

4345 FIRST AID KIT - 4345 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.

4345 First Aid Kit (Pyrocaine Sp, EW, Burn Jel, PVP wipe, BZK wipes, amm. Inh- Z019852)

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

Ammonia***Active ingredient***

Ammonia 15%

Ammonia***Purpose***

Respiratory stimulant

Ammonia***Uses***

- to prevent or treat fainting

Ammonia***Warnings*****For external use only****Do not use**

- if you have breathing problems such as 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.

Ammonia***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

Ammonia***Other information***

- store at room temperature away from light

Ammonia***Inactive ingredient***

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

Ammonia**Questions or Comments?**

1-800-430-5490

Pyrocaine**Active ingredient**

Benzocaine 20%

Benzethonium chloride 0.2%

Pyrocaine**Purpose**

Topical anesthetic

Topical antiseptic

Pyrocaine**Uses**

For the temporary relief of pain and itching, and to help protect against skin infection in:

- minor burns
- minor skin irritations
- minor cuts and scrapes
- insect bites
- sunburns

Do not use

- in or near the eyes or over large portions of the body
- in case of deep or puncture wounds or on:
 - raw surfaces
 - blistered areas
 - animal bites
 - serious burns

Keep out of reach of children

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

Pyrocaine**Warnings****For external use only****Flammable**

- keep away from fire or flame
- contents under pressure
- do not puncture, incinerate or expose container to temperatures above 120 o F

Stop use and ask a doctor if

- If condition persists or worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days

Pyrocaine***Directions***

- clean the affected area
- shake can well before using
- hold can 6 to 12 inches away from the affected area and spray liberally
- apply to affected area not more than 3 times daily
- for adult institutional use only
- not intended for use on children

Pyrocaine***Other information***

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

Pyrocaine***Inactive ingredients***

butane, dipropylene glycol, isobutane, propane

Burn Jel***Active ingredient***

Lidocaine HCL 2.0%

Burn Jel***Purpose***

External analgesic

Burn Jel***USes***

- temporarily relieves pain due to minor burns

Do not use

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

Burn Jel***Warnings*****For external use only****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

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

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 - 86⁰ F)

do not reuse towelette

BZK***Inactive ingredient***

water

BZK***Questions***

1-800-430-5490

4345**Z019852 Kit Contents**

1 AMMONIA INHALANTS 10 PER

1 EYE DRESS PKT W/4 ADH STRIPS

1 TRIANGULAR BDG, NON-STERILE

2 INSTANT COLD PACK 4" X 6"

1 BUFFERED EYE WASH 1 OZ BTL

1 BANDAGE COMP, 3" OFFSET, 2 PER

1 BANDAGE COMP, 4" OFFSET, 1 PER

2 BURN JEL 1/8 OZ, 6 PER

1 WATER JEL DRESSING 4" X 4"

1 PVP IODINE WIPES 10 PER

1 ANTIMCRBL ANTSPTC TWLETTS

1 FIRST AID GUIDE ASHI

LBL STOCK 6-3/8"X4"

LBL STOCK 4"X2-7/8"

1 LBL STOCK 3"x1-7/8"

1 LBL CONTS 8"X8",CUSTOM ID B

1 KIT PP 24 UNIT FA

8 BLUE DETECTABLE KNUCKLE

1 ADHS TAPE .5"X2.5YD 2

1 PYRO-CAINE AERO 2/BX

1 SCISSOR & FORCEP 1 EA

2 BLUE 1"X3" BANDS 16'S

1 BLUE FINGERTIP "8" 8'S

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



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)

