

**4078 FIRST AID KIT- 4078 first aid kit**

**4079 FIRST AID KIT- 4079 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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**4078, 4079 First Aid Kit (FABC, PVP wipes, alcohol wipes - Z019729-0016L, 019729-0016L)**

### **First Aid Burn Cream**

#### ***Active ingredient***

Benzalkonium chloride 0.13%

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

### **Povidone Iodine Swab**

#### ***Active ingredient***

Povidone-iodine solution USP, 10% (equivalent to 1% titratable iodine)

### **Povidone Iodine Swab**

#### ***Purpose***

First aid antiseptic

### **Povidone Iodine Swab**

#### ***Uses***

- first aid to help prevent the risk of infection in minor cuts, scrapes, and burns

### **Povidone Iodine Swab**

#### ***Warnings***

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

#### **Do not use**

- over large areas of the body
- on individuals who are allergic or sensitive to iodine

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

- deep or puncture wounds,
- animal bites

- serious burns

**When using this product**

- do not use longer than one week unless directed by a doctor

**Stop use and ask a doctor if**

- conditions persists or gets worse
- irritation and redness develops

**Keep out of reach of children**

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

**Povidone Iodine Swab*****Directions***

Reverse cardboard sleeve, then crush at dot between thumb and forefinger. Allow solution to saturate tip and apply solution to injury.

- clean affected area
- apply to affected area 1 to 3 times daily
- may be covered with a sterile bandage
- discard swab after single use

**Povidone Iodine Swab*****Other information***

- store at room temperature away from light
- keep from freezing or excessive heat
- do not use if package is torn or open

**Povidone Iodine Swab*****Inactive ingredients***

citric acid, disodium phosphate, nonoxynol-9, sodium hydroxide, water

**Povidone Iodine Swab*****Questions and comments***

1-800-430-5490

**Alcohol Wipe*****Active ingredient***

Isopropyl alcohol 70%

**Alcohol Wipe*****Purpose***

First aid antiseptic

**Alcohol Wipe*****Uses***

- first aid to help prevent infection in minor cuts, scrapes, and burns

## **Alcohol Wipe**

### ***Warnings***

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

#### **Do not use**

- in the eyes
- over large areas of the body

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

- deep or puncture wounds
- animal bites
- serious burn

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

- do not use longer than one week unless directed by a doctor

#### **Stop use and consult a doctor**

- if condition persists or gets worse

#### **Keep out of reach of children**

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

## **Alcohol Wipe**

### ***Directions***

- clean the affected area
- apply wipe to affected area 1 to 3 times daily
- may be covered with a sterile bandage
- discard wipe after single use

## **Alcohol Wipe**

### ***Other information***

store at room temperature 15<sup>0</sup> to 25<sup>0</sup> C (59<sup>0</sup> to 77<sup>0</sup>F)

## **Alcohol Wipe**

### ***Inactive ingredient***

water

## **Alcohol Wipe**

### ***Questions***

1-800-430-5490

**4078**

**Z019729-0016L Kit Contents**

1 FIRST AID BURN CREAM 6 PER  
1 EYE DRESS PKT W/4 ADH STRIPS  
1 TRIANGULAR BDG, NON-STERILE  
1 INSTANT COLD PACK 4" X 6"  
1 BANDAGE COMP, 4" OFFSET, 1 PER  
2 ADHESIVE BDG,PLSTIC,1"X3"16PER  
1 ALCOHOL PREP PADS 10P  
1 PVP IODINE WIPES 10 PER  
1 NITRILE GLOVES 2PR BBP  
1 TWEEZER PLASTICS 4"  
1 FIRST AID GUIDE ASHI  
LBL STOCK 6-3/8"X4"  
LBL STOCK 4"X2-7/8"  
1 LBL STOCK 3"x1-7/8"  
1 LBL CONTS 6 3/4"X3 1/2" ID B  
1 TAPE ADHESIVE 1/2 X 2.5 125133  
1 KIT STL 10 UN WHITE 01  
1 LBL 10U CVR NORTH CONST

