

4300 FIRST AID KIT- 4300 first aid kit

4397 FIRST AID KIT- 4397 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](#).

4300, 4397 First Aid Kit (FABC, EW, PVP wipes, BZK wipes, Sting relief- 019580-4601, 019580-3572)

First Aid Burn Cream

Active ingredient

Benzalkonium chloride 0.13%

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

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

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 ingredients

benzalkonium chloride, menthol, and purified water

Questions or Comments?

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

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

PVP

Questions

1-800-430-5490

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 15⁰ to 30⁰ C (59⁰ 0- 86⁰ F)
- do not reuse towelette

BZK

Inactive ingredients

water

BZK

Questions

1-800-430-5490

4300

019580-4601 Kit Contents

1 KNUCKLE BAND 8 PER
1 FIRST AID BURN CREAM 6 PER
1 TRIANGULAR BDG, NON-STERILE
1 INSTANT COLD PACK 4" X 6"
1 BUFFERED EYE WASH 1 OZ BTL
1 BANDAGE COMP, 2" OFFSET, 4 PER
1 BANDAGE COMP, 4" OFFSET, 1 PER
2 ADHESIVE BDG, PLSTIC, 1" X 3" 16 PER
1 PVP IODINE WIPES 10 PER
1 ANTIMCRBL ANTSPCTC TWLETTTS 6 PER
1 NITRILE GLOVES 2PR BBP
LBL STOCK 6-3/8" X 4"
LBL STOCK 4" X 2-7/8"
1 LBL STOCK 3" x 1-7/8"
1 KIT STL 16 UN (VERTICAL)
1 LBL INSTR FA REV A

1 STING Relief WIPES 10

4397

019580-3572

1 KNUCKLE BAND 8 PER

1 FIRST AID BURN CREAM 6 PER

1 TRIANGULAR BDG, NON-STERILE

1 INSTANT COLD PACK 4" X 6"

1 BUFFERED EYE WASH 1 OZ BTL

1 BANDAGE COMP, 2" OFFSET, 4 PER

1 BANDAGE COMP, 4" OFFSET, 1 PER

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

2 PVP IODINE WIPES 10 PER

1 ANTIMCRBL ANTSPCTC TWLETTTS 6PER

1 NITRILE GLOVES 2PR BBP

LBL STOCK 6-3/8"X4"

LBL STOCK 4"X2-7/8"

