#### 4271 FIRST AID KIT- 4271 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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4271 First Aid Kit (ammonia inh, EW, alcohol wipes, Burn Sray, Antiseptic Spray, BZK wipe, triple, sting relief- SF00001088)

#### **Eyes aline**

Active ingredient

Sterile Water 99%

### **Eyes aline**

Purpose

Eyewash

#### **Eyes aline**

Uses

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

#### **Eyes aline**

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.

#### **Eyes aline**

#### **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

#### **Eyes aline**

#### **Inactive ingredients**

sodium chloride, sodium phosphate dibasic, sodium phosphate monobasic

# Eyes aline *Questions*

1-800-430-5490 Honeywell Sadety Products USA, Inc. Smithfield, RI 02917

#### 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  $^{0}$  to 25  $^{0}$  C (59  $^{0}$  to 77  $^{0}$ F)

#### Alcohol Wipe Inactive ingredient

water

# Alcohol Wipe Questions

1-800-430-5490

# Antis eptic Spray Active ingredient

Benzalkonium chloride 0.13%

#### Antis eptic Spray Purpose

First aid antiseptic

## Antis eptic Spray

Uses

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

# Antis eptic Spray *Warnings*

#### For external use only

#### Do not use

- in or near the eyes
- over large areas of the body

#### 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

• the condition persists or gets worse

#### Keep out of reach of children

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

#### **Antiseptic Spray**

#### **Directions**

- clean the affected area
- spray a small amount of this product on the area 1 to 3 times daily
- may be covered with a sterile bandage
- if bandaged, let dry first

# Antis eptic Spray

### Other information

- shake well
- store at room temperature 15  $^{0}$ -30  $^{0}$  C (59  $^{0}$  -86  $^{0}$  F)

# Antis eptic Spray *Inactive ingredients*

diazolidinyl urea, edetate disodium, glycerin, hypromellose, methylparaben, octoxynol 9, propylene glycol, propylparaben, trolamine, water

# Antis eptic Spray Questions

1-800-430-5490

# Burn Spray Active ingredient

Benzethonium chloride 0.2% w/w

Benzocaine 10% w/w

Menthol 0.33% w/w

### Burn Spray Purpose

Benzethonium chloride 0.2% w/w

Benzocaine 10% w/w

Menthol 0.33% w/w

#### **Burn Spray**

#### **U**ses

for the temporary relief of pain and itching and helps protect against infection in:

- minor cuts and scrapes
- burns
- sunburn
- insect bites
- minor skin irritations

### **Burn Spray**

**Warnings** 

#### For external use only

#### **Flammable**

- keep away from fire or flame
- contents under pressure
- do not puncture or incinerate container
- do not expose to temperatures above 120 0 F

#### Do not use

- in or near the eyes or other mucous membranes
- in case of serious burns
- in case of deep or puncture wounds
- for prolonged period of time
- on large portion of the body

#### Stop use and ask a doctor if

- condition worsens or symptoms persist for more than 7 days
- condition clears up and recurs within a few days
- redness, swelling, or irritation occurs

#### Keep out of the reach of children

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

#### **Burn Spray**

#### Directions

- clean the affected area
- shake can well before using
- hold 4 6 inches from surface and spray area until wet
- may be covered with a sterile bandage, if bandaged let dry first
- for adult institutional use only
- not intended for use on children

#### **Burn Spray**

#### Other information

- avoid inhaling
- use only as directed
- intentional misuse by deliberately concentrating or inhaling the contents may be harmful or fatal

#### **Burn Spray**

#### **Inactive ingredients**

dipropylene glycol, isobutane, n-butane, propane

#### 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 right away.

#### 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 vapor

#### **Ammonia**

#### Other information

• store at room temperature away from light

#### **Ammonia**

#### **Inactive ingredients**

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

#### Ammonia

**Questions or Comments?** 

#### **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

#### Stop use and ask a doctor if

- if irritation, redness or other symptoms develop
- the condition persists or gets worse

