4238 FIRST AID KIT- 4238 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.

4238 First Aid Kit (FABC,EW, alcohol wipes, PVP wipes, sting relief- 019731-0018L)

First Aid Burn Cream
Active ingredient

Benzalkonium chloride o.13%

Lidocaine HCl 0.5%

First Aid Burn Cream
Purpose

First aid antiseptic

External analgesic

First Aid Burn Cream
Uses
- prevent skin infection
- for temporary relief of pain associated with minor burns

First Aid Burn Cream
Warnings

For external use only

Do not use
- in or near the eyes
- if you are allergic to any of the ingredients
- in large areas of the body, particularly over raw surfaces or blistered areas
- for more than 10 days

Ask a doctor before use if you have
- deep or puncture wounds
- animal bites
- serious burns

Stop use and ask a doctor if
- condition worsens
- symptoms persist for more than 7 days or clear up and occurs again within a few days

First Aid Burn Cream
Directions
- **adults and children 2 years of age and older:**
- clean the affected area

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

First Aid Burn Cream
Other information
- tamper evident sealed packets
- do not use if packet is opened or torn

First Aid Burn Cream
Inactive ingredients

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

First Aid Burn Cream
Questions

1-800-430-5490

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

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 wek 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 informatiion
- 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

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

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

Keep out of reach of children

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

Stig 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 ingredients

benzalkonium chloride, menthol, and purified water

Questions or Comments?

1-800-430-5490

4238
013087-1725A Kit Contents

1 KNUCKLE BAND 8 PER

1 FIRST AID BURN CREAM 6 PER

1 TRIANGULAR BDG, NON-STERILE

1 GAUZE PADS, 3" X 3", 4 PER

1 ADH TAPE, .5" X 2.5 YD, 2 PER

1 GAUZE COMPRESS, 1728 SQ IN 1

1 INSTANT COLD PACK 4" X 6"

1 BUFFERED EYE WASH 1 OZ BTL

1 BANDAGE COMP, 4" OFFSET, 1 PER

1 ADHESIVE BDG,PLSTIC,1"X3"16PER

1 PVP IODINE WIPES 10 PER

1 NITRILE GLOVES 2PR BBP

1 MICROSHIELD W/VNL GLV/ALCL

LBL STOCK 6-3/8"X4"

LBL STOCK 4"X2-7/8"