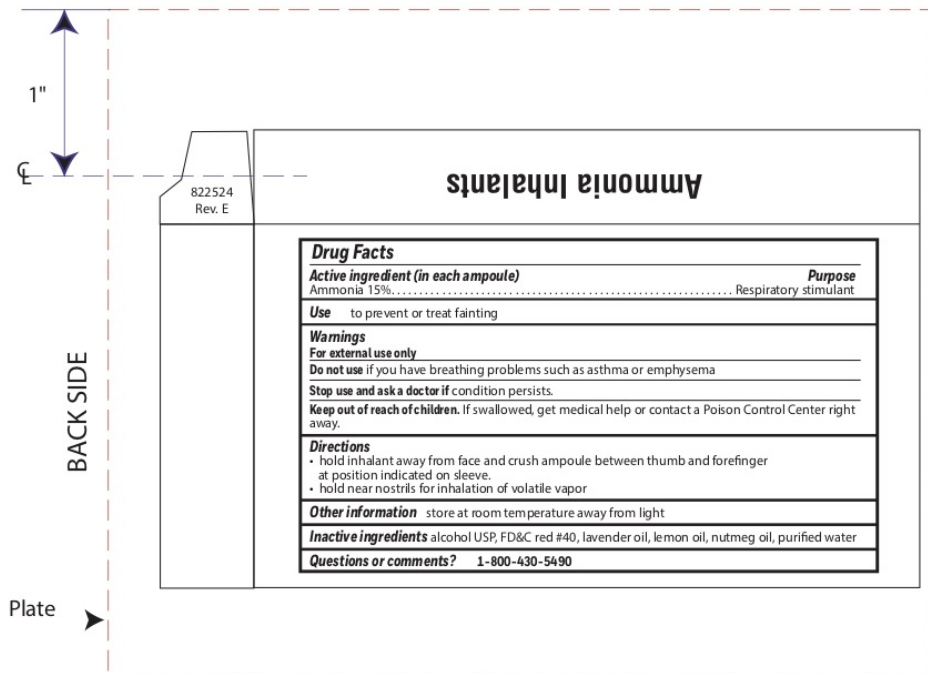
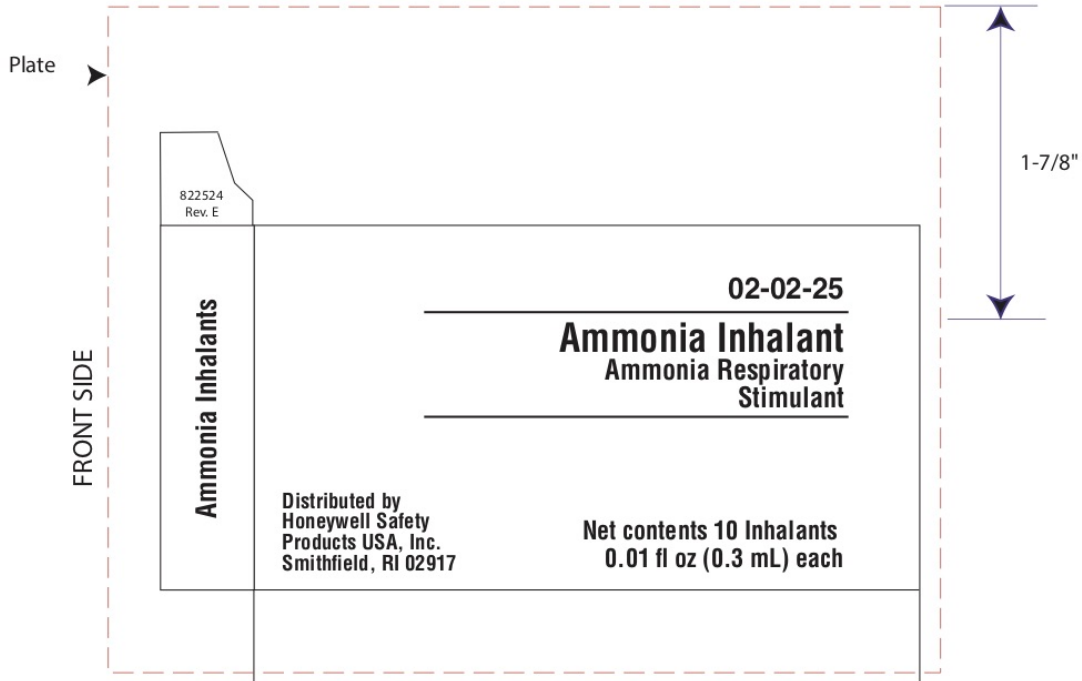
Ingrediente Activo Agua estéril 99% **Propósito** Lavaojos
Usos para el lavado de ojo para quitar las partículas sueltas y extrañas, los contaminantes aéreos, o agua de cloruro.
Advertencias Para el uso externo sólo - Obtenga tratamiento médico inmediato para todas las heridas abiertas en o cerca de 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 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

