| Product Information | |
|---|---|
| **Item Code (Source)** | NDC:0498-0903 |
| **Route of Administration** | TOPICAL |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **BENZALKONIUM CHLORIDE** (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y) | BENZALKONIUM CHLORIDE | 0.13 g in 100 g |
| **LIDOCAINE HYDROCHLORIDE** (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987) | LIDOCAINE HYDROCHLORIDE | 0.5 g in 100 g |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **ALOE VERA LEAF** (UNII: ZY81Z83H0X) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **STEARIC ACID** (UNII: 4ELV7Z65AP) | |
| **METHYLPARABEN** (UNII: A2I8C7HI9T) | |
| **CETYL ALCOHOL** (UNII: 936JST6JCN) | |
| **GLYCERYL MONOSTEARATE** (UNII: 230OU9XXE4) | |
| **PEG-100 STEARATE** (UNII: YD01N1999R) | |
| **LIGHT MINERAL OIL** (UNII: N6K5787QVP) | |
| **EDETATE DISODIUM** (UNII: 7FLD91C86K) | |
| **TROLAMINE** (UNII: 9O3K93S3TK) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **PROPYLPARABEN** (UNII: Z8IX2SC1OH) | |
| **DIAZOLIDINYL UREA** (UNII: H5RIZ3MPW4) | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | | 0.9 g in 1 PACKET; 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 | part333A | 12/20/2017 | |

## Part 2 of 4

## ANTISEPTIC TOWELETTE

benzalkonium chloride liquid

| Product Information | |
|---|---|
| **Item Code (Source)** | NDC:0498-0501 |
| **Route of Administration** | TOPICAL |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **BENZALKONIUM CHLORIDE** (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y) | BENZALKONIUM CHLORIDE | 1.3 mg in 1 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **WATER** (UNII: 059QF0KO0R) | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:0498-0501-00 | 1.4 mL in 1 PACKET; 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 | 09/18/2018 | |

## Part 3 of 4

## ASPIRIN

aspirin tablet

| Product Information | |
|---|---|
| **Item Code (Source)** | NDC:0498-0114 |
| **Route of Administration** | ORAL |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **ASPIRIN** (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E) | ASPIRIN | 325 mg |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **CELLULOSE, MICROCRYSTALLINE** (UNII: OP1R32D61U) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WJQ0SDW1A) | |
| **STEARIC ACID** (UNII: 4ELV7Z65AP) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **POVIDONE** (UNII: FZ989GH94E) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **CROSCARMELLOSE SODIUM** (UNII: M28OL1HH48) | |
| **HYPROMELLOSE 2208 (100 MPA.S)** (UNII: B1QE5P712K) | |
| **MINERAL OIL** (UNII: T5L8T28FGP) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | white | **Score** | 2 pieces |
| **Shape** | ROUND | **Size** | 10mm |
| **Flavor** | | **Imprint Code** | FR21 |
| **Contains** | | | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:0498-0114-01 | 2 in 1 PACKET; 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 | part343 | 09/18/2018 | |

## Part 4 of 4

## AMMONIA INHALENT

ammonia inhalent inhalant

| Product Information | |
|---|---|
| **Item Code (Source)** | NDC:0498-3334 |
| **Route of Administration** | RESPIRATORY (INHALATION) |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **AMMONIA** (UNII: 5138Q19F1X) (AMMONIA - UNII:5138Q19F1X) | AMMONIA | 0.045 g in 0.3 mL |

| Inactive Ingredients | |
|---|---|
| Ingredient Name | Strength |
| **ALCOHOL** (UNII: 3K9958V90M) | |

| Packaging | | | | |
|---|---|---|---|---|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| **1** | NDC:0498-3334-00 | 0.3 mL in 1 AMPULE; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| unapproved drug other | | 09/18/2018 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| unapproved drug other | | 10/18/2018 | |

## Labeler - Honeywell Safety Products USA, INC (079287321)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| James Alexander | | 040756421 | manufacture(0498-3334) |

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Honeywell Safety Products USA, INC | | 079287321 | pack(0498-4154, 0498-4139, 0498-4313) |

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Ultra Seal Corporation | | 085752004 | manufacture(0498-0114) |

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Water-Jel Technologies | | 155522589 | manufacture(0498-0903) |

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Changzhou Maokang Medical | | 421317073 | manufacture(0498-0501) |