

**4194 FIRST AID KIT - 4194 first aid kit**  
**4193 FIRST AID KIT - 4193 first aid kit**  
**4205 FIRST AID KIT - 4205 first aid kit**  
**4258 FIRST AID KIT - 4258 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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**4193, 4194, 4205, 4258 First Aid Kit (FABC, Amm Inh, EW, alcohol wipes, PVP wipes - 011565-1725, 019730-0017L, Z019730-0017L)**

### **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

## **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

**Ammonia Inhalent*****Active ingredient (in each ampule)***

Ammonia 15%

**Ammonia Inhalent*****Purpose***

Respiratory stimulant

**Ammonia Inhalent*****Uses***

- to prevent or treat fainting

## **Ammonia Inhalent**

### ***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 right away.

## **Ammonia Inhalent**

### ***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 vapor

## **Ammonia Inhalent**

### ***Other information***

- store at room temperature away from light

## **Ammonia Inhalent**

### ***Inactive ingredients***

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

## **Ammonia Inhalent**

### ***Questions***

1-800-430-5490

## **Eyewash**

### ***Active ingredient***

Sterile Water 99%

## **Eyewash**

### ***Purpose***

Eyewash

## **Eyewash**

### ***Uses***

- for flushing the eye to remove loose foreign material, air pollutants or chlorinated water

## **Eyewash**

### ***Warnings***

**For external use only** Obtain immediate medical treatment for all open wounds in or near eyes. To avoid contamination, do not touch tip of container to any surface. Do not reuse. Once opened, discard.

**Do not use**

- if solution changes color or becomes cloudy
- if you have open wounds in or near the eyes, get medical help right away.

**Stop use and ask a doctor if**

- you experience eye pain
- changes in vision
- continued redness or irritation of the eye
- condition worsens or persists

**Keep out of reach of children**

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

**Eyewash**

***Directions***

- remove contacts before using
- twist top to remove
- flush the affected area as needed
- control rate of flow by pressure on the bottle
- if necessary, continue flushing with emergency eyewash or shower

**Eyewash**

***Inactive ingredients***

sodium chloride, sodium phosphate dibasic, sodium phosphate monobasic

**Eyewash**

***Questions***

1-800-430-5490

**PVP**

***Active Ingredient***

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

**PVP**

***Purpose***

First aid antiseptic

**PVP**

***Uses***

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

**PVP**

***Warnings***

## **For external use only**

### **Do not use**

- in the eyes
- 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

## **PVP**

### ***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

## **PVP**

### ***Other information***

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

## **PVP**

### ***Inactive ingredient***

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

## **PVP**

### ***Questions***

1-800-430-5490

**4193****011565-1725 Kit Contents**

1 FIRST AID BURN CREAM 6 PER  
1 AMMONIA INHALANTS 10 PER  
1 TRIANGULAR BDG, NON-STERILE  
1 GAUZE PADS, 3" X 3", 4 PER  
1 INSTANT COLD PACK 4" X 6"  
2 ADHESIVE BDG,PLSTIC,1"X3"16PER  
1 ADH BAND, EXTRA LARGE, 6 PER  
1 1 OZ EYE WASH W/PADS & STRIPS  
1 ALCOHOL PREP PADS 10P  
1 PVP IODINE WIPES 10 PER  
2 NITRILE GLOVES 2PR BBP  
1 ABD COMBINE PAD 5" X 9"  
LBL STOCK 6-3/8"X4"  
LBL STOCK 4"X2-7/8"  
1 LBL STOCK 3"x1-7/8"  
1 KIT STL 16 UN (VERTICAL)  
1 LABL INSTR FA REV A

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1 ABD COMBINE PAD 5" X 9"  
LBL STOCK 6-3/8"X4"  
LBL STOCK 4"X2-7/8"  
1 LBL STOCK 3"x1-7/8"  
1 KIT STL 16 UN (VERTICAL)