**4079**

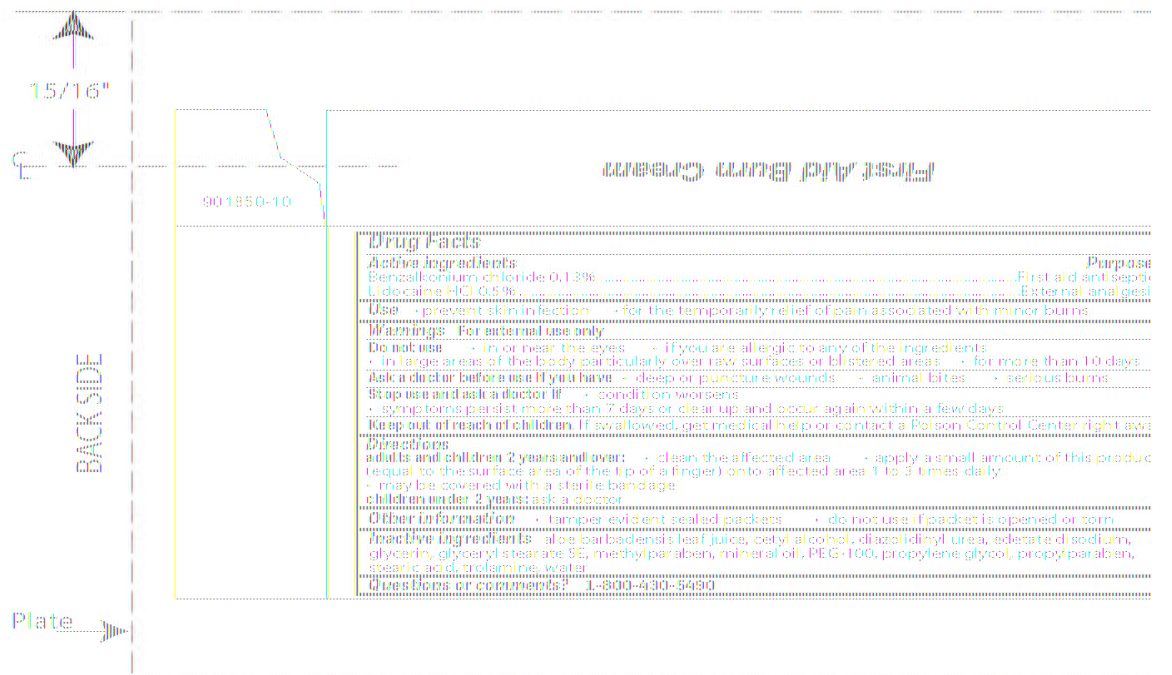
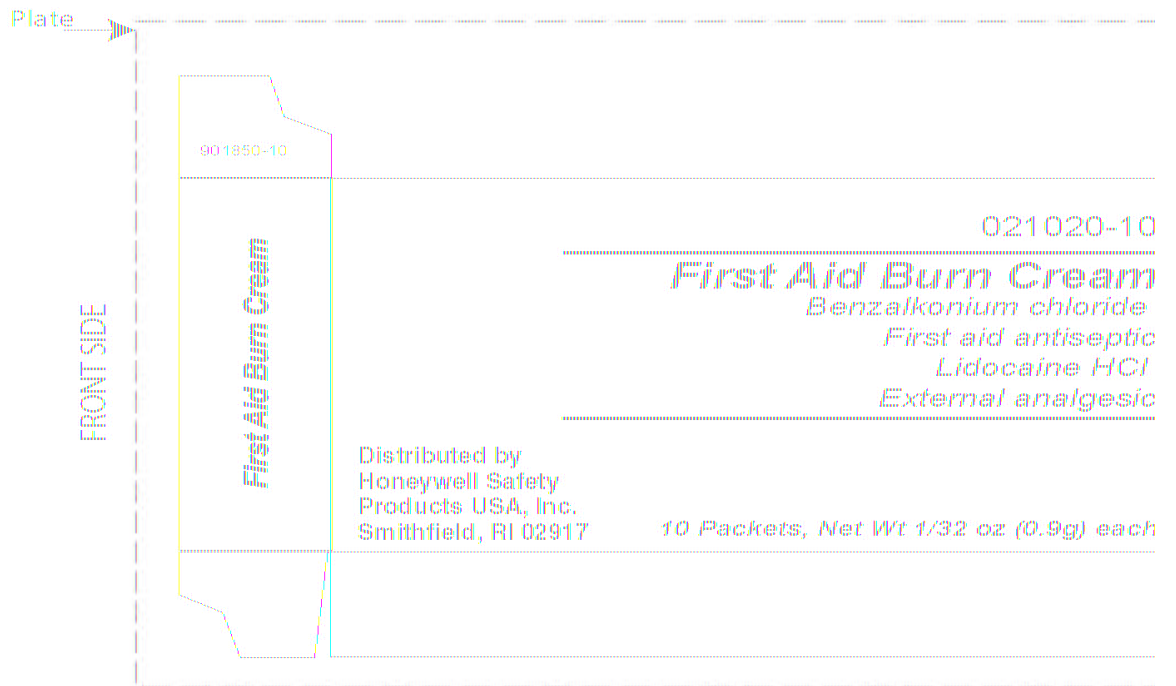
**019729-0016L Kit Contents**

