

4301 FIRST AID KIT- 4301 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](#).

4301 First Aid Kit (ammonia inh, EW, Burn Jel, PVP wipes, alcohol wipes- SF00004247)

Eyesaline

Active ingredient

Sterile Water 99%

Eyesaline

Purpose

Eyewash

Eyesaline

Uses

- for flushing the eye to remove loose foreign material, air pollutants or chlorinated water

Eyesaline

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.

Eyesaline

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

Eyesaline***Inactive ingredients***

sodium chloride, sodium phosphate dibasic, sodium phosphate monobasic

Eyesaline***Questions***

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

Ammonia Inhalent***Active ingredient***

Ammonia 15%

Ammonia Inhalent***Purpose***

Respiratory stimulant

Ammonia Inhalent***Uses***

- to prevent or treat fainting

Ammonia Inhalent***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 Inhalent***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 Inhalent***Other information***

- store at room temperature away from light

Ammonia Inhalent

Other information

- store at room temperature away from light

Ammonia Inhalent

Inactive ingredients

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

Ammonia Inhalent

Questions or Comments

1-800-430-5490

Burn Jel

Active ingredient

Lidocaine HCl 2.0%

Burn Jel

Purpose

External analgesic

Burn Jel

Uses

- temporarily relieves pain due to minor burns

Burn Jel

Warnings

For external use only

Do not use

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

When using this product

- avoid contact with eyes

Stop use and ask a doctor if

- the condition gets worse
- symptoms persist for more than 7 days
- condition clears up and recurs within a few days

Keep out of reach of children

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

Burn Jel

Directions

- adults and children 2 years of age and older; apply to affected area not more than 3 to 4 times daily
- children under 2 years of age: ask a doctor
- you may report a serious reaction to this product to 800-430-5490

Burn Jel

Other information

- store at room temperature
- do not use if opened or torn

Burn Jel

Inactive ingredients

carbopol 940, carbopol 1342, diazolidinyl urea, glycerin, melaleuca alternifolia (tea tree) leaf oil, methylparaben, octoxynol-9, propylene glycol, propylparaben, trolamine, water ...

Burn Jel

Questions

1-800-430-5490

Povidone Iodine Swab

Active ingredient

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

Povidone Iodine Swab

Purpose

First aid antiseptic

Povidone Iodine Swab

Uses

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

Povidone Iodine Swab

Warnings

For external use only

Do not use

- 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

- conditions persists or gets worse
- irritation and redness develops

Keep out of reach of children

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

Povidone Iodine Swab***Directions***

Reverse cardboard sleeve, then crush at dot between thumb and forefinger. Allow solution to saturate tip and apply solution to injury.

- clean affected area
- apply to affected area 1 to 3 times daily
- may be covered with a sterile bandage
- discard swab after single use

Povidone Iodine Swab***Other information***

- store at room temperature away from light
- keep from freezing or excessive heat
- do not use if package is torn or open

Povidone Iodine Swab***Inactive ingredients***

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

Povidone Iodine Swab***Questions and comments***

1-800-430-5490

Alcohol Wipe***Active ingredient***

Isopropyl alcohol 70%

Alcohol Wipe***Purpose***

First aid antiseptic

Alcohol Wipe***Uses***

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

Alcohol Wipe

Warnings

For external use only

Do not use

- in the eyes
- over large areas of the body

Ask a doctor before use if you have

- deep or puncture wounds
- animal bites
- serious burn

When using this product

- do not use longer than one 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 Wipe

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

Alcohol Wipe

Other information

store at room temperature 15⁰ to 25⁰ C (59⁰ to 77⁰F)

Alcohol Wipe

Inactive ingredient

water

Alcohol Wipe

Questions

1-800-430-5490

4301

SF00004247 Kit Contents

1 AMMONIA INHALANTS 10 PER

2 PAD,NON-ADHR 2" X 3", 4 PER
1 ADHESIVE BDG,PLSTIC,1"X3"16PER
1 1 OZ EYE WASH W/PADS & STRIPS
1 BURN JEL 1/8 OZ, 6 PER
1 PVP IODINE WIPES 10 PER
1 FIRST AID GUIDE ASHI
2 BLOODSTOPPER
1 MICROSIELD W/VNL GLV/ALCL
LBL STOCK 6-3/8"X4"
1 LBL STOCK 3"x1-7/8"
1 KIT STL 16 UN (HORIZONTAL)

Eyesaline
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 #32-004510 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)

