#### 4357 FIRST AID KIT- 4357 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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0498-4357: First Aid Kit (Burn Jel, alcohol wipe, Burn Sp WS, Triple, EW, HC cr, Foille- 6832649)

#### 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

## **Burn Relief Water Soluble Active ingredients**

Benzethonium chloride 0.2% w/w

Benzocaine 10% w/w

Menthol 0.33% w/w

#### Burn Relief Water Soluble Purpose

Topical antiseptic

Topical anesthetic

Topical anesthetic

#### Burn Relief Water Soluble Uses

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 Relief Water Soluble 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 Relief Water Soluble 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 Relief Water Soluble Other information

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

## **Burn Relief Water Soluble Inactive ingredients**

dipropylene glycol, isobutane, n-butane, propane

## Triple Active ingredients

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

#### Alcohol Active ingredient

Isopropyl alcohol 70%

#### Alcohol *Purpose*

First aid antiseptic

#### Alcohol

#### Uses

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

#### Alcohol Warnings

#### For external use only

Flammable, keep away from fire or flame.

#### 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 burns

#### 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 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 Other information

store at room temperature 15  $^{0}$  to 25  $^{0}$  C (59  $^{0}$  to 77  $^{0}$  F)

#### Alcohol Inactive ingredient

water

## Hydrocortisone Active ingredient (in each gram)

Hydrocortisone acetate (equivalent to Hydrocortisone 1%)

#### Hyrdocortisone *Purpose*

Anti-itch cream

### Hydrocortisone *Uses*

• for the temporary relief of itching associated with minor skin irritations and rashes

## Hydrocortisone *Warnings*

For external use only

#### Ask a doctor before use if

you are using any other hydrocortisone product

#### When using the product

- avoid contact with eyes
- do not begin use of any other hydrocortisone product unless you have consulted a doctor
- do not use for the treatment of diaper rash

#### Stop use and ask a doctor if

- condition worsens
- condition persists for more than 7 days
- condition clears up and recurs within a few days

#### Keep out of reach of children

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

#### Hydrocortisone Directions

- adults and children 2 years and older:
- clean the affected area
- apply to the area not more than 3 to 4 times daily
- children under 2 years of age: consult a doctor

### Hydrocortisone Other information

• store at room temperature (do not freeze)

#### Hydrocortisone Inactive ingredients

cetyl alcohol, citric acid, diazolidinyl urea, edetate disodium, glycerin, glyceryl monostearate, methylparaben, mineral oil, polyethylene glycol, propylene glycol, propylparaben, purified water, stearic acid, trolamine

### Hydrocortisone Questions or Comments?

1-800-430-5490

## Foille *Active ingredient*

Benzocaine 5.0% (w/w)

Chloroxylenol 0.1% (w/w)

#### Foille *Purpose*

External analgesic

Antiseptic

#### **Foille**

#### Uses

- For the temporary relief of pain associated with burns, sunburn, minor cuts, scrapes, insect bites, and minor skin irritations.
- First aid to help prevent infection in minor cuts, scrapes and burns.

#### Foille *Warnings*

#### For external use only

#### When using this product

avoid contact with the eyes

#### Stop use and ask a doctor if

- condition worsens, or symptoms persist for more than 7 days or clear up and occur again within a few days.
- Do not apply over large areas of the body. In case of deep or puncture wounds, animal bites, or serious burns, consult a doctor.

#### Keep out of reach of children.

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

#### Foille

#### **Directions**

- clean the affected area.
- adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily.
- children under 2 years of age: consult a physician.

### Foille Other information

Avoid contact with clothing

Foille may stain certain fabrics

#### **Foille**

#### Inactive ingredients

beeswax, benzyl alcohol, calcium disodium EDTA, calcium hydroxide, ceresin, eugenol, hydrogenated vegetable oil, maleic anhydride, mono- and di-glycerides, PEG-32, purified water, sodium borate, sodium lauryl sulfate, zea mays (corn) oil.