Ammonia
Principal Display Panel

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



796006 Rev. E (page 3 of 3)

Principal Display Panel

Honeywell

**PYRO-Caine
BURN SPRAY**
FOR SURFACE PAIN
AND ITCHING

**BENZOCaine
TETRACaine
PRILOCaine
LIDOCaine
CHLORbutOL
MENTHOL
MENTHyl SALICYlate
METHyl SALICYlate
ETHyl VANillin
ETHyl MENTHyl SULFONate
ETHyl MENTHyl SULFONate
ETHyl MENTHyl SULFONate
ETHyl MENTHyl SULFONate**

NET WT. 0.5 OZ. (14.2 g)
Distributed by:
Honeywell Safety
Products USA, Inc.
Smithfield, RI 02917

Drug Facts

Active Ingredients	Purpose
Benzocaine 4.0%	Topical anesthetic
Tetracaine 1.0%	Topical anesthetic
Prilocaine 0.5%	Topical anesthetic
Lidocaine 0.5%	Topical anesthetic
Chlorbutol 0.5%	Topical anesthetic
Menthol 0.5%	Topical anesthetic
Menthyl Salicylate 0.5%	Topical anesthetic
Methyl Salicylate 0.5%	Topical anesthetic
Ethyl Vanillin 0.5%	Topical anesthetic
Ethyl Menthyl Sulfonate 0.5%	Topical anesthetic
Ethyl Menthyl Sulfonate 0.5%	Topical anesthetic
Ethyl Menthyl Sulfonate 0.5%	Topical anesthetic
Ethyl Menthyl Sulfonate 0.5%	Topical anesthetic

Uses For the temporary relief of pain and itching, and to help prevent further skin irritation in:
 • Burns • Minor skin irritations
 • Minor cuts and scrapes • Insect bites • Allergies

Warnings
For external use only

Flammable • Use away from fire or flame • Avoid contact with eyes
 • Do not inhale, swallow or ingest when in vapors above 100°F

Do not use • Do not use the spray on any large portion of the body
 • Do not use on open or broken wounds or sores • Do not use on
 • Irritated areas • Painful blisters • Areas of infection

Keep out of reach of children • Contains 11.5 mg of Benzocaine per 0.5 oz (14.2 g) spray.
 • Contains 1.0 mg of Tetracaine per 0.5 oz (14.2 g) spray.
 • Contains 0.5 mg of Prilocaine per 0.5 oz (14.2 g) spray.
 • Contains 0.5 mg of Lidocaine per 0.5 oz (14.2 g) spray.
 • Contains 0.5 mg of Chlorbutol per 0.5 oz (14.2 g) spray.
 • Contains 0.5 mg of Menthol per 0.5 oz (14.2 g) spray.
 • Contains 0.5 mg of Menthyl Salicylate per 0.5 oz (14.2 g) spray.
 • Contains 0.5 mg of Methyl Salicylate per 0.5 oz (14.2 g) spray.
 • Contains 0.5 mg of Ethyl Vanillin per 0.5 oz (14.2 g) spray.
 • Contains 0.5 mg of Ethyl Menthyl Sulfonate per 0.5 oz (14.2 g) spray.