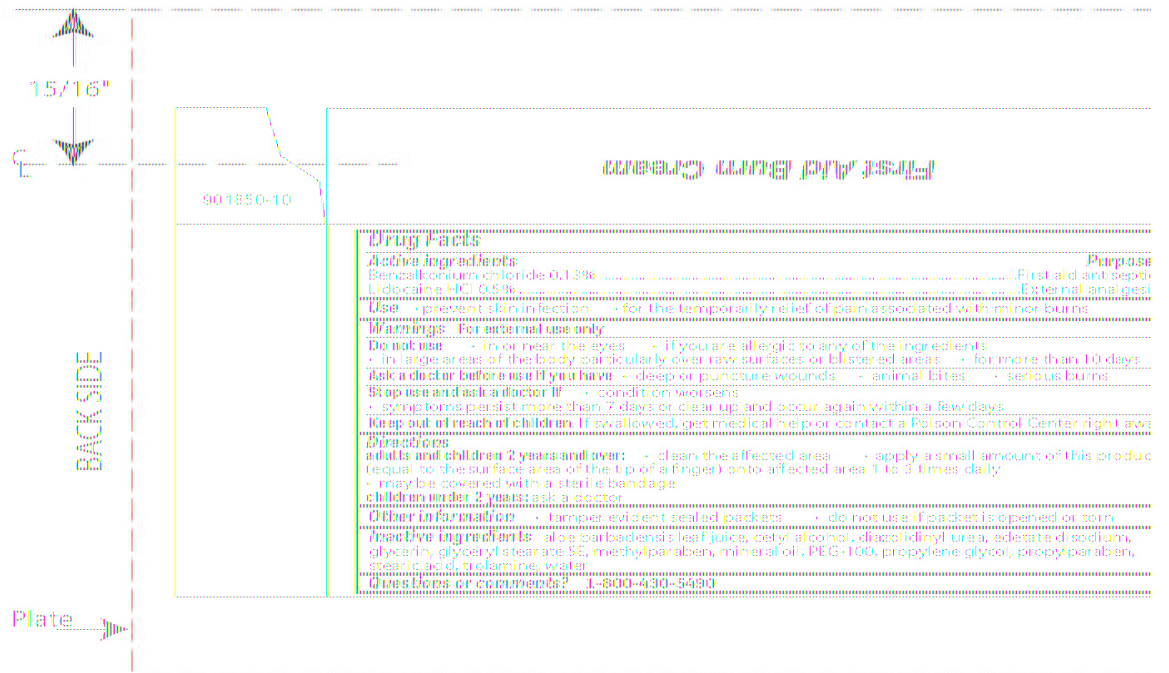
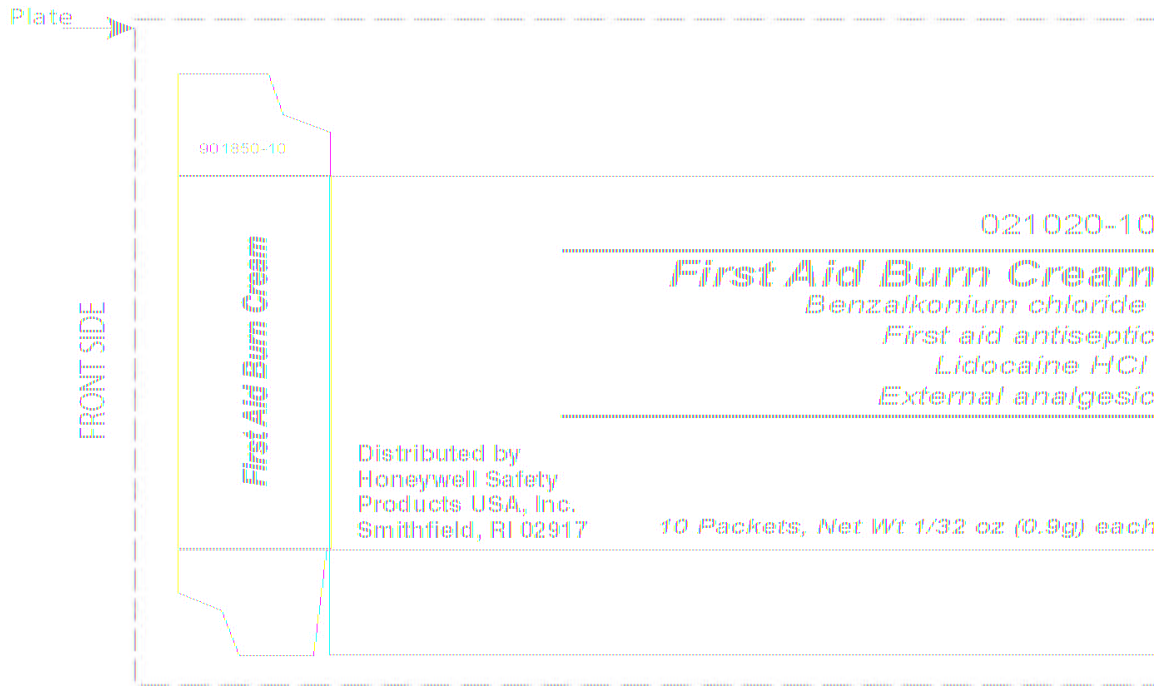
1 LBL STOCK 3"x1-7/8"

