

**4311 FIRST AID KIT- 4311 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](#).

4311 First Aid Kit (Burn Jel, alcohol wipes, PVP wipes, sting relief, EW- SF00004446)

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***Purposse***

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 ingredients

benzalkonium chloride, menthol, and purified water

Sting Relief

Questions or Comments?

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

Eyeash

Questions

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

Alcohol

Active ingredient

Isopropyl alcohol 70%

Alcohol

Purpose

First aid antiseptic

Alcohol

Uses

first aid to help prevent infection in

- minor cuts
- scrapes
- burns

Alcohol

Warnings

For external use only

Flammable, keep away from fire and flame

Do not use

- in or near 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 1 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
- may be covered with a sterile bandage
- apply wipe to affected area 1 to 3 times daily
- discard wipe after single use

Alcohol

Other information

- store at room temperature 15 ° to 25 ° C (59 ° to 77 ° F)
- do not use if packet is torn or opened

Alcohol

Inactive ingredient

water

Alcohol

Questions

1-800-430-5490

PVP

Active ingredient

Povidone-iodine 10% (equivalent to 1% titratable iodine)

PVP

Purpose

First aid antiseptic

PVP

Uses

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

PVP

Warnings

For external use only.

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 or persists for more than 72 hours
- 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

- clean the affected area
- apply 1 to 3 times daily
- may be covered with a sterile bandage
- if bandaged, let dry first
- discard wipe after single use

PVP

Other information

- do not use on individuals who are allergic or sensitive to iodine
- store at controlled temperature 59-86°F (15-30°C)
- do not use if pouch is open or torn

PVP

Inactive ingredients

nonoxynol 9, water

4311

SF00004446 Kit Contents

1 KNUCKLE BAND 8 PER
2 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" X 3" 16 PER
1 BURN JEL 1/8 OZ, 6 PER
1 ALCOHOL PREP PADS 10 P
1 PVP IODINE WIPES 10 PER
1 STING RELIEF WIPES 10 PER BOX
1 ADHESIVE TAPE W/P 1/2" X 5 YD
1 POISON OAK/IVY CLEANSER 4 OZ
1 KIT TWEEZER 3 1/2" SLANTED
LBL STOCK 6-3/8" X 4"

LBL STOCK 4"X2-7/8"

1 LBL STOCK 3"x1-7/8"

2 PR LRG NITRILE GLVES ZIP BAG

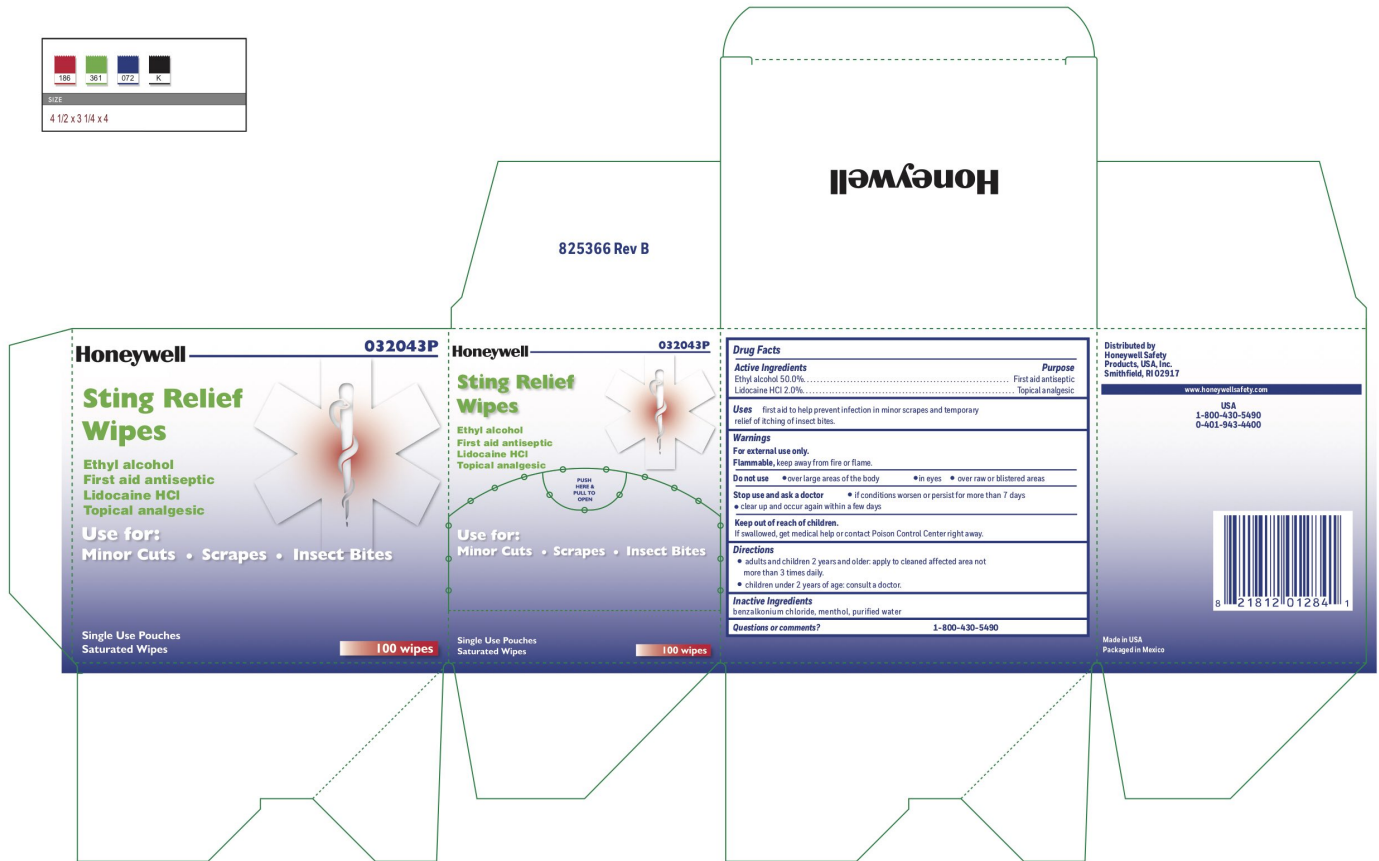
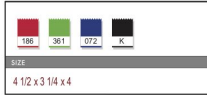
1 KIT STL 16 UN (HORIZONTAL)

