

**4293 FIRST AID KIT- 4293 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.

4293 First Aid Kit (Triple, ammonia, Burn Jel, alcohol wipes, HC cr, PVP wipes, sting relief, EW- SF00004080)

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

Triple

Active ingredient

Bacitracin zinc 400 units

Neomycin sulfate (5 mg equivalent to 3.5 mg Neomycin base)

Polymyxin B sulfate 5000 units

Triple

Purpose

First aid antibiotic

First aid antibiotic

First aid antibiotic

Triple

Uses

first aid to help prevent infection in:

- minor cuts
- scrapes
- burns

Triple

Warnings

For external use only

Allergy alert: do not use if you are allergic to any of the ingredients

Do not use

- in the eyes
- over large areas of the body
- Ask a doctor before use if you have
- a deep or puncture wounds
- animal bites
- serious burns

Stop use and ask a doctor if

- the condition persists or gets worse
- a rash or other allergic reaction develops
- you need to use longer than 1 week

Keep out of the reach of children

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

Triple***Directions***

- clean the affected area
- apply a small amount of the product (an amount equal to the surface area of the tip of a finger) on the area 1 to 3 times daily
- may be covered with a sterile bandage

Triple***Other information***

- store at 15⁰ to 25⁰ C (59⁰ to 77⁰ F)
- tamper evident sealed packets
- do not use if packet is torn or opened

Triple***Inactive ingredient***

petrolatum

Triple***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.

Eyeash***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

Hydrocortisone***Active ingredient (in each gram)***

Hydrocortisone acetate (equivalent to Hydrocortisone 1%)

Hydrocortisone***Purpose***

Anti-itch cream

Hydrocortisone***Uses***

- for the temporary relief of itching associated with minor skin irritations and rashes

Hydrocortisone

Warnings

For external use only

Ask a doctor before use if

- you are using any other hydrocortisone product

When using the product

- avoid contact with eyes
- do not begin use of any other hydrocortisone product unless you have consulted a doctor
- do not use for the treatment of diaper rash

Stop use and ask a doctor if

- condition worsens
- condition persists 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.

Hydrocortisone

Directions

- adults and children 2 years and older:
- clean the affected area
- apply to the area not more than 3 to 4 times daily
- children under 2 years of age: consult a doctor

Hydrocortisone

Other information

- store at room temperature (do not freeze)

Hydrocortisone

Inactive ingredients

cetyl alcohol, citric acid, diazolidinyl urea, edetate disodium, glycerin, glyceryl monostearate, methylparaben, mineral oil, polyethylene glycol, propylene glycol, propylparaben, purified water, stearic acid, trolamine

Hydrocortisone

Questions or Comments?

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 ingredients***

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

Ammonia***Questions or Comments?***

1-800-430-5490

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 15⁰ to 25⁰ C (59⁰ to 77⁰ 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

4293

SF00004080 Kit Contents

1 FNGRTIP-5 PER, KNCKL BDG-4 PER
 1 TRIPLE ANTIBIOTIC 10 PER
 1 AMMONIA INHALANTS 10 PER
 1 EYE DRESS PKT W/4 ADH STRIPS
 1 TRIANGULAR BDG, NON-STERILE
 1 FORCEPS & SCISSORS, 1 EA
 1 GAUZE BANDAGE, 2" X 6 YD, 2 PER
 1 INSTANT COLD PACK 4" X 6"
 1 ADH BDG W/NOADHR PAD, 1X3 32PER
 1 BURN JEL 1/8 OZ, 6 PER
 1 ALCOHOL PREP PADS 10P
 1 HYDROCORTISON, 1.0%, 1/32 OZ, 10P
 1 PVP IODINE WIPES 10 PER
 1 STING RELIEF WIPES 10 PER BOX
 1 ADH TAPE W/P 1/2" X 2 1/2 YD
 1 FIRST AID GUIDE ASHI
 1 1 OZ, BUFF EYEWASH
 1 BANDAGE COMP 4" W/TELFA PAD 1
 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 24 UN WHITE 01

Burn Jel

Principal Display Panel

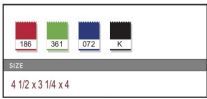
796353 Rev. E Unit Carton Printing Plate for "B" size cartor