#### Keep out of reach of children

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

#### **BZK**

#### **Directions**

• tear open packet and use as a washcloth

#### **BZK**

#### Other information

- store at room temperature 15  $^{0}$  to 30  $^{0}$  C (59  $^{0}$  8  $^{0}$ 6 F)
- do not reuse towelette

#### **BZK**

#### **Inactive** ingredient

water

#### **BZK**

#### **Questions**

1-800-430-5490

#### **Sting Relief**

Active ingredient (in each wipe)

Ethyl alcohol 50.0%

Lidocaine HCl 2.0%

### **Sting Relief**

#### **Purpose**

Antiseptic

Topical pain relief

#### **Sting Relief**

#### Uses

• prevent infection in minor scrapes, and temporary relief of itching of insect bites

#### Keep out of reach of children.

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

#### **Sting Relief**

**Warnings** 

#### For external use only

#### Flammable, keep away from open fire or flame

#### Do not use

- over large areas of the body
- in eyes
- over raw or blistered areas

#### Stop use and ask a doctor

• if conditions worsen or persist for more than 7 days or clear up and occur again within a few days

#### **Sting Relief**

#### Directions

- adults and children 2 years and older: Apply to cleaned affected area not more than 3 times daily.
- children under 2 years of age: consult a doctor.

#### **Sting Relief**

#### **Inactive ingredient**

benzalkonium chloride, menthol, and purified water

#### **Sting Relief**

**Questions or Comments?** 

#### **Triple**

#### Active ingredient (each gram contains)

Bacitracin zinc 400 units

Neomycin sulfate (5 mg equivalent to 3.5 mg Neomycin base)

Polymyxin B sulfate 5000 units

#### **Triple**

#### Purpose

First aid antibiotic

First aid antibiotic

First aid antibiotic

### Triple

#### Uses

first aid to help prevent infection in

- minor cuts
- scrapes
- burns

#### Triple

#### **Warnings**

#### For external use only

**Allergy alert** do not use if you are allergic to any of the ingredients

#### Do not use

- in the eyes
- over large areas of the body

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

- a deep or puncture wounds
- animal bites
- serious burns

#### Stop use and ask a doctor if

- the condition persists or gets worse
- a rash or other allergic reaction develops
- you need to use longer than 1 week

#### Keep out of the reach of children

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

# Triple

**Directions** 

- clean the affected area
- apply a small amount of the product (an amount equal to the surface area of the tip of a finger) on the area 1 to 3 times daily
- may be covered with a sterile bandage

#### Triple

### Other information

- store at 15  $^{0}$  to 25  $^{0}$  C (59  $^{0}$  to 77  $^{0}$  F)
- tamper evident sealed packets
- do not use if packet is torn or opened

# Triple Inactive ingredient

petrolatum

# Triple Questions

1-800-430-5490

#### 4271

#### SF00001088 Kit Contents

- 1 3/4 X 3 PLAS 100/BOX
- 1 1X3 PLASTIC 100/BOX
- 1 FINGERTIP "T" WOVEN 40/BOX
- 1 1X3 WOVEN SING 50/BOX
- 1 SWIFT KNUCKLE 40/BX
- 1 AMMONIA INHALANTS 10 PER
- 1 EYE DRESS PKT W/4 ADH STRIPS
- 1 INSTANT COLD PACK 4" X 6"
- 1 ELASTIC TAPE 1" X 5YD
- 1 O/H TAPE ADHESIVE TRI-CUT
- 1 O/H PUMP ANTISEPTIC 2 OZ ID F
- 1 O/H PUMP BURN RELIEF 2 OZ ID G
- 1 FIRST AID GUIDE ASHI
- 4 GAUZE CLEAN-WRAP BDGE N/S 2"
- 2 BLOODSTOPPER
- 1 NON ADHERENT PADS 2"X3" 50'S
- 2 GZE PADS STERILE 2"X 2" 25'S
- 1 GZE PADS STERILE 4"X 4" 25'S
- 1 CO-FLEX BANDAGE 2"X 5YDS TAN
- 2 CPR FILTERSHIELD 77-100