1 LBL STOCK 3"x1-7/8"

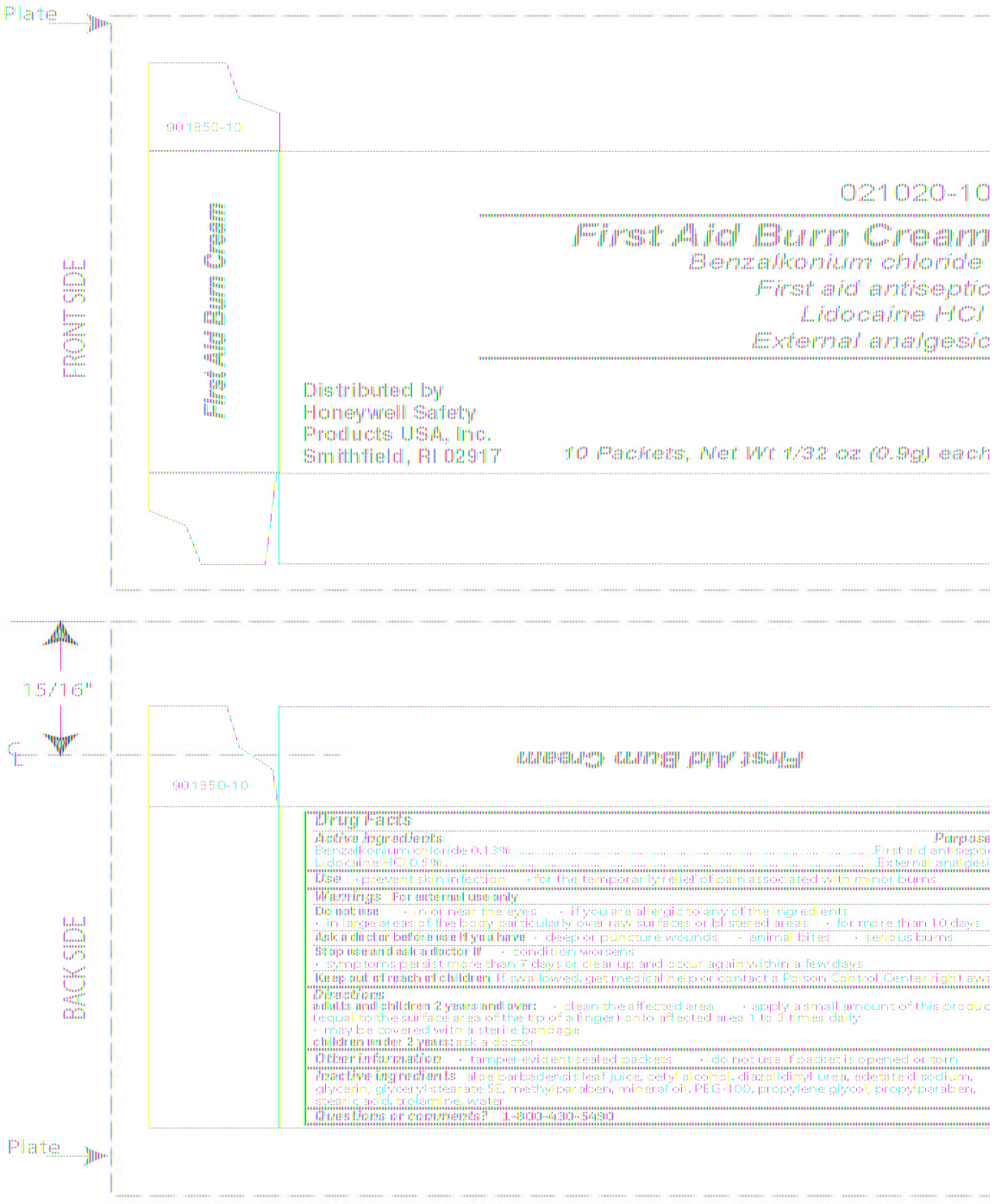
1 KIT STL 16 UN (VERTICAL)