1 LABL INSTR FA REV A

**4205**

**019730-0017L Kit Contents**

1 FIRST AID BURN CREAM 6 PER  
1 AMMONIA INHALANTS 10 PER  
1 EYE DRESS PKT W/4 ADH STRIPS  
1 TRIANGULAR BDG, NON-STERILE  
1 GAUZE PADS, 3" X 3", 4 PER  
1 ADH TAPE, .5" X 2.5 YD, 2 PER  
1 INSTANT COLD PACK 4" X 6"  
1 BUFFERED EYE WASH 1 OZ BTL  
1 BANDAGE COMP, 4" OFFSET, 1 PER  
2 ADHESIVE BDG, PLSTIC, 1" X 3" 16 PER  
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" X 4"  
LBL STOCK 4" X 2-7/8"  
1 LBL STOCK 3" X 1-7/8"  
1 LBL NORTH CONTS 6.75 X 3.5 ID B  
1 KIT STL 16 UN (HORIZONTAL)  
1 LBL 16U CVR NORTH CONST

**4258**

**Z019730--0017L kit contents**

1 FIRST AID BURN CREAM 6 PER  
1 AMMONIA INHALANTS 10 PER  
1 EYE DRESS PKT W/4 ADH STRIPS  
1 TRIANGULAR BDG, NON-STERILE  
1 GAUZE PADS, 3" X 3", 4 PER  
1 ADH TAPE, .5" X 2.5 YD, 2 PER  
1 INSTANT COLD PACK 4" X 6"  
1 BUFFERED EYE WASH 1 OZ BTL  
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"

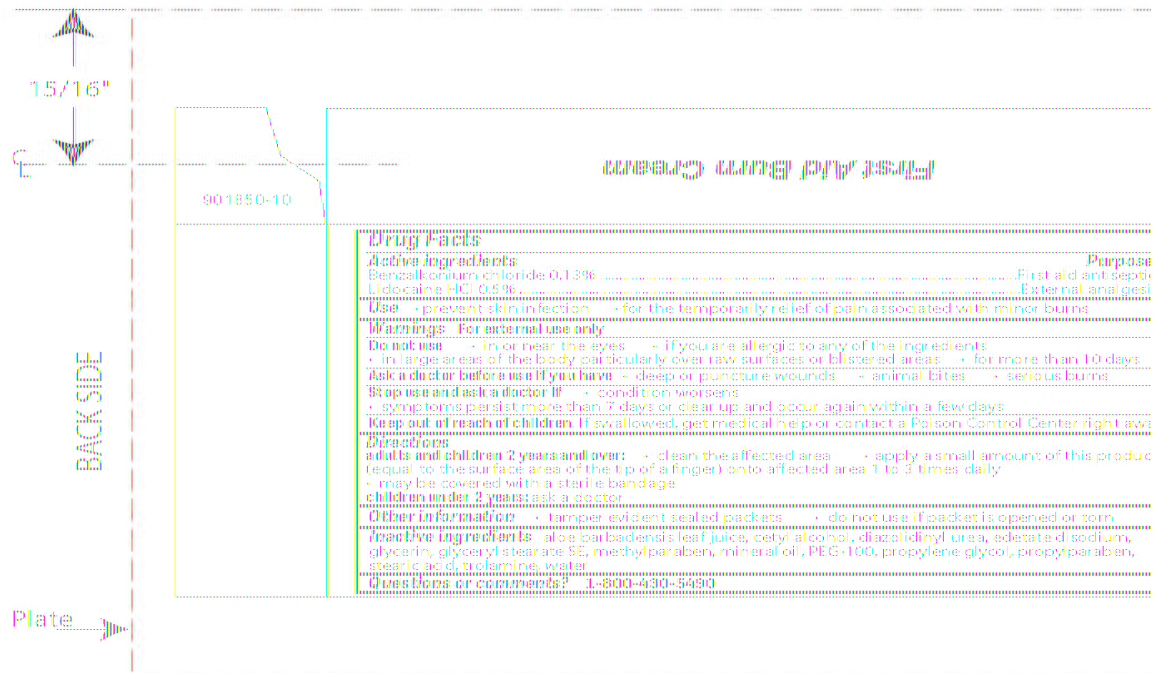
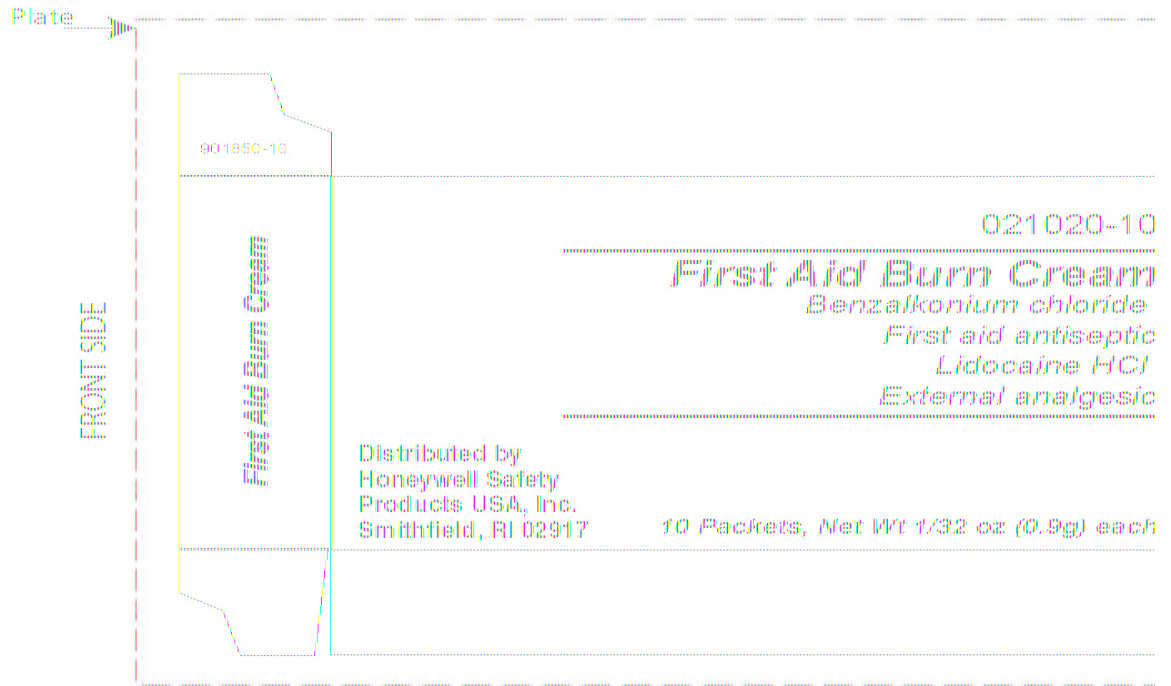
1 LBL STOCK 3"x1-7/8"