Directions • Spray the affected area • Shake can well before using
 • Hold can 6-12 inches away from the affected area and spray liberally
 • Apply to affected area approximately 3 times daily
 • Do not rub into skin • Do not use if you are allergic

Other Information • Read labeling • See only at store
 • Contains menthyl salicylate, salicylic acid, and other ingredients that may be harmful if swallowed

Inactive Ingredients Water, Glycerin, Propylene Glycol, Hydroxyethylcellulose

47-0833

Burn Jel Principal Display Panel

Rev E
001002

02-10-20

Burn Jel®

Burn Jel®
Lidocaine HCl 2%
External Analgesic

6 Packets, Net Wt 1/8 oz (3.5 g) each

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

PACKAGE NOT CHILD-RESISTANT

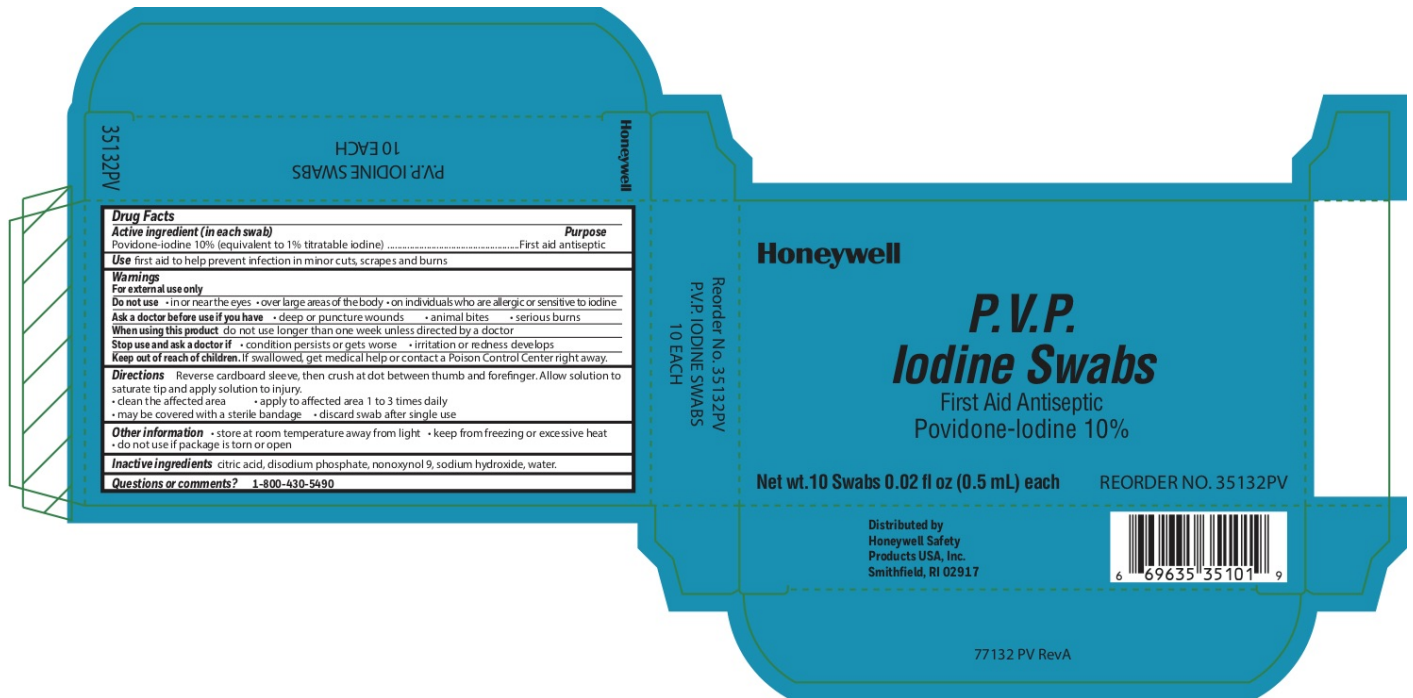
ANSI Z396.1-2003

Rev E
001003

Burn Jel®

Drug Facts	
Active ingredient	Lidocaine HCl 2% Purpose External Analgesic
Uses	Temporarily relieves pain due to minor burns.
Warnings	
For external use only	
Do not use	on large areas of the body, particularly on the surface or blistered area.
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 Poison Control or right away.
Directions	
	Adults and children 2 years of age and older: apply to affected area not more than 3-4 times daily.
	Children under 2 years of age: ask a doctor.
	You may report a serious adverse reaction to this product to 800-438-4400.
Other information	Store at room temperature (59-77°F) (15-25°C). Do not use if the cap is open.
Inactive ingredient	alcohol 96%, calcium 1.5%, dimethyl urea, glycerin, methylhexylamine hydrochloride, methylparaben, polyoxyethylene glycol, propylparaben, stearic acid, water.
Questions or comments?	1-800-438-5460

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

4345 Kit Label
Z019852

46001404 Rev. C
prints 2 colors black and red (pms 485)

Refill Information

US Poison Control 1-800-222-1222

46001404 Rev. C

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

4345 first aid kit kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0498-4345
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-4345-01	1 in 1 KIT; Type 0: Not a Combination Product	10/18/2018	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	30 mL
Part 2	10 AMPULE	3 mL
Part 3	2 CAN	28.4 g
Part 4	10 POUCH	3 mL
Part 5	12 PACKET	42 g
Part 6	1 PACKET	1.4 mL

Part 1 of 6

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: 059QF0K00R) (WATER - UNII:059QF0K00R)	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
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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 2 of 6

AMMONIA INHALENT

ammonia inhalent inhalant