Principal Display Panel



Sting Relief Principal Display Panel



Honeywell

825366 Rev B

Honeywell **032043P** **Honeywell** **032043P**

Sting Relief Wipes

Ethyl alcohol
First aid antiseptic
Lidocaine HCl
Topical analgesic

Use for:
Minor Cuts • Scrapes • Insect Bites

Single Use Pouches
Saturated Wipes

100 wipes

Sting Relief Wipes

Ethyl alcohol
First aid antiseptic
Lidocaine HCl
Topical analgesic

Use for:
Minor Cuts • Scrapes • Insect Bites

Single Use Pouches
Saturated Wipes

100 wipes

Drug Facts

Active Ingredients	Purpose
Ethyl alcohol 50.0% Lidocaine HCl 2.0%	First aid antiseptic Topical analgesic
Uses first aid to help prevent infection in minor scrapes and temporary relief of itching of insect bites.	
Warnings For external use only. Flammable, keep away from 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	
Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away.	
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.	
Inactive Ingredients Benzalkonium chloride, menthol, purified water	
Questions or comments?	1-800-430-5490

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

USA
1-800-430-5490
0-401-943-4400



8 12 18 12 10 1284 1

Made in USA
Packaged in Mexico

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 #32-004510 Rev. J REORDER / NUEVO PEDIDO / REAPPROVISIONNEMENT #32-000454-0000

space for lot code and supplier part number

PEEL / PELAR / PELEL

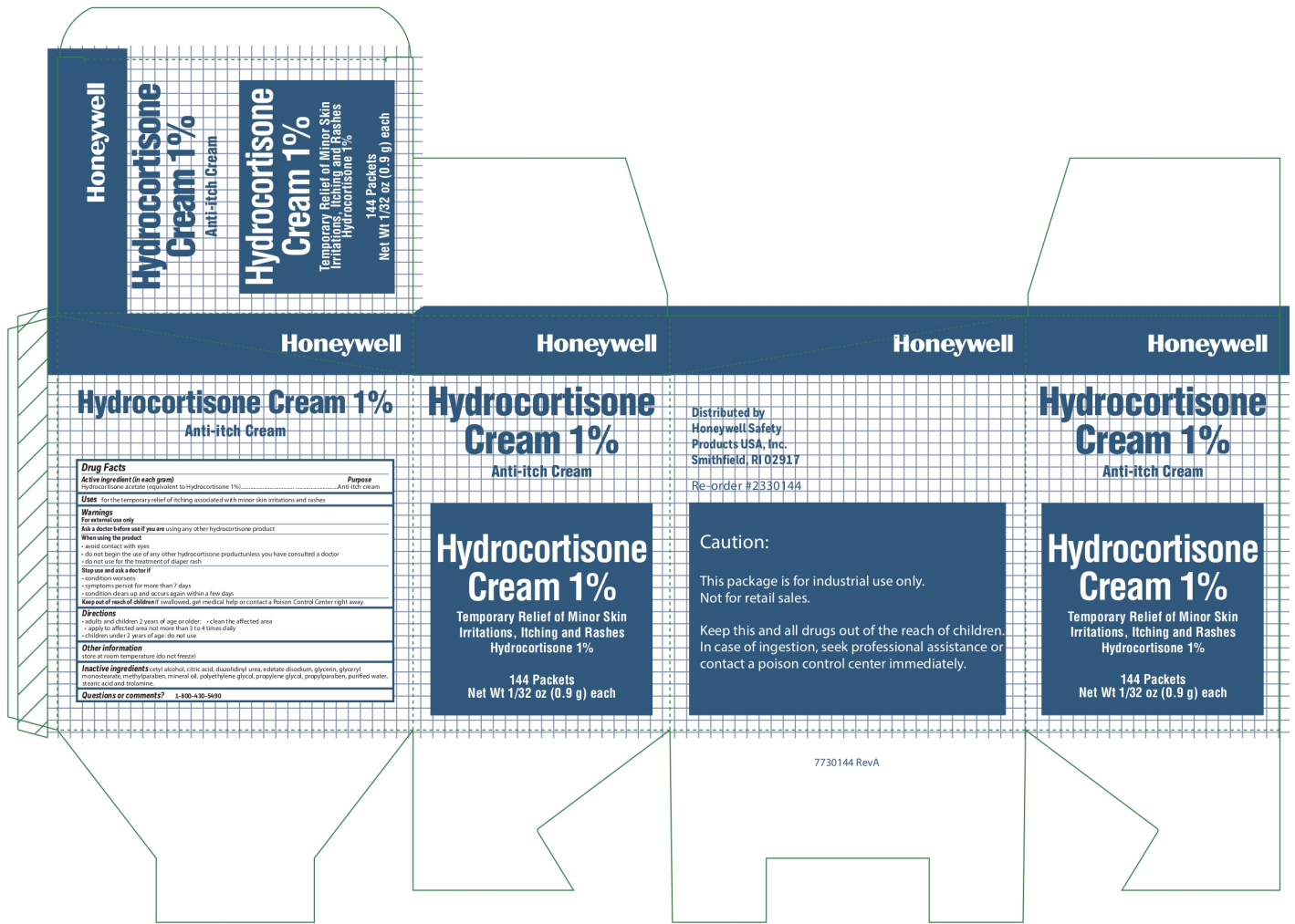
Datos de medicamento (Para EE.UU. solamente)