Burn Jel

Principal Display Panel



Principal Display Panel



Eyewash Principal Display Panel

Honeywell

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 1 45033 117

Drug Facts (for USA only)

Active ingredient Sterile water 99% **Purpose** Eyewash
Uses for flushing the eye to remove loose foreign material, air pollutants, or chlorinated water.
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.
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 consult 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.
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
Inactive ingredients sodium chloride, sodium phosphate dibasic, sodium phosphate monobasic
Questions? Call 1-800-430-5490
Honeywell Safety Products USA, Inc. Smithfield, RI. 02917

LABEL #32-0045/0 Rev. J REORDER / NUEVO PEDIDO / REAPPROVISIONNEMENT #32-000454-0000

space for lot code and supplier part number

PEEL / PELAR / PELEL

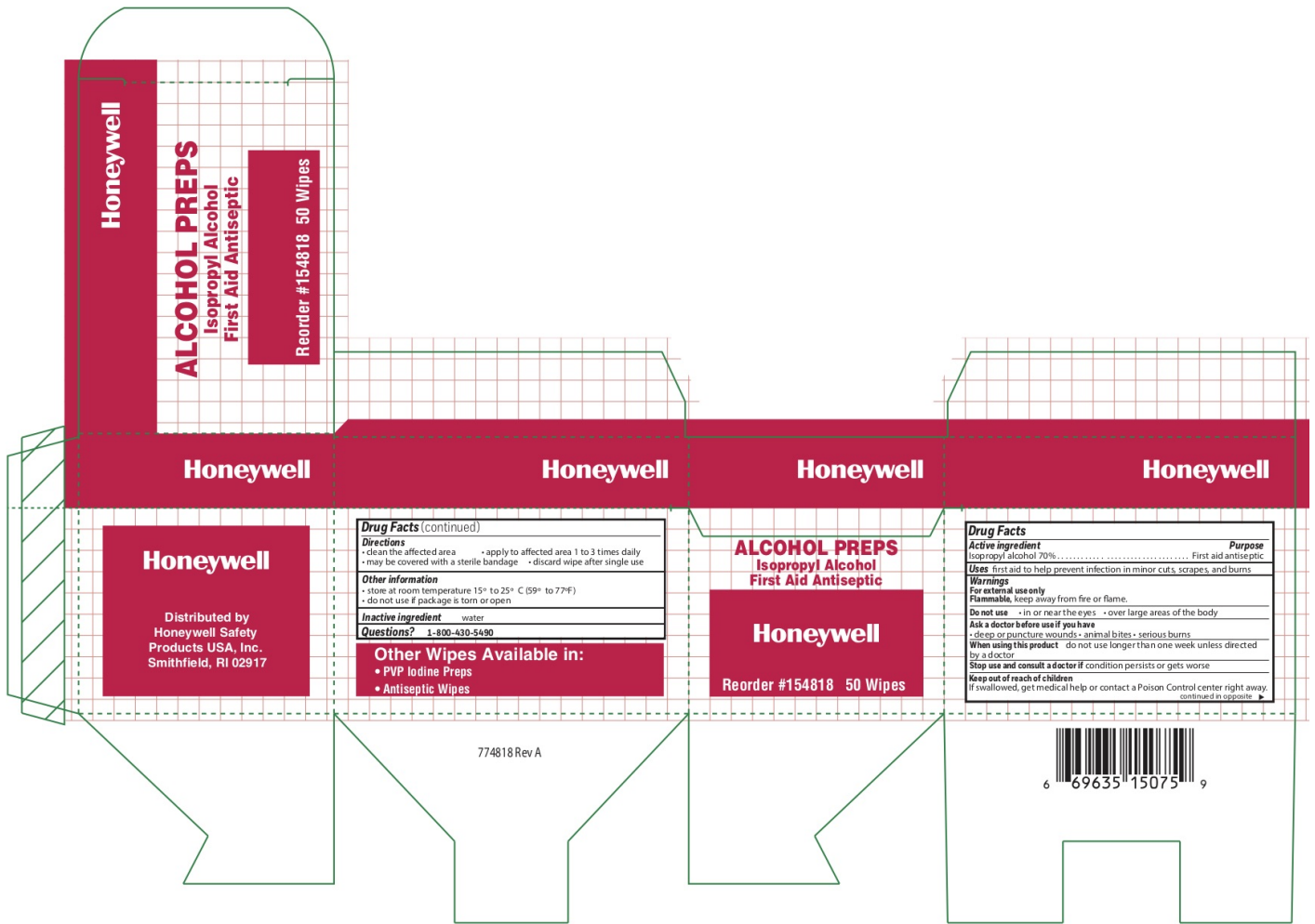
Datos de medicamento (Para EE.UU. solamente)