1 FIRST AID BURN CREAM 6 PER  
1 EYE DRESS PKT W/4 ADH STRIPS  
1 TRIANGULAR BDG, NON-STERILE  
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1 LBL STOCK 3"x1-7/8"  
1 LBL NORTH CONTS 6.75X3.5 ID B  
1 TAPE ADHESIVE 1/2 X 2.5 125133

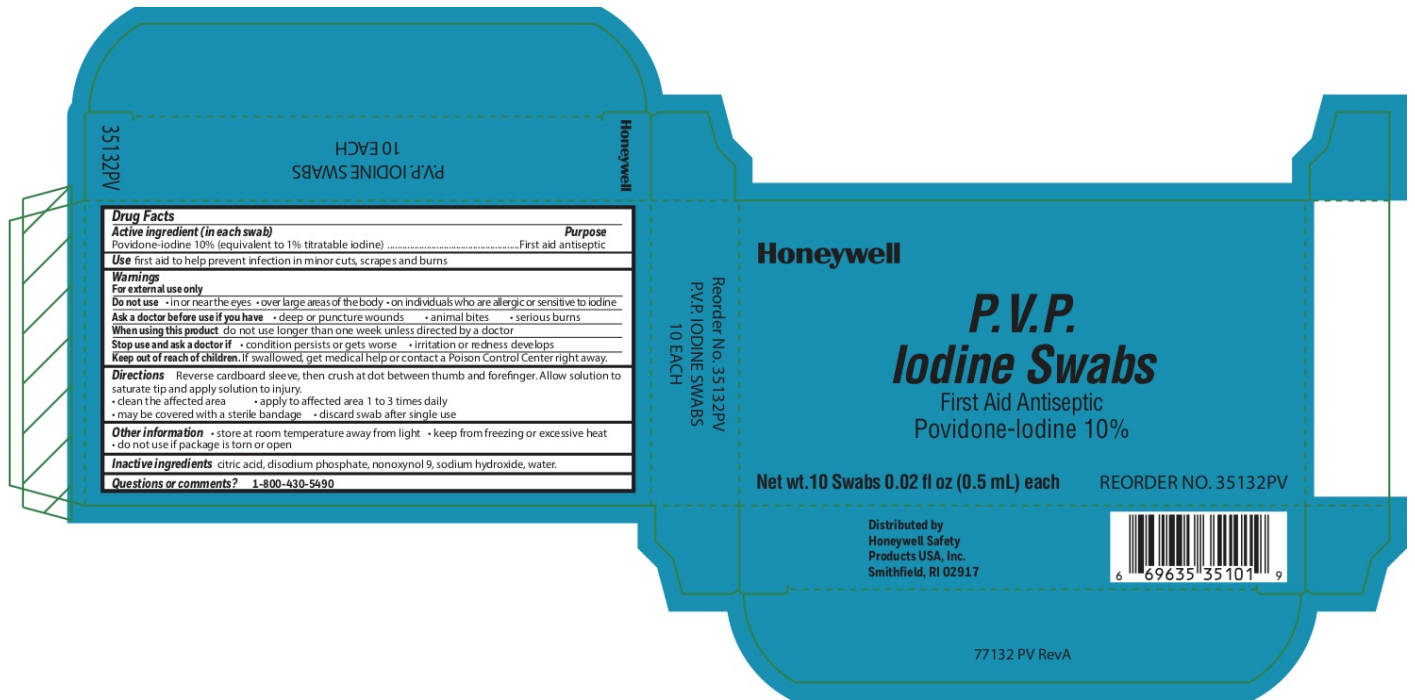
1 KIT STL 10 UN WHITE 01

