4191 FIRST AID KIT- 4191 first aid
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.

0498-4191: First Aid Kit (Ammonia Inh, EW, Burn Jel, PVP Wipes, Sting Relief)
10875-4514

Active ingredient

Ammonia 15%

Purpose

Respiratory stimulant

Uses

to prevent or treat fainting

Warnings

For external use only

Do not use

- if you have 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.

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

Other information

store at room temperature away from light

Inactive ingredients

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

Questions or Comments

1-800-430-5490

Burn Jel
Active ingredient

Lidocaine HCl 2.0%

Burn Jel
Purpose

External analgesic

Burn Jel
Uses

- temporarily relieves pain due to minor burns

Burn Jel
Warnings

For external use only

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

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.

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?

1-800-430-5490

PVP
Active ingredient

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

PVP
Purpose

First aid antisepti

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

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
Directioons

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 ingredients

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

PVP
Questions and Comments?

1-800-430-5490

4191
010875-0349 Kit Contents

1 KNUCKLE BAND 8 PER

1 AMMONIA INHALANTS 10 PER

1 GAUZE BANDAGE, 4" X 6 YD

1 TOURNIQUET, 1 PER

1 TRIANGULAR BDG, NON-STERILE

1 WIRE SPLINT 1 PER

1 GAUZE COMP, 1 SQ YARD, 1 PER

1 BANDAGE COMP, 2" OFFSET, 4 PER

1 BANDAGE COMP, 4" OFFSET, 1 PER

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

1 FINGERTIP BANDAGE, 10 PER

1 1 OZ EYE WASH W/PADS & STRIPS

1 BURN JEL 1/8 OZ, 6 PER

2 PVP IODINE WIPES 10 PER

LBL STOCK 6-3/8"X4"