1 KIT STL 16 UN (VERTICAL)


1 LABL INSTR FA REV A

1 NOX A STING WIPES 10

**First Aid Burn Cream
Principal Display Panel**



Principal Display Panel



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 11 45033 17

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	

space for lot code and supplier part number

REORDER / NIEVO PEDIDO / REAPPROVISIONNEMENT #32-00064-0000

Rev. J

PEEL / PELAR / PELER

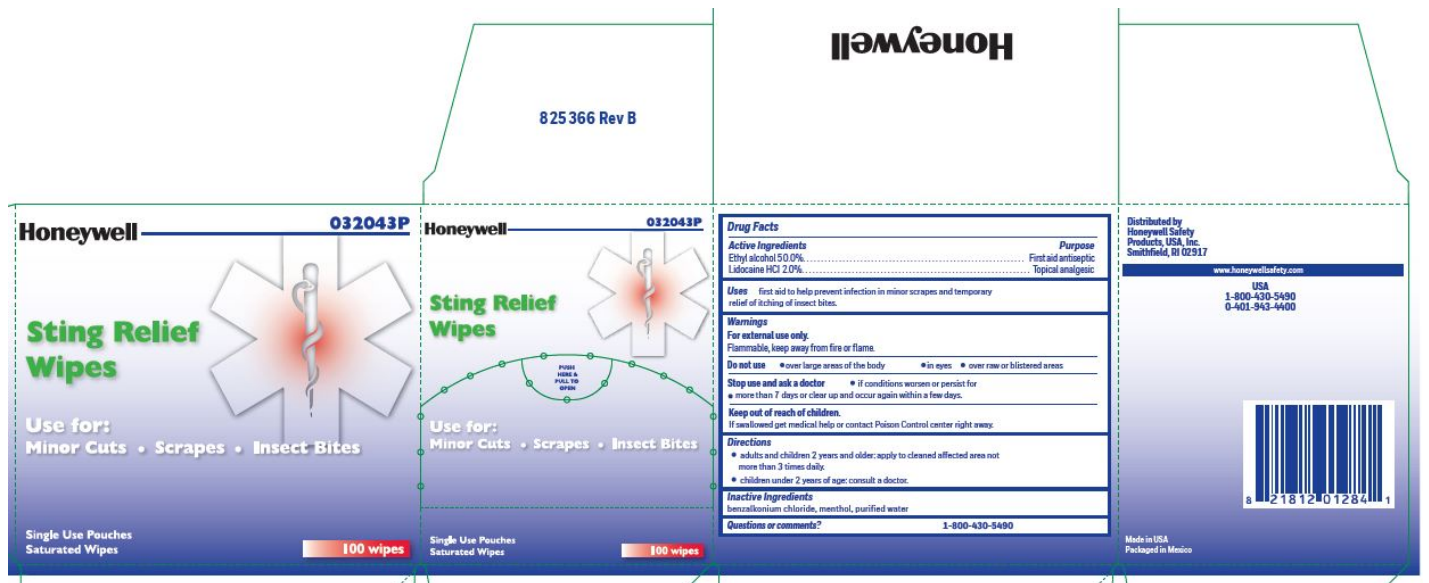
Datos de medicamento (Para EE.UU. solamente)

Ingrediente Activo Agua estéril 99%	Propósito Lavaojos
Usos para el lavado de ojo para quitar las partículas sueltas y extrañas, los contaminantes aéros, 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 médica 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 en la botella • si es necesario, sigue enjuagado con un lavado 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	