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

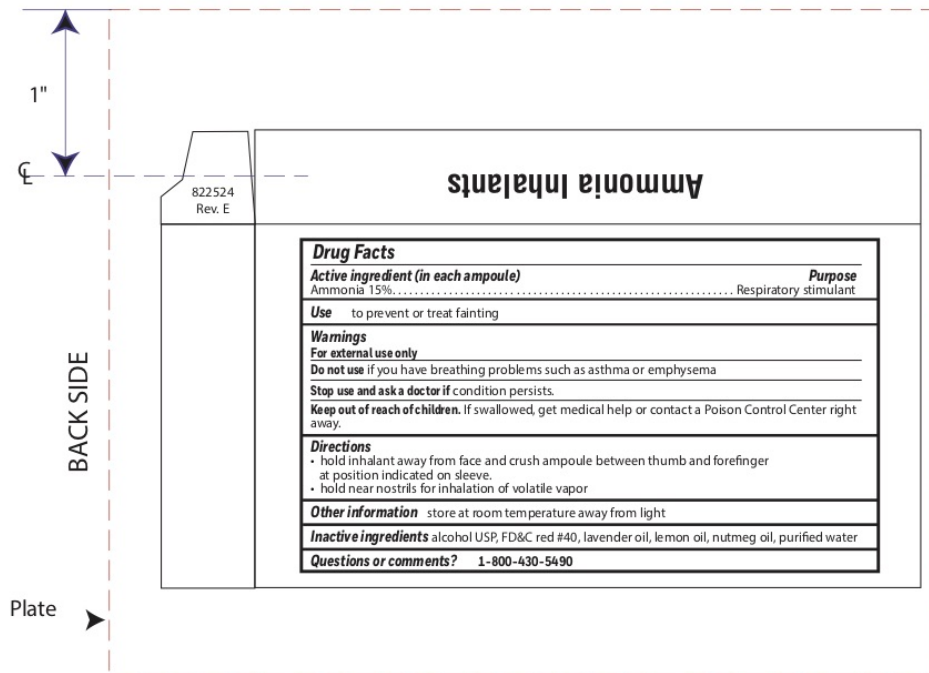
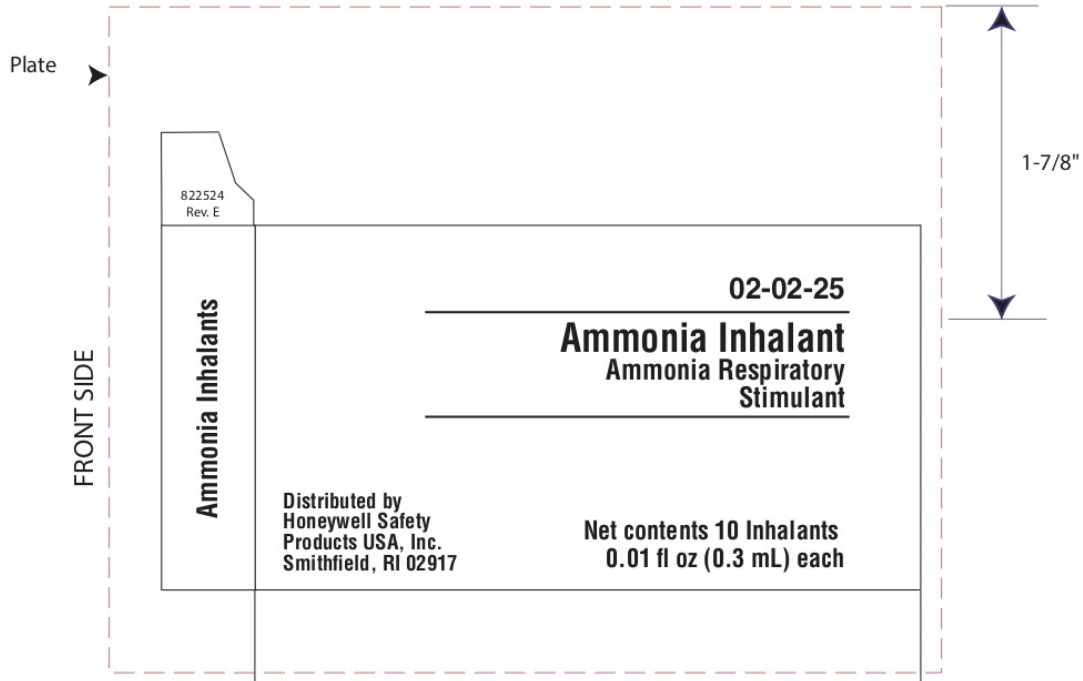
Usages
Pour le rinçage des yeux afin d'enlever un corps étranger, des polluants atmosphériques ou de l'eau chlorée.
Advertissements
Pour usage externe seulement - Obtenir immédiatement des soins médicaux pour toutes les plaies ouvertes dans ou près des yeux. Pour éviter toute contamination, ne pas toucher 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
• 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