1 LBL CONTS 6 3/4"X3 1/2" ID B

1 KIT STL 16 UN (HORIZONTAL)

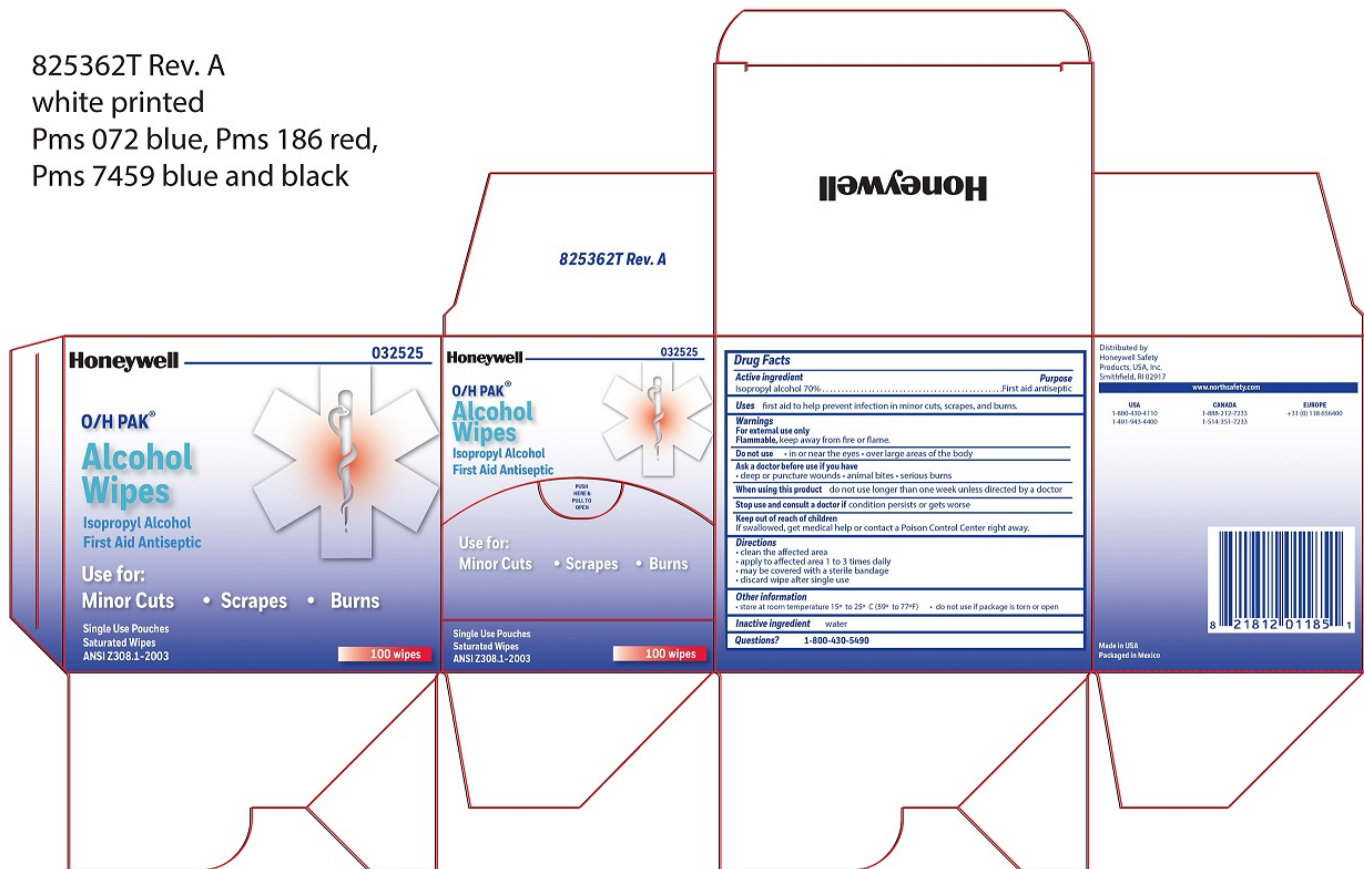
1 LBL 16U CVR NORTH CONST