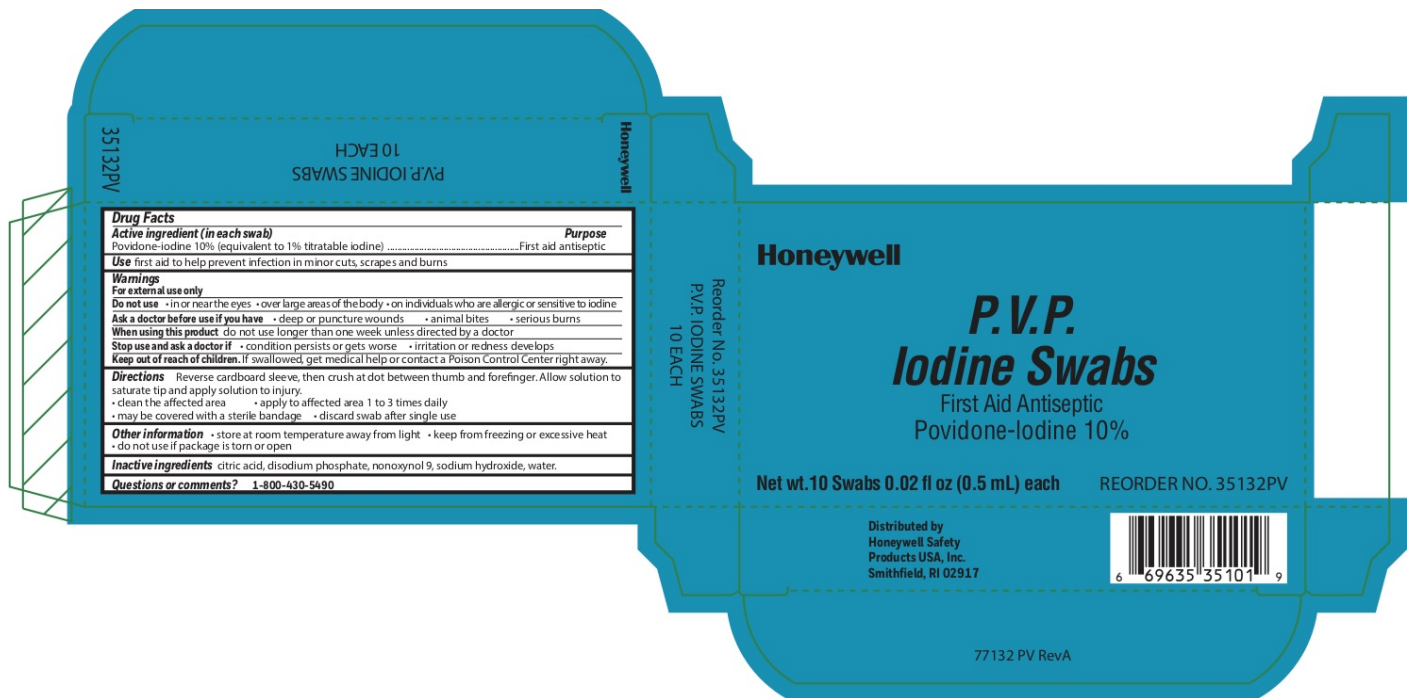
Information

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, jetez-les. 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 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

Sting Relief Principal Display Panel



PVP
Principal Display Panel



BZK
Principal Display Panel

47001083
Rev B

Antiseptic Towelettes

Honeywell

02-16-35MD

Antiseptic Towelettes

Benzalkonium chloride
First aid antiseptic

Six-Saturated Towelettes

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

47001083
Rev B

Antiseptic Towelettes

Honeywell

Drug Facts

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

Warnings
For external use only

When using this product • do not use in the eyes or apply over large 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 • condition persists or gets worse

Do not use • longer than 1 week unless directed by doctor

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

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

Inactive ingredient water

Questions or comments 1-800-430-5490

4300 Kit Label
019580-4601

Cover Dimensions: 6.5" x 9.75"

(Two Color Job) First Pass PMS 152 Orange Second Pass Black



This drawing has been submitted for your approval.

- Needs changes (indicate changes and fax back to North Safety Products).
- Approved (Sign below and fax to North Safety Products).

Engineering Graphic Design

Name _____

Signature _____

Date _____

4397 Kit Label
019580-3572

46001363 Rev.C
Prints 3 colors
Black, Red (PMS 186) and Blue (PMS 072)

Refill Information

US Poison Control 1-800-222-1222



Contact your authorized Honeywell Safety Products
Distributor with your refill orders.

Honeywell

www.honeywellsafety.com

USA	CANADA	EUROPE
1-401-943-4400	1-514-351-7233	+31 (0) 118 656400
1-800-430-4110	1-888-212-7233	

46001363 Rev. C

4300 first aid kit kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0498-4300
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-4300-01	1 in 1 KIT; Type 0: Not a Combination Product	10/18/2018	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	6 PACKET	5.4 g
Part 2	1 BOTTLE	30 mL
Part 3	10 POUCH	4 mL
Part 4	10 POUCH	3 mL
Part 5	6 PACKET	8.4 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: 059QF0K00R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
METHYL PARABEN (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

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
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.5 mL in 1 mL
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	20 mg 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
OTC monograph not final	part348	12/23/2017	

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: 059QF0K00R)	

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

ANTISEPTIC TOWELETTE

benzalkonium chloride liquid

Product Information

Item Code (Source) NDC:0498-0501

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0501-00	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	12/22/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/18/2018	

4397 FIRST AID KIT

4397 first aid kit kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0498-4397
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-4397-01	1 in 1 KIT; Type 0: Not a Combination Product	10/18/2018	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	6 PACKET	5.4 g
Part 2	1 BOTTLE	30 mL
Part 3	10 POUCH	4 mL
Part 4	10 POUCH	3 mL
Part 5	6 PACKET	8.4 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)	
METHYL PARABEN (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)	
PROPYL PARABEN (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

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
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.5 mL in 1 mL
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	20 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
MENTHOL (UNII: L7T10EP3A)	
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
OTC monograph not final	part348	12/23/2017	

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

ANTISEPTIC TOWELETTE

benzalkonium chloride liquid

Product Information

Item Code (Source)	NDC:0498-0501
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0501-00	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	12/22/2017	

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
Honeywell Safety Products USA, INC		079287321	pack(0498-4300, 0498-4397)

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(0498-0501)

Establishment

Name	Address	ID/FEI	Business Operations
Sion Medical Biotext		532775194	manufacture(0498-0121)

Establishment

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