1 LBL STOCK 3"x1-7/8"

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

1 KIT STL 16 UN (VERTICAL)

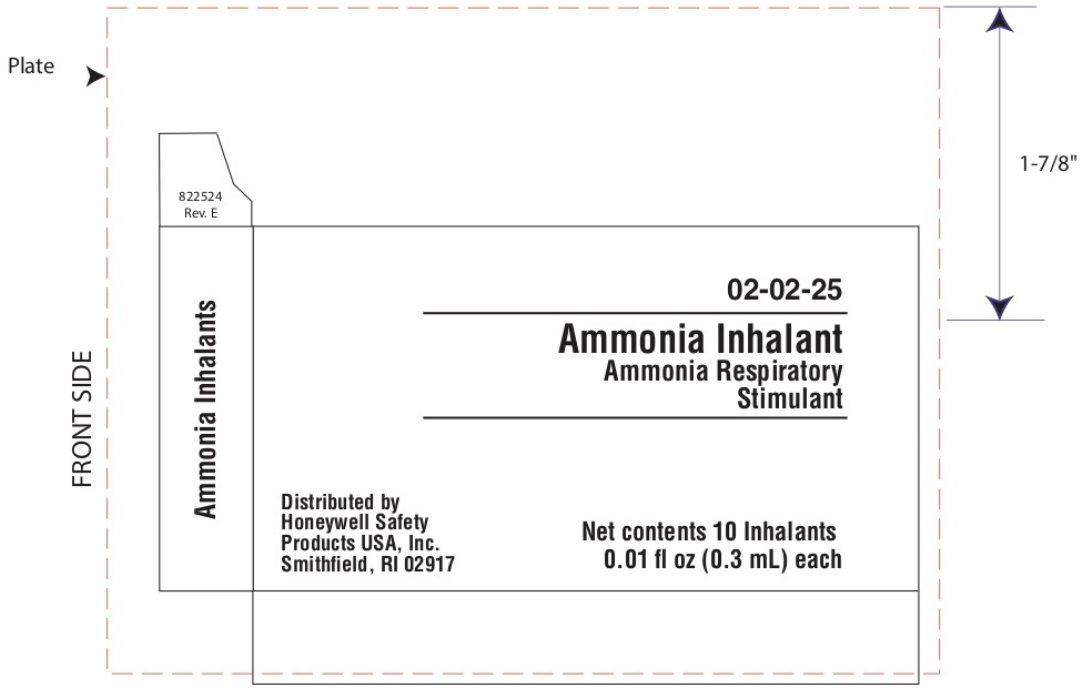