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



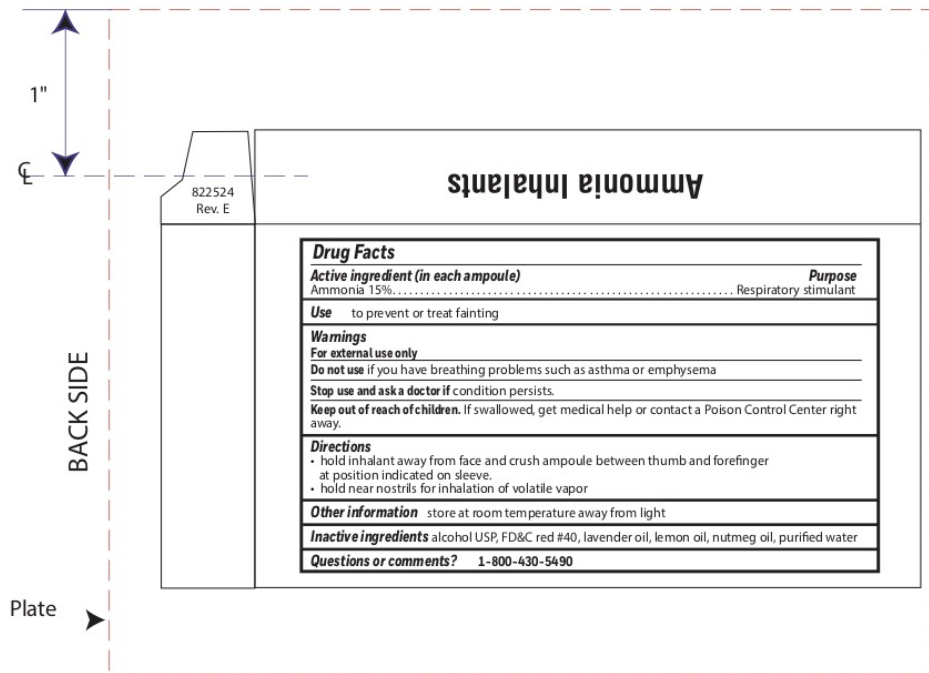
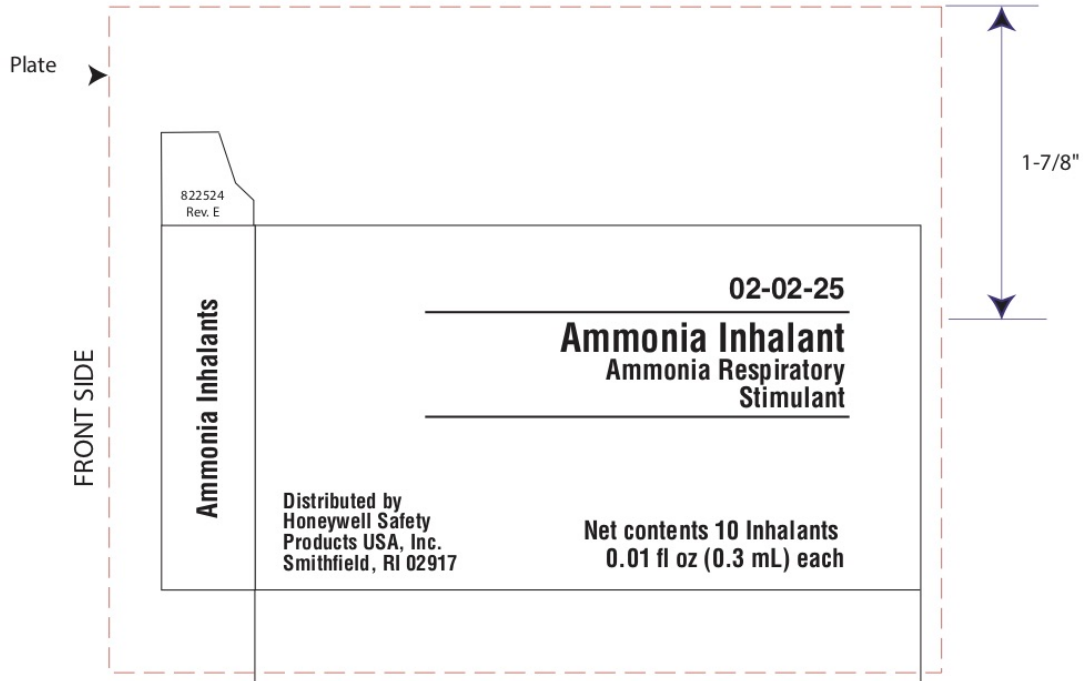
## Principal Display Panel