Hydrocortisone
Principal Display Panel



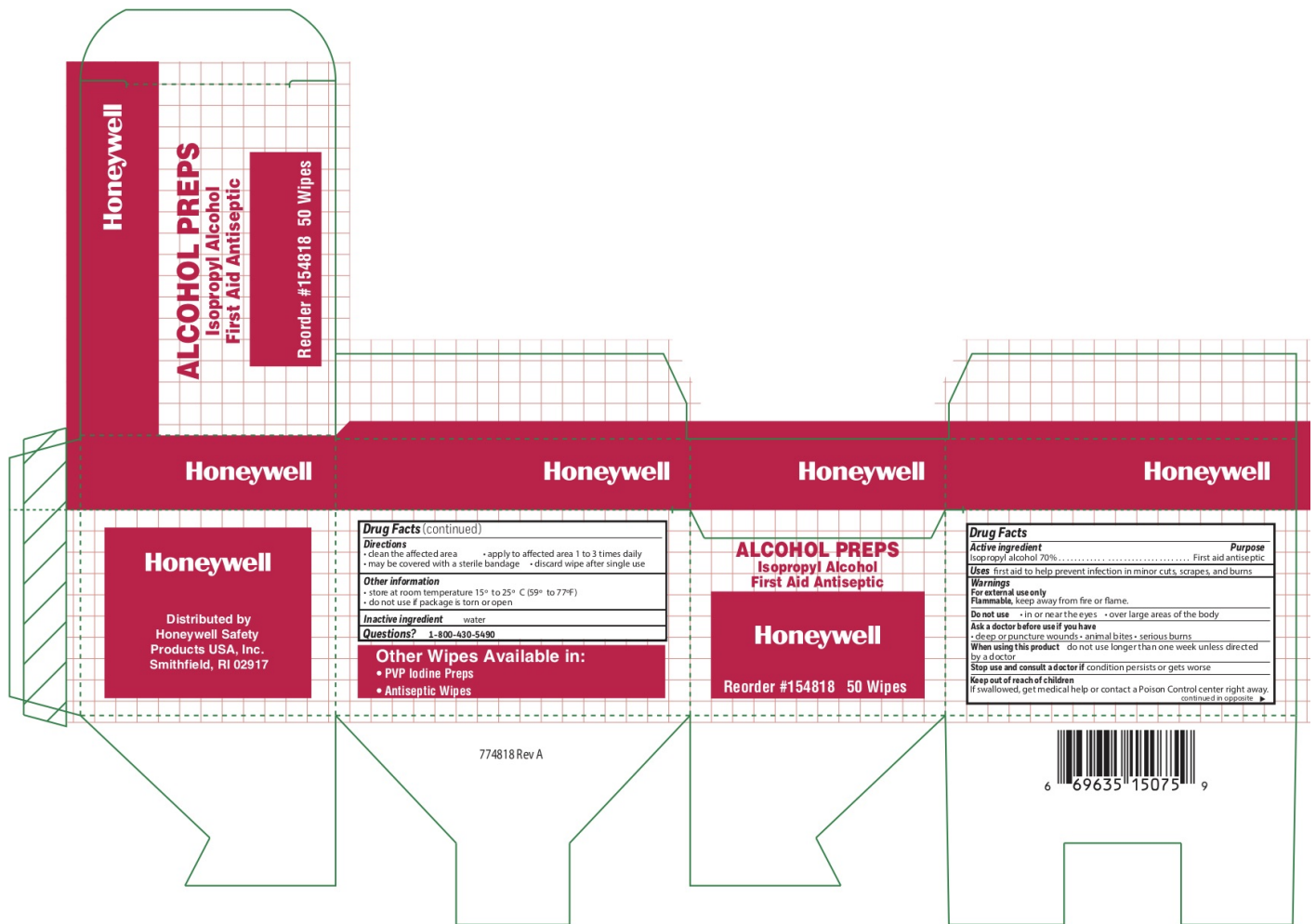
Ammonia
Principal Display Panel

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



796006 Rev. E (page 3 of 3)

Principal Display Panel



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



4293 Kit Label
SF-00004080



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

4293 FIRST AID KIT

4293 first aid kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0498-4293
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-4293-01	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 PACKET	9 g
Part 4	10 POUCH	4 mL
Part 5	10 POUCH	4 mL
Part 6	10 PACKET	9 g
Part 7	10 AMPULE	3 mL
Part 8	10 POUCH	3 mL
Part 9	10 PACKET	9 g

Part 1 of 9

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 HOMO POLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
CARBOMER HOMO POLYMER 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
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1	NDC:0498-0203-00	3.5 g in 1 PACKET; Type 0: Not a Combination Product		
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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 9

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 9

TRIPLE ANTIBIOTIC

bacitracin zinc, polymyxin b sulfate, neomycin sulfate ointment

Product Information

Item Code (Source) NDC:0498-0750

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B	5000 [iU] in 1 g
BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN	400 [iU] in 1 g
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:I16QD7X297)	NEOMYCIN	3.5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0750-35	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 final	part333B	09/19/2018	

Part 4 of 9

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 mono graph not final	part333A	09/18/2018	

Part 5 of 9**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
OTC monograph not final	part348	12/23/2017	

Part 6 of 9

HYDROCORTISONE

anti-itch cream ointment