1 INSERT FA INSTR 16UN PHIL ELEC

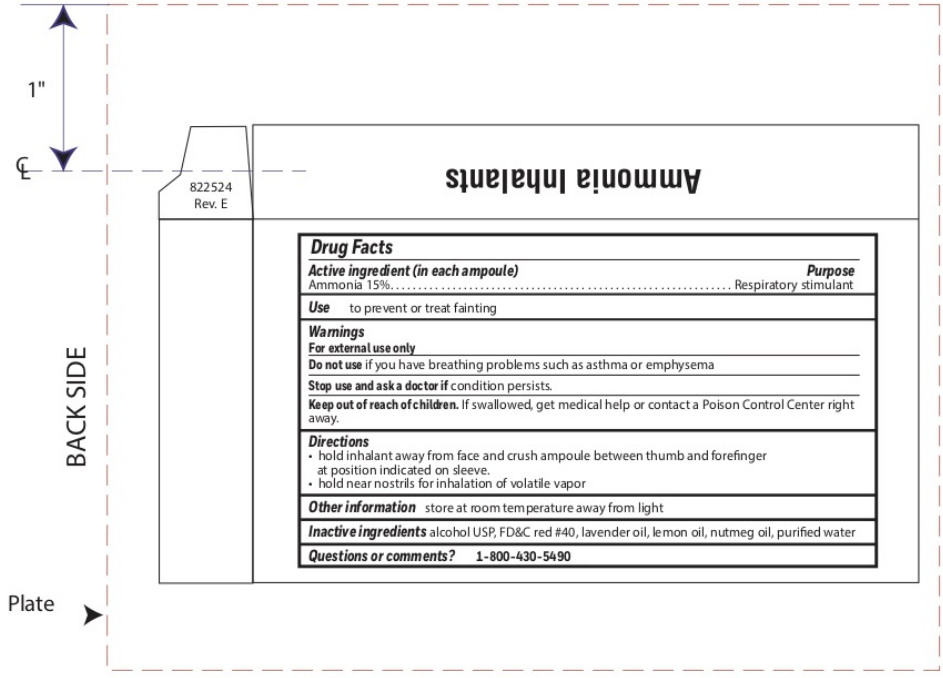
1 58 LBL REFILL 010875-0349

1 NOX A STING WIPES 10

Principal Display Panel