1 LBL 10U CVR NORTH CONST

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

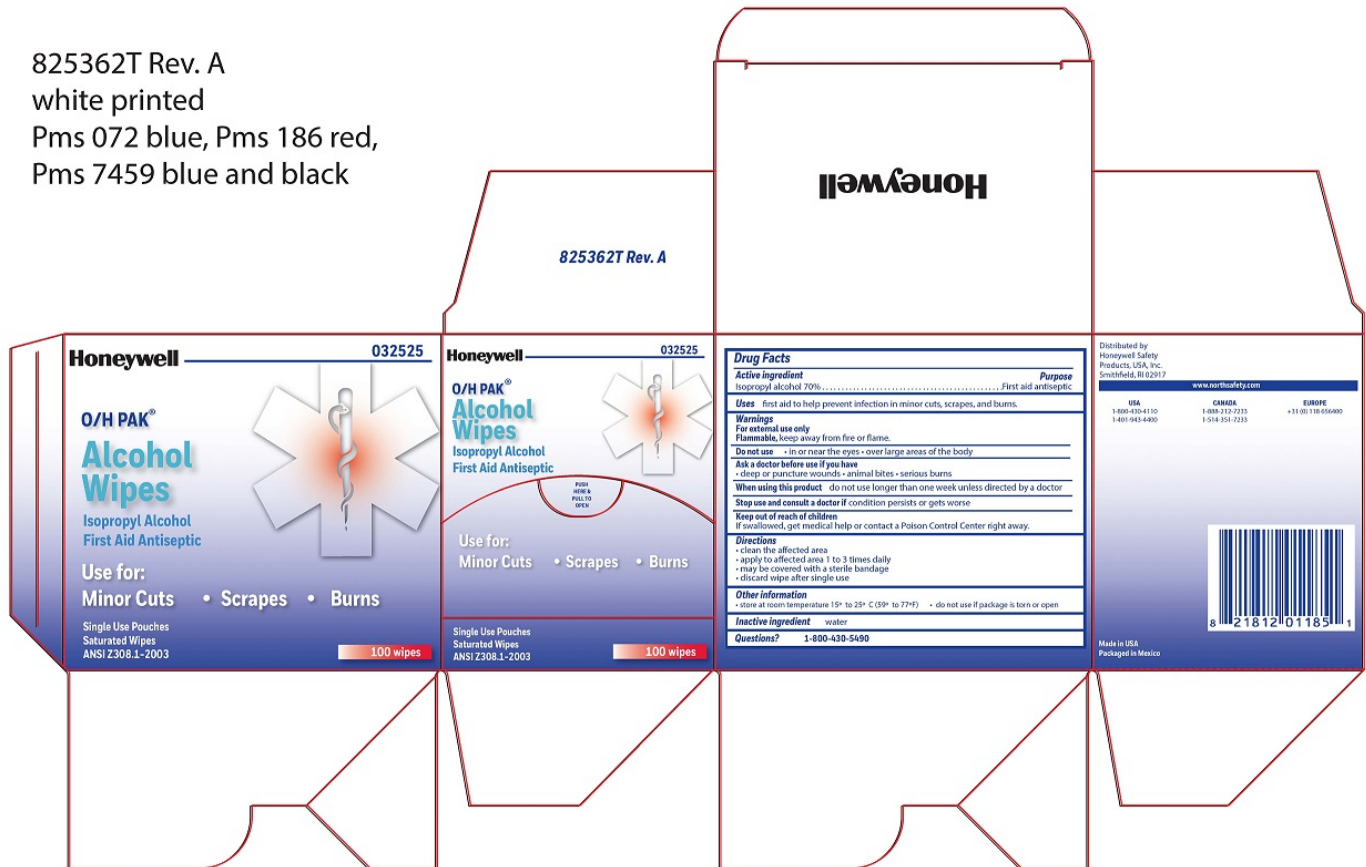


# Principal Display Panel



# Alcohol Wipe Principal Display Panel

825362T Rev. A  
white printed  
Pms 072 blue, Pms 186 red,  
Pms 7459 blue and black