- 1 COTTON TIPS 100 PER VIAL
- 2 ANTISEPTIC WIPES BZK CHL 20'S
- 1 ALCOHOL WIPES 50'S
- 1 TRIPLE BIOTIC .5 GRAM PKT 20
- 1 4OZ BFS EYEWASH TRILINGUAL BOTTLE
- 1 SCISSOR BDGE 4" RED PLS HDL
- 1 KIT TWEEZER 3 1/2" SLANTED
- 1 180 EMPTY BLANK NO LOGO
- 1 POCKET INSERT RED #180 KIT 4R
- 1 TONGUE BLADES SR WRAPPED 6'S
- 1 LBL STOCK 6-3/8"X4"
- 1 LBL STOCK 4"X2-7/8"
- 1 LBL STOCK 3"x1-7/8"
- 2 PR LRG NITRILE GLVES ZIP BAG
- 10 SAFETEC STING RELIEF WIPES BULK
- 2 TRI BNDG NON WOVEN 40"X40"X56"
- 1 RED BIO BAGS 2/BX

Eyes aline Principal Display Panel





#32-000454-0000 RÉAPPROVISIONNEMENT REORDER #32-004510 Rev. J

Datos de medicamento (Para EE.UU. solamente) Propósito Ingrediente Activo Agua estéril 99% ....... Usos para el lavado de ojo para quitar las particulas sueltas y extrañas, los contaminantes aeros, o agua de cloruro Advertencias
Para el uso externo sólo - 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
inguna superficie. No vuelva a usar. Vez abierto, descarte. No se use • si la solución se enturbia o cambia de color • si tiene heridas abiertas en o cerca del ojo, obtenga ayuda medica de inmediato de inmediato

Deje de usar y consulte a un médico si:

• experimenta dolor de ojo
• cambio de visión
• rojez continuo o irritación del ojo
• la condición empecra o persiste

Manténgase fuera del alcance de los niños.
En caso de ingestión accidental, obtenga atención médica o llame a un Centro de control de envenenamiento inmediatamente. Instrucciones

- quitese 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 el la botella
- si es necesario, sigue enjuagado con un lavaojos o ducha de emergencia Ingredientes inactivos cloruro de sodio, fosfato de sodio dibásico, fosfato de sodio monobásico. ¿Preguntas? Llame al 1-800-430-5490

#### Information

Usages
Pour le rinçage des yeux afin d'enlever un corps étranger, des polluants atmospheriques où de l'eau chlorée.

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

Advertissements

Pour usage externs seulement - 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, jetze-jes.

Ne pas utiliser

• 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

Cesser d'utiliser la solution et consulter un médecin

• vous ressentez une douleur oculaire • si votre vision change

• rougeur ou inflation persistante des yeux

• condition empire ou persiste

Garder hors de la portée des enfants.
En cas d'ingestion, communiquer immédiatement avec un médecir ou avec un centre antipoison.

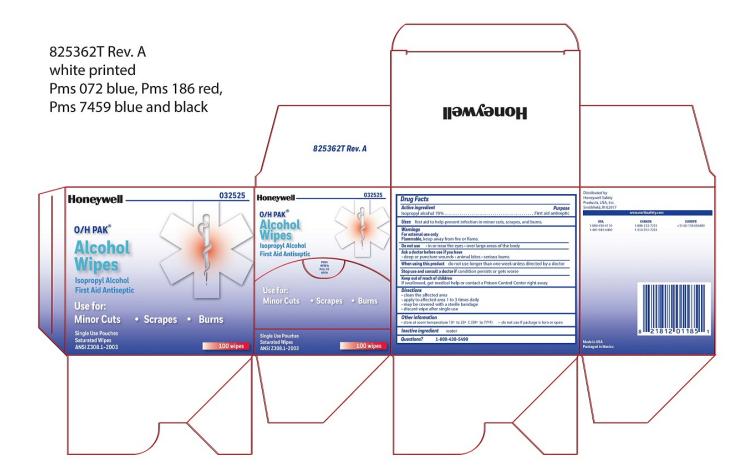
Mode d'emploi

• enlever les verres de contact avant l'utilisation • dévisser le bouchon pour l'enlever • incer la zone touchée selon les besoins • ajuster le debt d'écoulement de la solution en partier le confirment de la solution en contenant et inécessaire, continuer de rincer avec unesolution de rinçage oculaire d'urgence ou une douche