#### Burn Jel Active ingredient

Lidocaine HCl 2.0 %v

#### Burn Jel *Purpose*

External analgesic

#### Burn Jel *Uses*

temporarily relieves pain due to minor burns

#### Burn Jel *Warnings*

#### For external use oonly

#### Do not use

• on large areas of the body, particularly over raw surfaces or blistered areas

#### When using this product

avoid contact with eyes

#### Stop use and ask a doctor if

- the condition gets worse
- symptoms persist for more than 7 days
- condition clears up and recurs within a few days

#### Keep out of reach of children

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

#### Burn Jel Directions

• adults and children 2 years of age and older; apply to affected area not more than 3

- to 4 times daily
- children under 2 years of age: ask a doctor
- you may report a serious reaction to this product to 800-430-5490

#### Burn Jel Other information

store at room temperature - do not use if opened or torn

#### Burn Jel Inactive ingredients

carbopol 940, carbopol 1342, diazolidinyl urea, glycerin, melaleuca alternifolia (tea tree) leaf oil, methylparaben, octoxynol-9, propylene glycol, propylparaben, trolamine, water

#### Burn Jel Questions

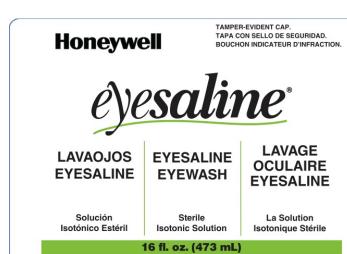
1-800-430-5490

#### 4357 6832649 KIT CONTENTS

- 1 BLUE DETEC FNGERTP 8 WVN 25/B
- 1 BLUE DETEC KNUCKLE WVN 40/BX
- 1 BLUE DETEC 1X3 WVN 100/BX
- 1 INSTANT COLD PACK 4" X 6"
- 5 BURN JEL 1/8 OZ, 6 PER
- 1 ADHESIVE TAPE W/P 1/2"X 5 YD
- 1 FIRST AID GUIDE ASHI
- 1 GAUZE CLEAN-WRAP BDGE N/S 2"
- 1 GZE PADS STERILE 2"X 2" 25'S
- 1 GZE PADS STERILE 3"X 3" 25'S
- 1 CO-FLEX BANDAGE 2"X 5YDS TAN
- 1 ALCOHOL WIPES 50'S
- 1 TRIPLE BIOTIC .5 GRAM PKT 20
- 1 HYDROCORTISONE 1% .9 GRM 20'S
- 1 40Z BFS EYEWASH TRILINGUAL BOTTLE
- 1 SCISSOR BDGE 4" RED PLS HDL
- 1 SPLINTER OUT 10 PIECES/PK

- 1 KIT TWEEZER 3 1/2" SLANTED
- 1 F A KIT EMPTY BLANK 140
- 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
- 5 WATER-JEL BURN DRESSING 4 X 4
- 3 FOILLE BURN .50Z 2'S

Eyewash Principal Display Panel



Drug Facts (for USA only) Active ingredient Purpose Uses for flushing the eye to remove loose foreign material, air pollutants, Warnings
For external use only - 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. Stop use and consult a doctor if: 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 sodium phosphate dibasic, sodium phosphate monobasic Questions? Call 1-800-430-5490 Honeywell Safety Products USA, Inc. Smithfield, RI. 02917

> Datos de medicamento (Para EE.UU. solamente) 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
>
> - en juaque el área afectada según se necesite
>
> - controle el chorro haciendo presión el la botella
>
> - si es necesario, sigue enjuagado con un lavados o ducha de emergencia Ingredientes inactivos cloruro de sodio, fosfato de sodio dibásico, fosfato de sodio monobásico. ¿Preguntas? Llame al 1-800-430-5490 Honeywell Safety Products USA, Inc. Smithfield, RI. 02917

#32-000454-0000

RÉAPPROVISIONNEMENT

REORDER

#32-004510 Rev. J

#### Information

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

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, jetez-les.