4078 Kit Label  
Z019729-0016L



777039 RA  
white printed 4 color process,  
Pms 072C blue & Pms 186C red



**Honeywell**

**First Aid Kit**

**Construction**

**Unitized**

For Up To 5 People

Meets OSHA 1926.50(d)(2) Requirements for Construction

Latex Free

777039 RA

Distributed by Honeywell Safety Products USA Inc Smithfield, RI02917

The label features a central graphic of a white caduceus (a staff with two snakes entwined around it) set against a large, stylized white Star of Life. The background of the label is a gradient from light blue at the top to dark blue at the bottom. The text is arranged in a clear, hierarchical manner, with the brand name at the top, followed by the product name in large, bold letters. A red banner highlights the capacity, and a yellow box indicates OSHA compliance. A circular logo for 'Latex Free' is also present.

**4079 Kit Label**  
**019729-0016L**

777039 RA  
 white printed 4 color process,  
 Pms 072C blue & Pms 186C red



## 4078 FIRST AID KIT

4078 first aid kit kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0498-4078
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-4078-01	1 in 1 KIT; Type 0: Not a Combination Product	10/18/2018	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	6 PACKET	5.4 g
Part 2	10 POUCH	3 mL
Part 3	10 POUCH	4 mL

## Part 1 of 3

### 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
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 g
<b>LIDOCAINE HYDROCHLORIDE</b> (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE	0.5 g in 100 g

#### Inactive Ingredients

Ingredient Name	Strength
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)	
<b>LIGHT MINERAL OIL</b> (UNII: N6K5787QVP)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>DIAZOLIDINYL UREA</b> (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 3

### PVP IODINE WIPE

povidone-iodine 10% swab

#### Product Information

Item Code (Source) NDC:0498-0121

Route of Administration TOPICAL

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	10 mg in 1 mL

#### Inactive Ingredients

Ingredient Name	Strength
NONOXYNOL-9 (UNII: 48Q180SH9T)	
WATER (UNII: 059QF0KO0R)	

#### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0121-00	0.3 mL in 1 POUCH; 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	

## Part 3 of 3

### ALCOHOL WIPE

isopropyl alcohol swab

#### Product Information

Item Code (Source) NDC:0498-0143

Route of Administration TOPICAL

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	0.7 mL in 1 mL
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### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0143-04	0.4 mL in 1 POUCH; 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	09/18/2018	

### Marketing Information

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

## 4079 FIRST AID KIT

4079 first aid kit kit

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0498-4079
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-4079-01	1 in 1 KIT; Type 0: Not a Combination Product	10/18/2018	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	6 PACKET	5.4 g
Part 2	10 POUCH	3 mL
Part 3	10 POUCH	4 mL

## Part 1 of 3

### 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
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 g
<b>LIDOCAINE HYDROCHLORIDE</b> (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE	0.5 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>METHYL PARABEN</b> (UNII: A2I8C7HI9T)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)	
<b>LIGHT MINERAL OIL</b> (UNII: N6K5787QVP)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PROPYL PARABEN</b> (UNII: Z8IX2SC1OH)	
<b>DIAZOLIDINYL UREA</b> (UNII: H5RIZ3MPW4)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0903-34	10 in 1 BOTTLE, UNIT-DOSE		
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	

## PVP IODINE WIPE

povidone-iodine 10% swab

### Product Information

Item Code (Source) NDC:0498-0121

Route of Administration TOPICAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	10 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
NONOXYNOL-9 (UNII: 48Q180SH9T)	
WATER (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0121-00	0.3 mL in 1 POUCH; 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	

## Part 3 of 3

## ALCOHOL WIPE

isopropyl alcohol swab

### Product Information

Item Code (Source) NDC:0498-0143

Route of Administration TOPICAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	0.7 mL in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0143-04	0.4 mL in 1 POUCH; 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	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
Honeywell Safety Products USA, INC		079287321	pack(0498-4079, 0498-4078)

**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(0498-0143)

**Establishment**

Name	Address	ID/FEI	Business Operations
Sion Biotext Medical		532775194	manufacture(0498-0121)