Ingrédients eau stérile, chlorure de sodium, phosphate dibasique de sodium, phosphate monobasique de sodium

Des questions? Faites le 1-800-430-5490 Honeywell Safety Products USA, Inc. Smithfield, RI. 02917

Alcohol Wipe **Principal Display Panel** 



#### Antis eptic Spray Principal Display Panel



SHAKE WELL BEFORE USING Honeywell **BURN SPRAY** Water soluble Benzethonium chloride Topical antiseptic Benzocaine Topical anesthetic Menthol Topical anesthetic Provides antiseptic treatment and helps relieve the pain of minor burns and sunburn. CAUTION: FLAMMABLE Contents under pressure Read warning on back panel. NET WT. 3 OZ (85gm.)

Cat. No. 201005

#### DRUG FACTS Active ingredients Purpose Benzethonium chloride 0.2% w/w. Benzocaine 10% w/w. Topical antiseptic Topical anesthetic Topical anesthetic Uses • for the temporary relief of pain and itching and helps to protect against infection in minor cuts and scrapes burns sunburn insect bites minor skin irritations Warnings Flammable • keep away from fire or flame • do not puncture or incinerate container • do not expose to temperatures above 120°F Do not use • in or near eyes or other mucus membranes • in case of serious burns • in case of deep or puncture wounds • for a prolonged period of time · on large portion of the body Stop use and ask a doctor if: · conditions worsens or symptoms persist for more than 7 days · condition clears up and recurs within a few days redness, swelling or irritation occurs Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. Directions . clean the affected area . shake can well before using . hold 4-6 inches from surface and spray area until wet may be covered with a sterile bandage. If bandaged, let dry first for adult institutional use only not intended for use on children Other information • avoid inhaling • use only as directed • intentional misuse by deliberately concentrating and inhaling the contents may be harmful

Inactive ingredients dipropylene glycol, isobutane, n-butane, propane

Questions or comments? 1-800-430-5490

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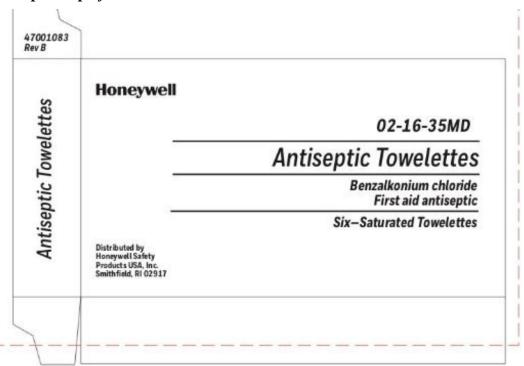


Ammonia Principal Display Panel

47.0306

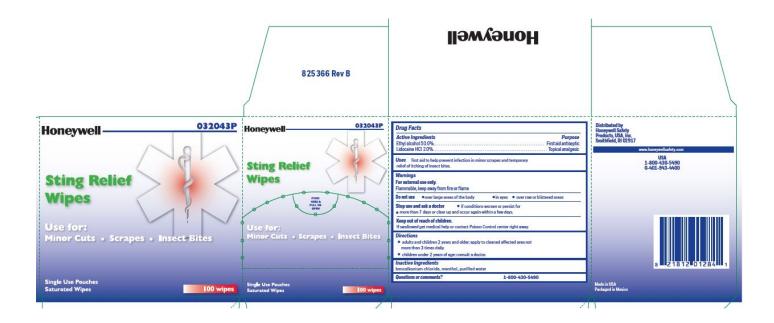
796006 Rev. E (page 3 of 3)