Product Information

Item Code (Source)	NDC:0498-0800
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	HYDROCORTISONE ACETATE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
TROLAMINE (UNII: 9O3K93S3TK)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0800-34	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	part348	03/06/2013	10/15/2019

Part 7 of 9

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 8 of 9

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	

Part 9 of 9**HYDROCORTISONE**

anti-itch cream

Product Information

Item Code (Source)	NDC:0498-0801
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:W14X0X7BPJ)	HYDROCORTISONE ACETATE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
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LIGHT MINERAL OIL (UNII: N6K5787QVP)
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)
CETYL ALCOHOL (UNII: 936JST6JCN)
METHYL PARABEN (UNII: A2I8C7HI9T)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
EDETATE DISODIUM (UNII: 7FLD91C86K)
STEARIC ACID (UNII: 4ELV7Z65AP)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
TROLAMINE (UNII: 9O3K93S3TK)
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)
PROPYL PARABEN (UNII: Z8IX2SC1OH)
WATER (UNII: 059QF0KO0R)
GLYCERIN (UNII: PDC6A3C0OX)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)

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	part348	10/15/2019		

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	
James Alexander		040756421	manufacture(0498-3334)	

Establishment				
Name	Address	ID/FEI	Business Operations	
Honeywell Safety Products USA, Inc		079287321	pack(0498-4293)	

Establishment				
Name	Address	ID/FEI	Business Operations	
Water-Jel Technologies		155522589	manufacture(0498-0203, 0498-0750, 0498-0800, 0498-0801)	

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 Biotext		532775194	manufacture(0498-0121)

Establishment

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

Revised: 10/2019

Honeywell Safety Products USA, Inc.