Ne pas utiliser

• si la solution a changé de couleur ou si elle est brouillée

• si vous avez des plaies ouverles 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 infaliation 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 continent de la solution et l'encer avec une solution de rinçage oculaire d'urgence ou une douche

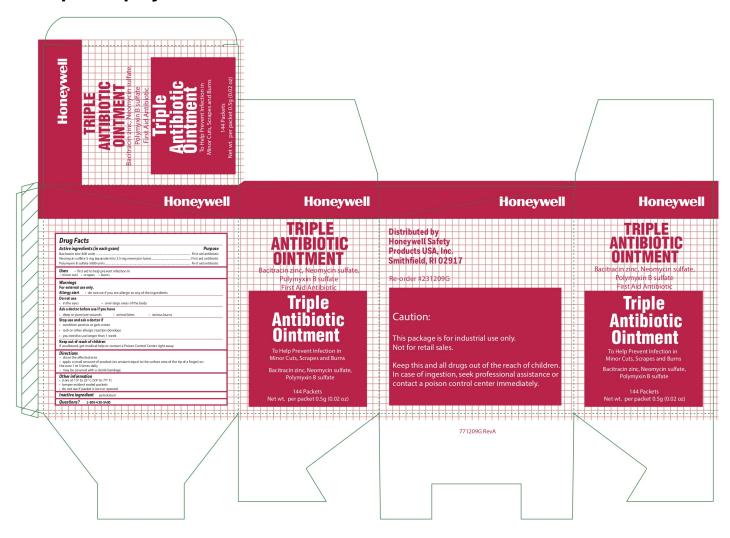
Ingrédients eau stérile, chlorure de sodium, phosphate dibasique de sodium, phosphate monobasique de sodium

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

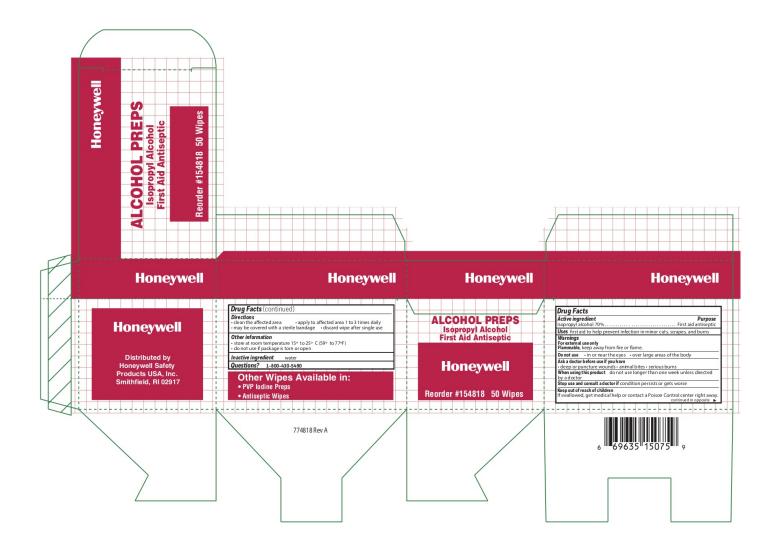
**Burn Relief Water Soluble** Principal Display Panel



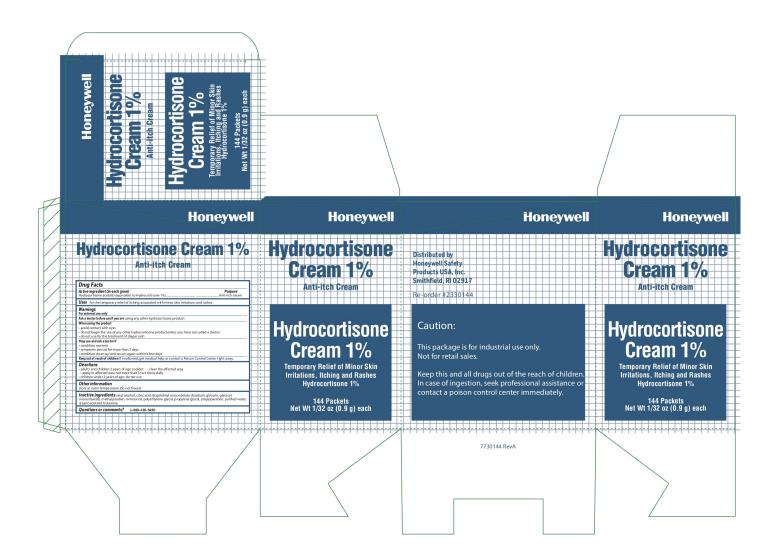
#### **Principal Display Panel**



Alcohol Principal Display Panel



Hydrocortisone Principal Display Panel



Foille Principal Display Panel Purpose

**Drug Facts** 

6 (w/w) External Analgesic Active ingredients

NDC 10157-9302-4

associated with burns, surburn, minor cuts, scrapes, insect bites, and minor For the temporary relief of pain skin irritations.