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



## Ammonia Inhalant Principal Display Panel

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



796006 Rev. E (page 3 of 3)

# Principal Display Panel



TAMPER-EVIDENT CAP.  
TAPA CON SELLO DE SEGURIDAD.  
BOUCHON INDICATEUR D'INFRACTION.

## eyesaline®

**LAVAOJOS  
EYESALINE**

Solución  
Isotónico Estéril

**EYESALINE  
EYEWASH**

Sterile  
Isotonic Solution

**LAVAGE  
OCULAIRE  
EYESALINE**

La Solution  
Isotonique Stérile

**16 fl. oz. (473 mL)**

NPN: 80057528



64809 11 45033 17

**Drug Facts (for USA only)**

<b>Active ingredient</b> Sterile water 99% .....	<b>Purpose</b> Eyewash
<b>Uses</b> for flushing the eye to remove loose foreign material, air pollutants, or chlorinated water.	
<b>Warnings</b> <b>For external use only</b> - Obtain immediate medical treatment for all open wounds in or near the eyes. To avoid contamination, do not touch tip of container to any surface. Do not reuse. Once opened, discard.	
<b>Do not use</b> • if solution changes color or becomes cloudy • if you have open wounds in or near the eyes, get medical help right away	
<b>Stop use and consult a doctor if:</b> • you experience eye pain • changes in vision • continued redness or irritation of the eye • condition worsens or persists	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> • remove contacts before using • twist top to remove • flush the affected area as needed • control rate of flow by pressure on the bottle • if necessary, continue flushing with emergency eyewash or shower	
<b>Inactive ingredients</b> sodium chloride, sodium phosphate dibasic, sodium phosphate monobasic	
<b>Questions?</b> Call 1-800-430-5490 Honeywell Safety Products USA, Inc. Smithfield, RI. 02917	