Ingrediente Activo Agua estéril 99% **Propósito** Lavaojos
Usos para el lavado de ojo para quitar las partículas 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 ninguna 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
Deje de usar y consulte a un médico si:
• experimenta dolor de ojo • cambio de visión
• rojez continuo o irritación del ojo
• la condición empeora 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
• 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 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
Honeywell Safety Products USA, Inc. Smithfield, RI. 02917

Information

Usages Pour le rinçage des yeux afin d'enlever un corps étranger, des polluants atmosphériques ou de l'eau chlorée.
Advertissements Pour usage externe 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, jeter.
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 si vous ressentez une douleur oculaire si votre vision change
rougeur ou irritation persistante des yeux
condition empire ou persiste
Garder hors de la portée des enfants. En cas d'ingestion, communiquer immédiatement avec un médecin ou avec un centre antipoison.
Mode d'emploi 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
Ingédients 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
Principal Display Panel



PVP
Principal Display Panel

FRONT SIDE

822569 X
Rev. *

PVP Iodine Wipes

02-12-01X



PVP Iodine Wipes
Povidone-Iodine 10%
First Aid Antiseptic
10 Saturated Wipes
ANSI Z308.1-2009

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

BACK SIDE

822569 X
Rev. *



PVP Iodine Wipes

Drug Facts

Active ingredient	Purpose
Povidone-iodine 10% (equivalent to 1% titrable iodine)	First aid antiseptic

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

Warnings For external use only

Do not use
• in or near 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 • condition persists or gets worse • irritation or redness develops

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

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

Other information • store at room temperature: 15-30° C (59-86° F)

• do not use if package is torn or open • do not use on individuals who are allergic or sensitive to iodine

Inactive ingredients nonoxonyl-9, water

Questions or comments? 1-800-430-5490



4311 Kit Label
SF0004446



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

4311 FIRST AID KIT

4311 first aid kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0498-4311
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-4311-01	1 in 1 KIT	09/13/2018	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	6 PACKET	21 g
Part 2	1 BOTTLE	30 mL
Part 3	10 POUCH	4 mL
Part 4	10 POUCH	4 mL
Part 5	10 POUCH	3 mL

Part 1 of 5

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)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER HOMO POLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
CARBOMER HOMO POLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
PROPYL PARABEN (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
OTC monograph not final	part348	09/19/2018	

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, 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 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: 059QF0K00R)	

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**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: L7T10EP3A)	
WATER (UNII: 059QF0K00R)	

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	12/23/2017	

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
WATER (UNII: 059QF0KO0R)	
NONOXYNOL-9 (UNII: 48Q180SH9T)	

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		09/13/2018	

Labeler - Honeywell Safety Products USA, Inc. (079287321)

Registrant - Honeywell Safety Products USA, Inc. (079287321)

Establishment

Name	Address	ID/FEI	Business Operations
Honeywell Safety Products USA, Inc		079287321	pack(0498-4311)

Establishment

Name	Address	ID/FEI	Business Operations
Water-Jel Technologies		155522589	manufacture(0498-0203)

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 Medical Biotech		532775194	manufacture(0498-0121)

Establishment

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