# Principal Display Panel

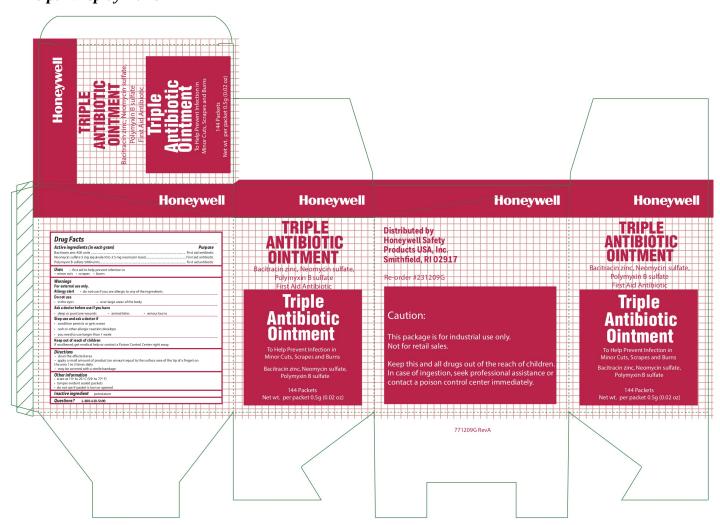


47001083 Rev B	- Antiseptic Towelettes	Honeywell
	Drug Facts	٦
	Active Ingredient Purpose Benzalkonium chloride 0.133% w/v First aid antiseptic	
	Uses • antiseptic cleaning of face, hands and body without soap and water. • air dries in seconds	1
	Warnings For external use only	7
	When using this product • do not use in the eyes or apply overlarge areas of the body	
	Ask a doctor before use  In case of deep or puncture wounds, animal bites, or serious burns  Stop use and consult a doctor if Irritation, redness or other symptoms develop  ocnolition persists or gets worse	1
	Do not use ● longer than I week unless directed by doctor	П
	Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	4
	Directions • tear open packet, unfold and use as washcloth  Other Information • store at room temperature 15° -30° C(59° -86° F) • do not reuse towelette	1
	Inactive ingredient water	٦
	Questions or comments 1-800-430-5490	1

Sting Relief Principal Display Panel



Triple Principal Display Panel





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#### **4271 FIRST AID KIT**

4271 first aid kit kit

P	ro	d	u	ct	Inf	O	rma	tion	ı
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:0498-4271

	Packaging						
:	# Item Code	Package Description	Marketing Start Date	Marketing End Date			
	1 NDC:0498-4271-01	1 in 1 KIT; Type 0: Not a Combination Product	10/18/2018				

Quant	tity of Parts				
Part #	Package Quantity	Total Product Quantity			
Part 1	10 AMPULE	3 mL			
Part 2	1 BOTTLE	118 mL			
Part 3	50 POUCH	20 mL			
Part 4	1 BOTTLE, SPRAY	59 mL			
Part 5	1 BOTTLE, SPRAY	59 mL			
Part 6	20 PACKET	10 g			
Part 7	40 PACKET	56 mL			
Part 8	10 POUCH	4 mL			

# Part 1 of 8

## **AMMONIA INHALENT**

ammonia inhalent inhalant

<b>Product Information</b>	oduct Information			
Item Code (Source)	NDC:0498-3334			
Route of Administration	RESPIRATORY (INHALATION)			

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
<b>AMMO NIA</b> (UNII: 5138 Q 19 F1X) (AMMO NIA - UNII:5138 Q 19 F1X)	AMMO NIA	0.045 g in 0.3 mL			

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

l	Packaging							
l	#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>			
l	1 N	DC: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 2 of 8

#### **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: 0590	)F0KO0R) (WATER - UNII:059QF0KO0R)	WATER	98.6 mL in 100 mL

#### **Inactive Ingredients**

Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SO DIUM PHO SPHATE, DIBASIC (UNII: GR686LBA74)	

**SODIUM PHO SPHATE, MO NO BASIC, MO NO HYDRATE** (UNII: 593YOG76RN)

#### Packaging

П	_				
ı	#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
1	1	NDC:0409 0100 02	110 mL in 1 POTTI E. Type O. Not a Combination Product		