1 LABL INSTR FA REV A

1 LBL CONTENTS ANSI Z308.1-2009 REV B

1 STING Relief WIPES 10

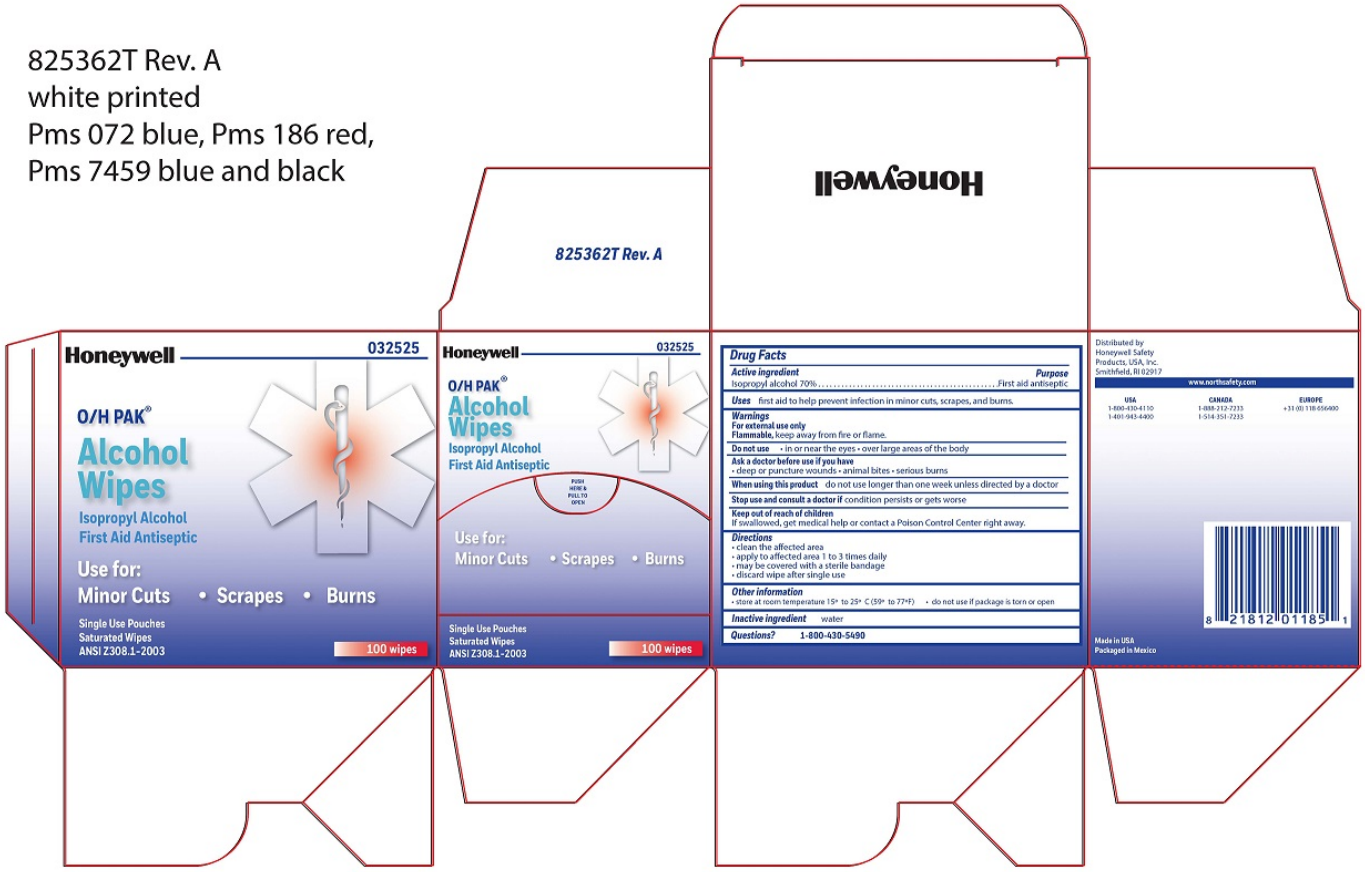
First Aid Burn Cream
Principal Display Panel