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

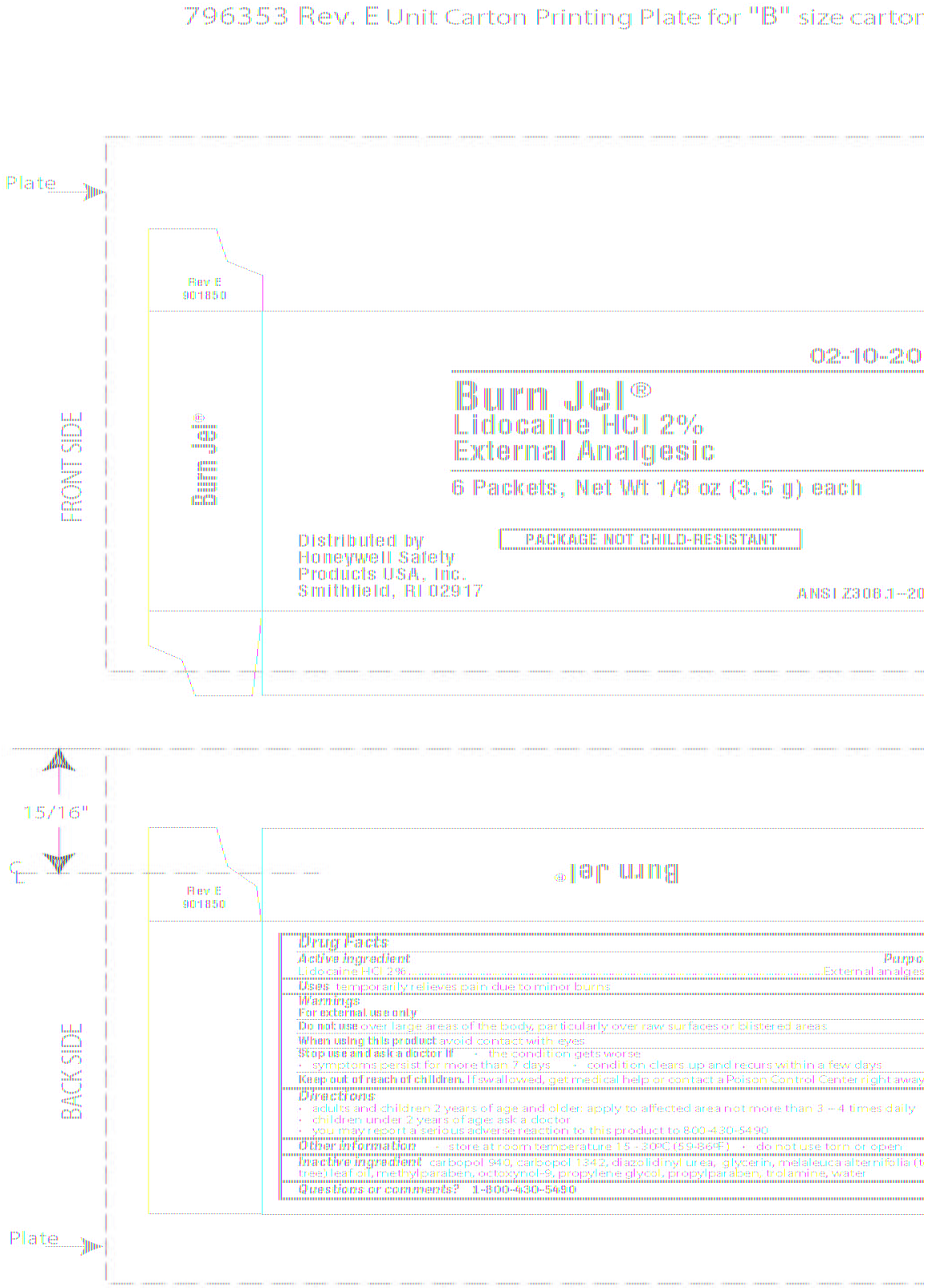




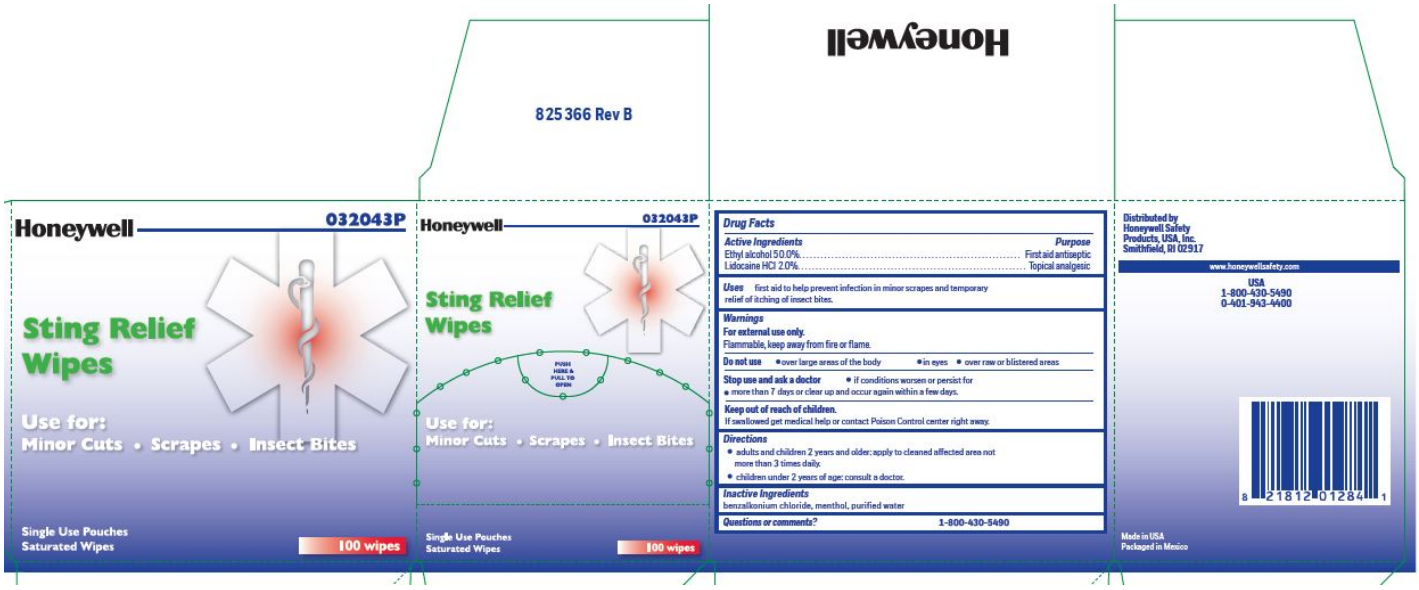
796006 Rev. E (page 3 of 3)