1 NDC:0498-0100-02 118 mL in 1 BOTTLE; Type 0: Not a Combination Product

# **Marketing Information**

9			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	nart349	12/18/2018	

### Part 3 of 8

### **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	0.7 mL in 1 mL	

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

ı	Packaging			
ı	# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
ı	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 4 of 8

## **BURN RELIEF**

lidocaine hydrochloride spray

Product Information	
Item Code (Source)	NDC:0498-0221
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
<b>LIDO CAINE HYDRO CHLO RIDE</b> (UNII: V13007Z41A) (LIDO CAINE - UNII: 98 PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	24.64 mg in 1 mL

Inactive Ingredients		
Ingredient Name	Strength	
EDETATE DISO DIUM (UNII: 7FLD91C86K)		
GLYCERIN (UNII: PDC6A3C0OX)		
TROLAMINE (UNII: 903K93S3TK)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		

OCTOXYNOL-9 (UNII: 7JPC6Y25QS)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
TEA TREE O IL (UNII: VIF565UC2G)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
DIAZO LIDINYL UREA (UNII: H5RIZ3MPW4)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:0498-0221- 59	59 mL in 1 BOTTLE, SPRAY; 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	part348	09/18/2018	

# Part 5 of 8

## **ANTISEPTIC**

benzalkonium chloride spray

<b>Product Information</b>	
Item Code (Source)	NDC:0498-0402
Route of Administration	TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>BENZALKO NIUM CHLO RIDE</b> (UNII: F5UM2KM3W7) (BENZALKO NIUM - UNII:7N6 JUD5X6 Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
OCTOXYNOL 9 (UNII: 7JPC6 Y25QS)		
GLYCERIN (UNII: PDC6A3C0OX)		
DIAZO LIDINYL UREA (UNII: H5RIZ3MPW4)		
DIPROPYLENE GLYCOL (UNII: E107L85C40)		
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)		
TROLAMINE (UNII: 9O3K93S3TK)		
METHYLPARABEN (UNII: A2I8 C7HI9 T)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:0498-0402- 59	59 mL in 1 BOTTLE, SPRAY; 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 6 of 8

### TRIPLE ANTIBIOTIC

bacitracin zinc, polymyxin b sulfate, neomycin sulfate ointment

Product Information	
Item Code (Source)	NDC:0498-0750
Route of Administration	TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B	5000 [iU] in 1 g		
BACITRACIN ZINC (UNII: 89 Y4M234ES) (BACITRACIN - UNII:58 H6 RWO 52I)	BACITRACIN	400 [iU] in 1 g		
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:116QD7X297)	NEOMYCIN	3.5 mg in 1 g		

Inactive Ingredients		
	Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)		

Product Characteristics				
Color	white	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				

Pa	ckaging			
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>

# **Marketing Information**

Marketing Category Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part333B	09/19/2018	

### Part 7 of 8

### **ANTISEPTIC TOWELETTE**

benzalkonium chloride liquid

#### **Product Information**

Item Code (Source) NDC:0498-0501

Route of Administration TOPICAL

#### Active Ingredient/Active Moiety

8 44 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4			
Ingredient Name	Basis of Strength	Strength	
	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL	

### **Inactive Ingredients**

- 1		
	Ingredient Name	Strength
1	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	12/21/2017	

### Part 8 of 8

#### STING RELIEF PAD

ethyl alcohol, lidocaine swab

Product Information	
Item Code (Source)	NDC:0498-0733
Route of Administration	TOPICAL

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
LIDO CAINE HYDRO CHLO RIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98 PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	20 mg in 1 mL			
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.5 mL in 1 mL			

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
MENTHOL (UNII: L7T10EIP3A)			
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7)			

Packaging					
l	#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ı	1 N	DC:0498-0733-00	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	part348	12/23/2017	

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(0498-4271)

Establishment				
Name	Address	ID/FEI	Business Operations	
Water-Jel Technologies		155522589	manufacture(0498-0750, 0498-0402, 0498-0221)	

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, 0498-0501)				

Establishment							
Name	Address	ID/FEI	Business Operations				
Safetec of America Inc		874965262	manufacture(0498-0733)				

Revised: 4/2019 Honeywell Safety Products USA, INC