First aid to help prevent infection in minor outs, scrapes and burns.

Warnings For external use only.

condition worsens, or symptoms persist Stop use and ask a doctor if Avoid contact with the eyes When using this product

wounds, animal bites, or serious burns for more than 7 days or clear up and Donotapply overlarge areas of the body. In case of deep or puncture occur again within a few days. consult a doctor.

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

Directions

Adults and children 2 years of age and older. Apply to affected area not more Children under 2 years of age: consult Clean the affected area. han 3 to 4 times daily

Fast, Soothing Relief Of Pain Due To:

Cuts & Scrapes • Minor Burns

Sunburn • Insect Bites

Fast, Soothing Relief Of Pain Due To:

**Cuts & Scrapes • Minor Burns** 

Sunburn • Insect Bites

normal activities righ

NET WT. 1 oz (28g)

continued) Drug Facts

Other information clothing. Faile may stain Avoid contact with certain fabrics

nactive ingredient egetable oil, maleic anhyc eeswax, benzyl alcohol nono- and di-glycerides um disodium EDTA

orate, sodium lauryl sulfat

ea mays (com) oil.

unified water, sodium

non-poisonous insec bites, and minor skin relief of pain due to scrapes, cuts, minor irritation. Foille First Aid Ointment stops For the temporary pain on contact and burns, sunburn, lets you resume

oil-based formula that has a medicated prevent infection. helps heal and away. Foille

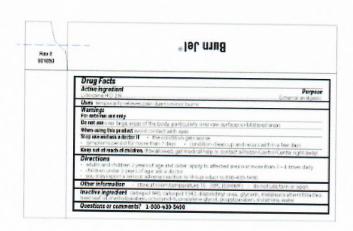
Blistex SATISFACTION

P.O. Box 5392 Oak Brook, IL 60522-539 2009 Blistex Inc. #39013

◆ Carton is 100% Recyclable

**Burn Jel Principal Display Panel** 







# "Be Safe For Life"

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

#### **4357 FIRST AID KIT**

4357 first aid kit kit

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:0498-4357

#### **Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-4357- 01	1 in 1 KIT; Type 0: Not a Combination Product	10/18/2018	

#### **Quantity of Parts**

Quant		
Part #	Package Quantity	Total Product Quantity
Part 1	20 PACKET	18 g
Part 2	1 BOTTLE	118 mL
Part 3	1 CAN	85 g
Part 4	20 PACKET	10 g
Part 5	50 POUCH	20 mL

Part 6	20 PACKET	18 g
Part 7	6 TUBE	84 g
Part 8	30 PACKET	105 g

#### Part 1 of 8

#### **HYDROCORTISONE**

anti-itch cream

UNII:W4X0X7BPJ)

#### **Product Information**

Item Code (Source) NDC:0498-0801

Route of Administration TOPICAL

# Active Ingredient/Active Moiety Ingredient Name Basis of Strength HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - HYDROCORTISONE 1 g

in 100 g

ACETATE

**Inactive Ingredients Ingredient Name** Strength STEARIC ACID (UNII: 4ELV7Z65AP) TROLAMINE (UNII: 903K93S3TK) METHYLPARABEN (UNII: A2I8C7HI9T) WATER (UNII: 059QF0KO0R) EDETATE DISODIUM (UNII: 7FLD91C86K) **LIGHT MINERAL OIL** (UNII: N6K5787QVP) PROPYLENE GLYCOL (UNII: 6DC9Q167V3) **DIAZOLIDINYL UREA** (UNII: H5RIZ3MPW4) PROPYLPARABEN (UNII: Z8IX2SC10H) **GLYCERIN** (UNII: PDC6A3C0OX) CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) **GLYCERYL MONOSTEARATE** (UNII: 2300U9XXE4) POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) CETYL ALCOHOL (UNII: 936JST6JCN)