Product Information

Item Code (Source)	NDC:0498-3334
Route of Administration	RESPIRATORY (INHALATION)

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMMONIA (UNII: 5138Q19F1X) (AMMONIA - UNII:5138Q19F1X)	AMMONIA	0.045 g in 0.3 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-3334-00	0.3 mL in 1 AMPULE; 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 3 of 6

PYROCAINE BURN

benzocaine, benzethonium chloride aerosol, spray

Product Information

Item Code (Source)	NDC:0498-0011
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Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	20 g in 100 g
BENZETHONIUM CHLORIDE (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP)	BENZETHONIUM CHLORIDE	0.2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
1,1,3-TRI(3-TERT-BUTYL-4-HYDROXY-6-METHYLPHENYL)BUTANE (UNII: BF6E9O0XJN)	
ISOBUTANE (UNII: BXR49TP611)	
1,1,3-TRIS(2-CHLOROETHOXY)PROPANE (UNII: 4FEX9N888E)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0011-77	14.2 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
OTC monograph not final	part348	01/01/2018	

Part 4 of 6**PVP IODINE WIPE**

povidone-iodine 10% swab

Product Information

Item Code (Source)	NDC:0498-0121
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Route of Administration	TOPICAL
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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 6

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
CARBOMER HOMO POLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
GLYCERIN (UNII: PDC6A3C0OX)	
TEA TREE OIL (UNII: VIF565UC2G)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER HOMO POLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
OCTOXYNOL-9 (UNII: 7JPC6Y25QS)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	

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 6 of 6

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	12/21/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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unapproved drug other		10/18/2018	
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Labeler - Honeywell Safety Products USA, INC (079287321)

Establishment

Name	Address	ID/FEI	Business Operations
James Alexander		040756421	manufacture(0498-3334)

Establishment

Name	Address	ID/FEI	Business Operations
Honeywell Safety Products USA, INC		079287321	pack(0498-4345)

Establishment

Name	Address	ID/FEI	Business Operations
Dixon Investments		115315822	manufacture(0498-0011)

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(0498-0501)

Establishment

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