space for lot code and supplier part number

PEEL / PELAR / PELER

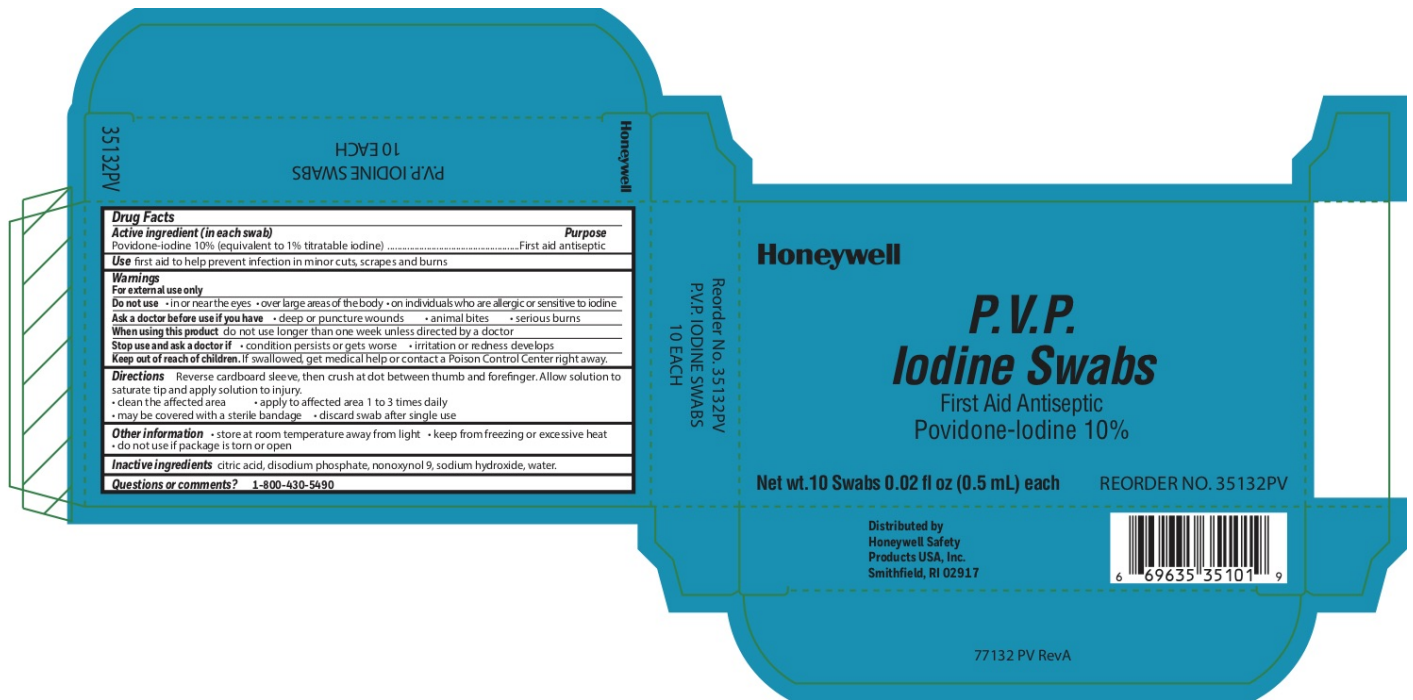
### Datos de medicamento (Para EE.UU. solamente)

<b>Ingrediente Activo</b> Agua estéril 99% .....	<b>Propósito</b> Lavaojos
<b>Usos</b> para el lavado de ojo para quitar las partículas sueltas y extrañas, los contaminantes aéreos, o agua de cloruro.	
<b>Advertencias</b> <b>Para el uso externo sólo</b> - Obtenga tratamiento médico inmediato para todas las heridas abiertas en o cerca de los ojos. Para evitar la contaminación, no toque la punta del envase con ninguna superficie. No vuelva a usar. Vez abierto, descarte. <b>No se use</b> • si la solución se enturbia o cambia de color • si tiene heridas abiertas en o cerca del ojo, obtenga ayuda médica de inmediato	
<b>Deje de usar y consulte a un médico si:</b> • experimenta dolor de ojo • cambio de visión • rojez continuo o irritación del ojo • la condición empeora o persiste	
<b>Manténgase fuera del alcance de los niños.</b> En caso de ingestión accidental, obtenga atención médica o llame a un Centro de control de envenenamiento inmediatamente.	
<b>Instrucciones</b> • quite los lentes de contacto antes de usar la solución • tuerza la tapa para quitar • enjuague el área afectada según se necesite • controle el chorro haciendo presión en la botella • si es necesario, sigue enjuagado con un lavaojos o ducha de emergencia	
<b>Ingredientes inactivos</b> cloruro de sodio, fosfato de sodio dibásico, fosfato de sodio monobásico	
<b>¿Preguntas?</b> Llame al 1-800-430-5490 Honeywell Safety Products USA, Inc. Smithfield, RI. 02917	