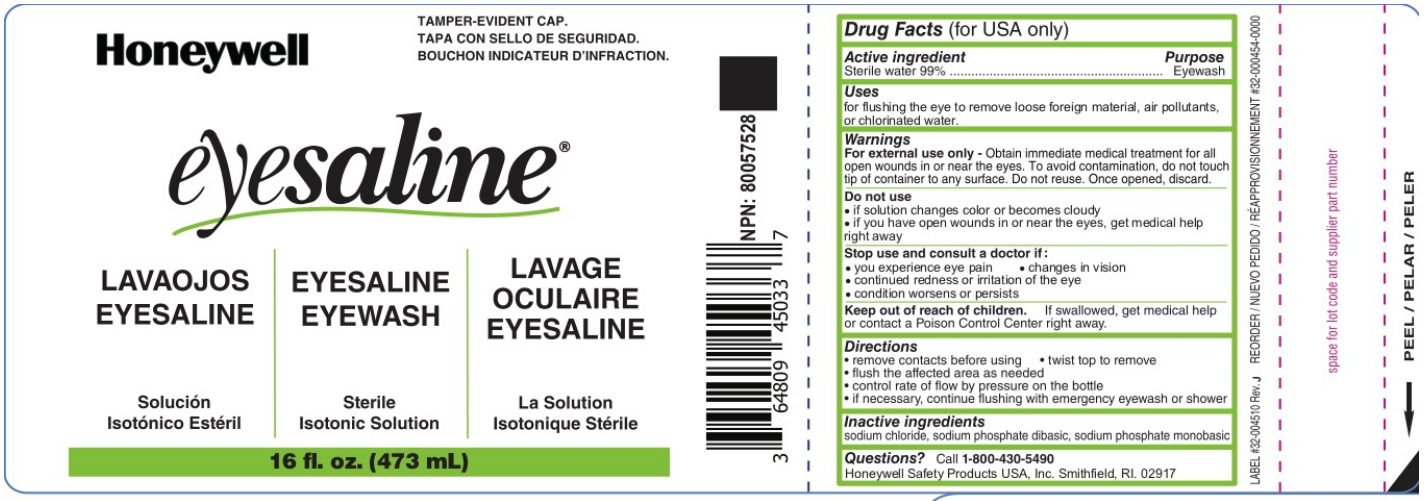
Alcohol Wipe

Principal Display Panel

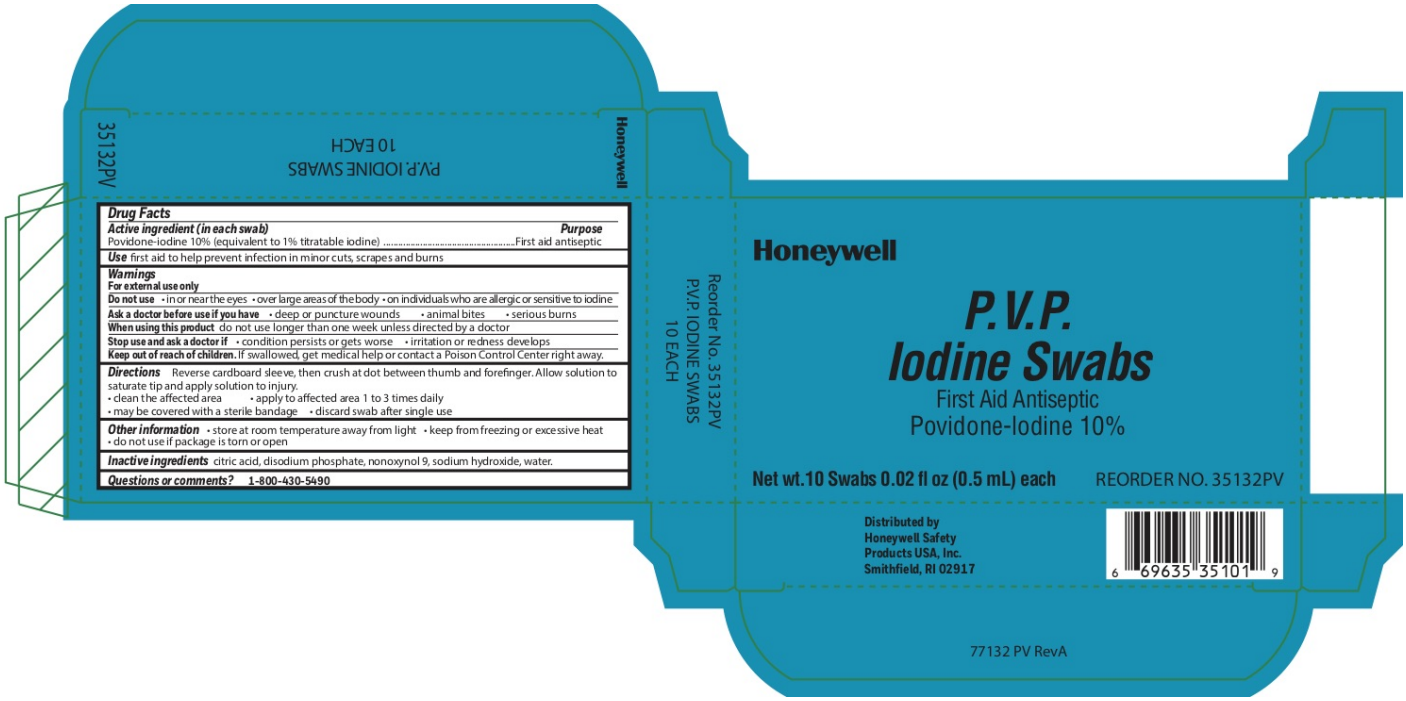
825362T Rev. A
white printed
Pms 072 blue, Pms 186 red,
Pms 7459 blue and black