Burn Jel

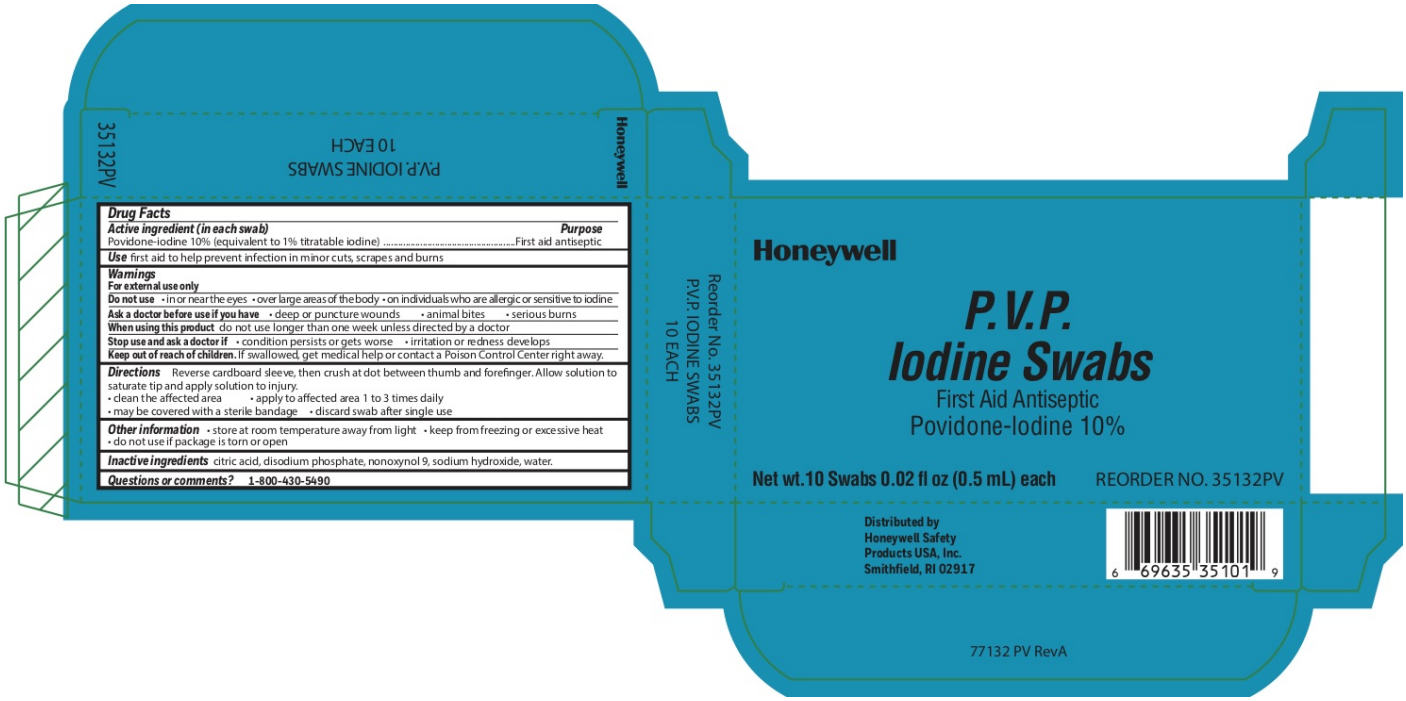
Principal Display Panel



Sting Relief
Principal Display Panel

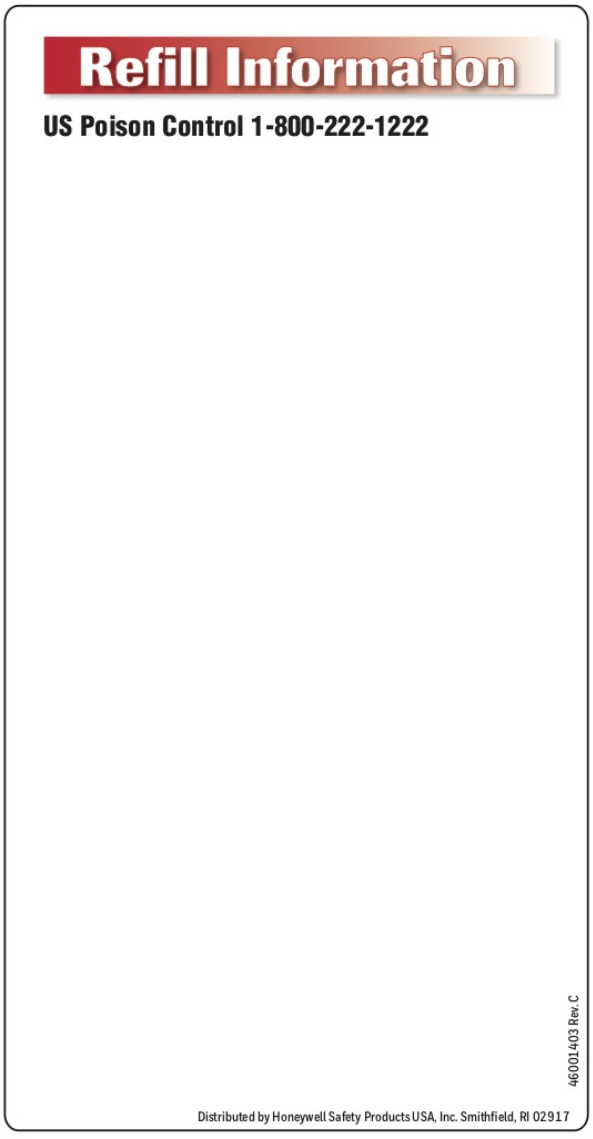


PVP
Principal Display Panel



4191 Kit Label
010875-0349

46001403 Rev. C
Prints 2 colors
Black and Red (PMS 485)



4191 FIRST AID KIT

4191 first aid kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0498-4191

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0498-4191-01	1 in 1 KIT	09/13/2018	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	6 PACKET	21 g
Part 2	10 POUCH	4 mL
Part 3	20 POUCH	6 mL
Part 4	1 BOTTLE	30 mL

Part 1 of 4

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	
Ingredient Name	**Strength**
TEA TREE OIL (UNII: VIF565UC2G)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII:	

HHT01ZNK31)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
OCTOXYNOL-9 (UNII: 7JPC6Y25QS)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	

Packaging

#	Item 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	

Part 2 of 4

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
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
MENTHOL (UNII: L7T10EIP3A)	
WATER (UNII: 059QF0KO0R)	

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
unapproved drug other		12/23/2017	

Part 3 of 4

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 4 of 4

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

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 Drug	M018	12/18/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/13/2018	

Labeler - Honeywell Safety Products USA, Inc. (118768815)