### Information

<b>Usages</b> Pour le rinçage des yeux afin d'enlever un corps étranger, des polluants atmosphériques ou de l'eau chlorée.
<b>Advertissements</b> <b>Pour usage externe seulement</b> - Obtenir immédiatement des soins médicaux pour toutes les plaies ouvertes dans ou près des yeux. Pour éviter toute contamination, ne pas toucher la pointe du récipient à n'importe quelle surface. Ne pas réutiliser. Une fois ouvert, jetez-les. <b>Ne pas utiliser</b> • si la solution a changé de couleur ou si elle est brouillée • si vous avez des plaies ouvertes aux yeux ou à proximité, consultez immédiatement un médecin
<b>Cesser d'utiliser la solution et consulter un médecin</b> • vous ressentez une douleur oculaire • si votre vision change • rougeur ou irritation persistante des yeux • condition empire ou persiste
<b>Garder hors de la portée des enfants.</b> En cas d'ingestion, communiquer immédiatement avec un médecin ou avec un centre antipoison.
<b>Mode d'emploi</b> • enlever les verres de contact avant l'utilisation • dévisser le bouchon pour l'enlever • rincer la zone touchée selon les besoins • ajuster le débit d'écoulement de la solution en augmentant ou en réduisant la pression exercée sur le contenant • si nécessaire, continuer de rincer avec une solution de rinçage oculaire d'urgence ou une douche
<b>Ingredients</b> eau stérile, chlorure de sodium, phosphate dibasique de sodium, phosphate monobasique de sodium
<b>Des questions?</b> Faites le 1-800-430-5490 Honeywell Safety Products USA, Inc. Smithfield, RI. 02917

# PVP Principal Display Panel



4193 Kit Label  
011565-1725

# Honeywell

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# First Aid Kit

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

**4194 Kit Label**  
**011565-1725**

**Honeywell**

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***First Aid Kit***



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

**4205 Kit Label**  
**019730-0017L**



777040 RA  
white printed 4 color process,  
Pms 072C blue & Pms 186C red



**Honeywell**

**First Aid Kit**

**Construction**

**Unitized**



**For Up To 8 People**

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

**Latex Free**

777040 Rev. A

Distributed by Honeywell Safety Products USA, Inc Smithfield, RI02917

**4258 Kit Label**  
**Z019730-0017L**

777040 RA  
 white printed 4 color process,  
 Pms 072C blue & Pms 186C red

## 4194 FIRST AID KIT

4194 first aid kit kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0498-4194
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-4194-01	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 AMPULE	3 mL
Part 3	1 BOTTLE	30 mL
Part 4	10 POUCH	4 mL
Part 5	10 POUCH	3 mL

## Part 1 of 5

### 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 5

### 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	

## Part 3 of 5

### EYESALINE EMERGENCY EYEWASH

purified water liquid

#### Product Information

Item Code (Source)	NDC:0498-0100
Route of Administration	OPHTHALMIC

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>WATER</b> (UNII: 059QF0KO0R) (WATER - UNII:059QF0KO0R)	WATER	98.6 mL in 100 mL
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### Inactive Ingredients

Ingredient Name	Strength
<b>SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE</b> (UNII: 593YOG76RN)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>SODIUM PHOSPHATE, DIBASIC</b> (UNII: GR686LBA74)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0100-01	30 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
OTC monograph final	part349	12/18/2018	

### Part 4 of 5

### ALCOHOL WIPE

isopropyl alcohol swab

### Product Information

<b>Item Code (Source)</b>	NDC:0498-0143
<b>Route of Administration</b>	TOPICAL

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (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	

## Part 5 of 5

### 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: 059QF0K00R)	

## 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	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/18/2018	10/19/2018

## 4193 FIRST AID KIT

4193 first aid kit kit

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0498-4193
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**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-4193-01	1 in 1 KIT; Type 0: Not a Combination Product	10/18/2018	

**Quantity of Parts**

Part #	Package Quantity	Total Product Quantity
Part 1	10 POUCH	4 mL
Part 2	10 POUCH	3 mL
Part 3	6 PACKET	5.4 g
Part 4	10 AMPULE	3 mL
Part 5	1 BOTTLE	30 mL