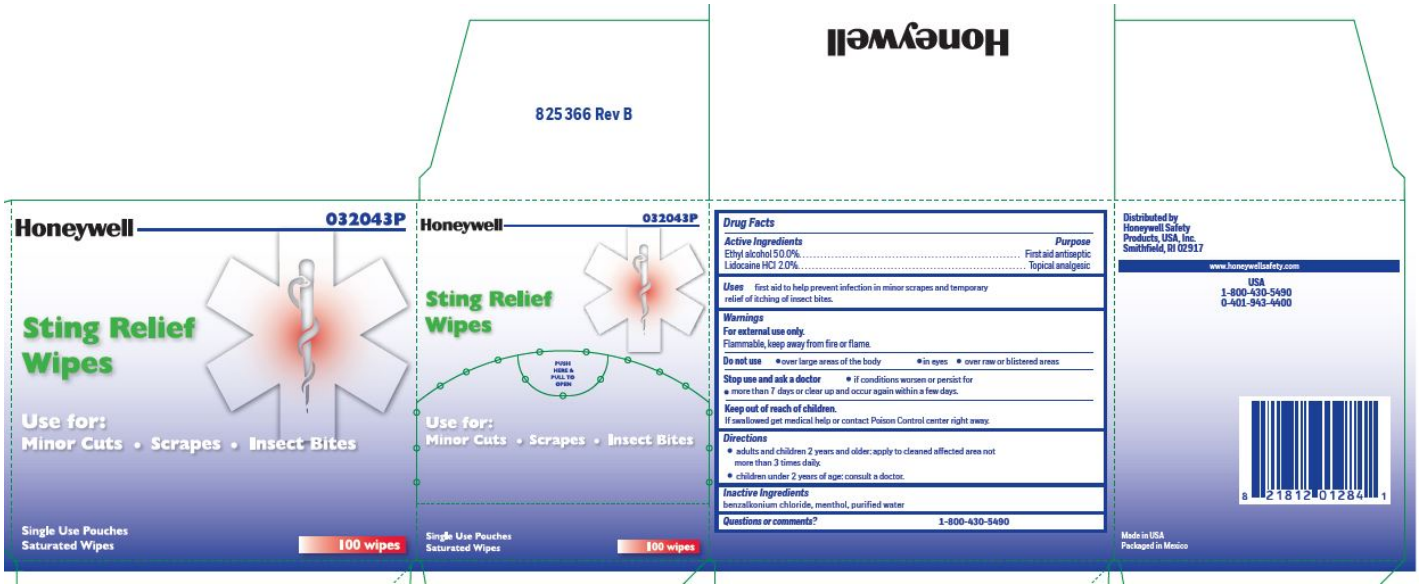
Eyewash
Principal Display Panel



PVP
Principal Display Panel



Sting Relief
Principal Display Panel



4238 Kit Label
013087-1725A

Honeywell

First Aid Kit

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

4238 FIRST AID KIT

4238 first aid kit kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0498-4238

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-4238-01	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	1 BOTTLE	30 mL
Part 3	4 POUCH	1.6 mL
Part 4	10 POUCH	3 mL
Part 5	10 POUCH	4 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

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	

Part 3 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 4 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 5 of 5

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
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	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
MENTHOL (UNII: L7T10EIP3A)	
WATER (UNII: 059QF0KO0R)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC: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	03/14/2019	

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
Honeywell Safety Products USA, INC		079287321	pack(0498-4238)

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 Biotext Medical		532775194	manufacture(0498-0121)

Establishment

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