	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		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		
unapproved drug other		10/15/2019			

#### 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: 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)				

l	P	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
		NDC:0498-0100- 02	118 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 Drug	M018	12/18/2018		

#### Part 3 of 8

#### **BURN WATER SOLUBLE**

benzocaine, benzethonium chloride, menthol spray

#### **Product Information**

Item Code (Source) NDC:0498-0021

**Route of Administration** TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	Strength		
BENZETHONIUM CHLORIDE (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP)	BENZETHONIUM CHLORIDE	0.2 g in 100 g		
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	10 g in 100 g		
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.33 g in 100 g		

Inactive Ingredients			
Ingredient Name	Strength		
ISOBUTANE (UNII: BXR49TP611)			
BUTANE (UNII: 6LV4FOR43R)			
PROPANE (UNII: T75W9911L6)			
DIPROPYLENE GLYCOL (UNII: E107L85C40)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0021- 40	85 g in 1 CAN; Type 0: Not a Combination Product		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other		11/12/2018		

### Part 4 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: J2VZ 07J96K)	POLYMYXIN B	5000 [iU] in 1 g	
BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RW052I)	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			

l	P	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
		NDC:0498-0750- 36	0.5 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	
unapproved drug other		09/19/2018		

### Part 5 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 (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	0.7 mL in 1 mL

<b>Inactive Ingredients</b>		
	Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)		

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		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	
unapproved drug other		09/18/2018		

### Part 6 of 8

#### **HYDROCORTISONE**

anti-itch cream ointment

Product Information		
Item Code (Source)	NDC:0498-0800	
Route of Administration	TOPICAL	

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII: W4X0X7BPJ)	HYDROCORTISONE ACETATE	1 g in 100 g	

Inactive Ingredients			
Ingredient Name	Strength		
STEARIC ACID (UNII: 4ELV7Z65AP)			
TROLAMINE (UNII: 903K93S3TK)			
METHYLPARABEN (UNII: A218C7H19T)			

WATER (UNII: 059QF0KO0R)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
GLYCERIN (UNII: PDC6A3C0OX)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
CETYL ALCOHOL (UNII: 936JST6JCN)	

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:0498-0800- 35	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
unapproved drug other		03/06/2013	10/15/2019

### Part 7 of 8

### **BLISTEX FOILLE MEDICATED FIRST AID**

benzocaine and chloroxylenol ointment

Product Information		
Item Code (Source)	NDC:10157-9302	
Route of Administration	TOPICAL	

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	5 g in 100 g	
CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q)	CHLOROXYLENOL	0.1 g in 100 g	

Inactive Ingredients	
Ingredient Name	Strength
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

BENZYL ALCOHOL (UNII: LKG8494WBH)	
EDETATE CALCIUM DISODIUM ANHYDROUS (UNII: 8U5D034955)	
CERESIN (UNII: Q1LS2UJO3A)	
EUGENOL (UNII: 3T8H1794QW)	
MALEIC ANHYDRIDE (UNII: V5877ZJZ25)	
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	
CORN OIL (UNII: 8470G57WFM)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CALCIUM HYDROXIDE (UNII: PF5DZ W74VN)	
WATER (UNII: 059QF0KO0R)	

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		14 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/05/2013	

### Part 8 of 8

### **BURN JEL**

gel for burns gel

Product Information		
Item Code (Source)	NDC:0498-0203	
Route of Administration	TOPICAL	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	2 g in 100 g	

	Inactive Ingredients	
ı	Ingredient Name	Strength
ı	TROLAMINE (UNII: 903K93S3TK)	
	CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII:	

4Q93RCW27E)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01Z NK31)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
OCTOXYNOL-9 (UNII: 7JPC6Y25QS)	
TEA TREE OIL (UNII: VIF565UC2G)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

F	Packaging			
#	tem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0203- 00	3.5 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
unapproved drug other		09/19/2018	

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 (118768815)

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