**Part 1 of 5****ALCOHOL WIPE**

isopropyl alcohol swab

**Product Information**

<b>Item Code (Source)</b>	NDC:0498-0143
<b>Route of Administration</b>	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	

## Part 2 of 5

### 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 5

### FIRST AID BURN

benzalkonium chloride, lidocaine hydrochloride cream

## Product Information

Item Code (Source)	NDC:0498-0903
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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 4 of 5

### AMMONIA INHALENT

ammonia inhalent inhalant

### Product Information

Item Code (Source)	NDC:0498-3334
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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	

## Part 5 of 5

### EYESALINE EMERGENCY EYEWASH

purified water liquid

### Product Information

Item Code (Source)	NDC:0498-0100
Route of Administration	OPHTHALMIC

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
WATER (UNII: 059QF0KO0R) (WATER - UNII:059QF0KO0R)	WATER	98.6 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0100-01	30 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
OTC monograph final	part349	12/18/2018	

**Marketing Information**

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

**4205 FIRST AID KIT**

4205 first aid kit kit

**Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0498-4205
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**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-4205-01	1 in 1 KIT; Type 0: Not a Combination Product	03/14/2019	

**Quantity of Parts**

Part #	Package Quantity	Total Product Quantity
Part 1	6 PACKET	5.4 g
Part 2	10 AMPULE	3 mL
Part 3	1 BOTTLE	30 mL
Part 4	10 POUCH	4 mL
Part 5	10 POUCH	3 mL

**Part 1 of 5****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>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 5****AMMONIA INHALENT**

ammonia inhalent inhalant

**Product Information**

<b>Item Code (Source)</b>	NDC:0498-3334
<b>Route of Administration</b>	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	

**Part 3 of 5****EYESALINE EMERGENCY EYEWASH**

purified water liquid

**Product Information**

Item Code (Source)	NDC:0498-0100
Route of Administration	OPHTHALMIC

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
WATER (UNII: 059QF0K00R) (WATER - UNII:059QF0K00R)	WATER	98.6 mL in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0100-01	30 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
OTC monograph final	part349	12/18/2018	

## Part 4 of 5

### 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	

## Part 5 of 5

### PVP IODINE WIPE

povidone-iodine 10% swab

**Product Information**

Item Code (Source)	NDC:0498-0121
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Route of Administration	TOPICAL
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**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: 059QF0K00R)	

**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	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/14/2019	

**4258 FIRST AID KIT**

4258 first aid kit kit

**Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0498-4258
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**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-4258-01	1 in 1 KIT; Type 0: Not a Combination Product	03/14/2019	

## Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	6 PACKET	5.4 g
Part 2	10 AMPULE	3 mL
Part 3	1 BOTTLE	30 mL
Part 4	10 POUCH	4 mL
Part 5	10 POUCH	3 mL

## Part 1 of 5

### 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
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1	0.9 g in 1 PACKET; Type 0: Not a Combination Product		
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## 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 5

### 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	

## Part 3 of 5

### EYESALINE EMERGENCY EYEWASH

purified water liquid

**Product Information**

<b>Item Code (Source)</b>	NDC:0498-0100
<b>Route of Administration</b>	OPHTHALMIC

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>WATER</b> (UNII: 059QF0K00R) (WATER - UNII:059QF0K00R)	WATER	98.6 mL in 100 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE</b> (UNII: 593YOG76RN)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>SODIUM PHOSPHATE, DIBASIC</b> (UNII: GR686LBA74)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:0498-0100-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part349	12/18/2018	

**Part 4 of 5****ALCOHOL WIPE**

isopropyl alcohol swab

**Product Information**

<b>Item Code (Source)</b>	NDC:0498-0143
<b>Route of Administration</b>	TOPICAL

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
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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	

### Part 5 of 5

### 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	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/14/2019	

**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(0498-4193, 0498-4194, 0498-4205, 0498-4258)

## Establishment

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

## Establishment

Name	Address	ID/FEI	Business Operations
Honeywell Safety Products USA, Inc.		167518617	manufacture(0498-0100)

## Establishment

Name	Address	ID/FEI	Business Operations
Changzhou Maokang Medical		421317073	manufacture(0498-0143)

## Establishment

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

Revised: 4/2019

Honeywell Safety Products USA, INC