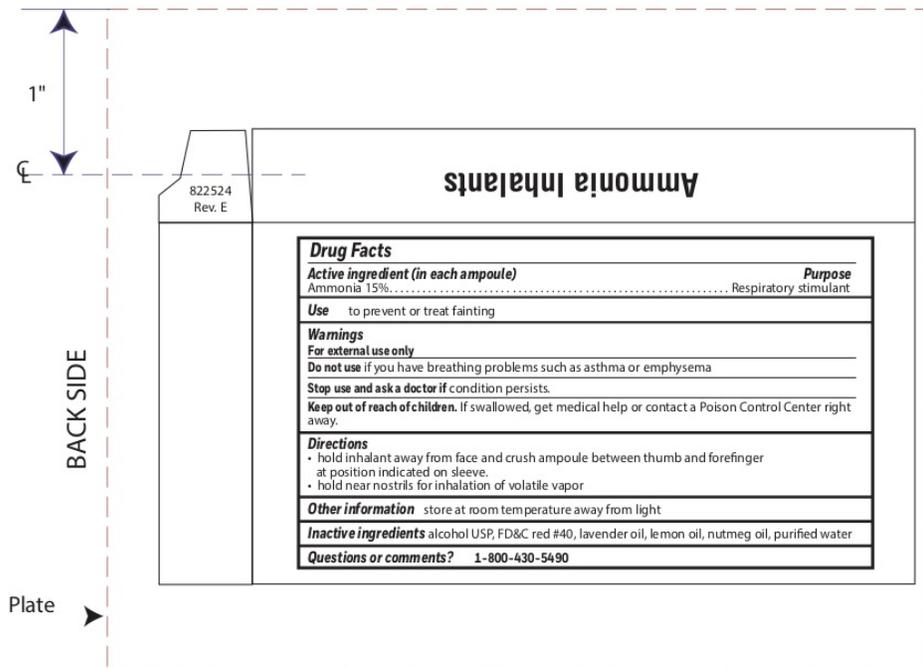
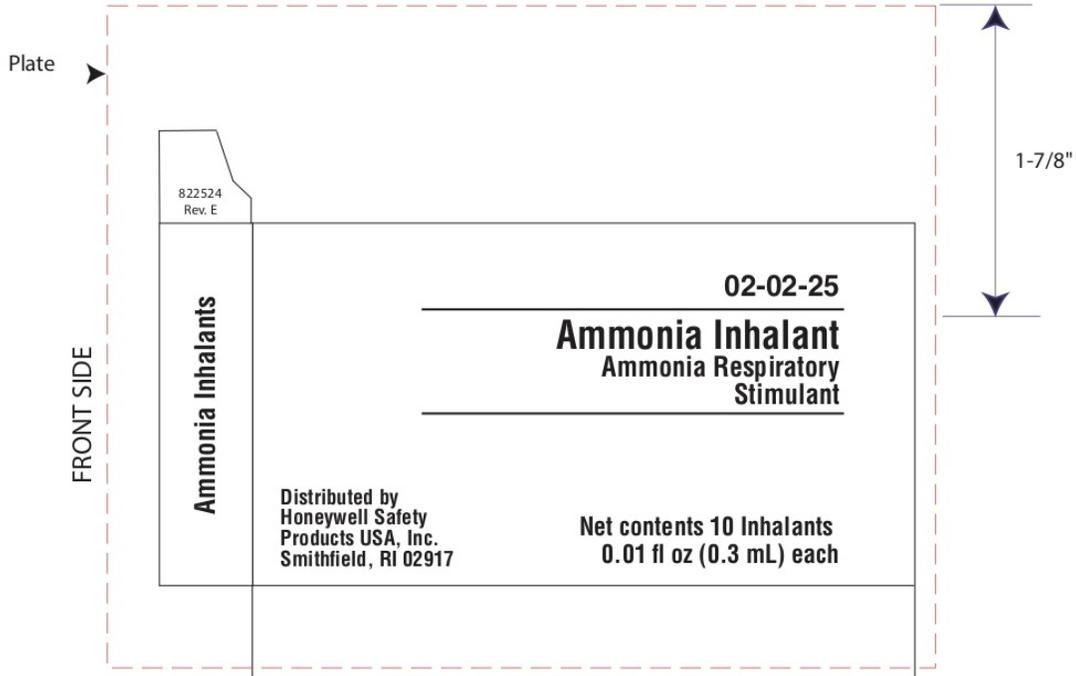
Ingrediente Activo Agua estéril 99% **Propósito** Lavaojos
Usos para el lavado de ojo para quitar las partículas sueltas y extrañas, los contaminantes aéreos, o agua de cloruro.
Advertencias Para el uso externo sólo - Obtenga tratamiento médico inmediato para todas las heridas abiertas en o cerca de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

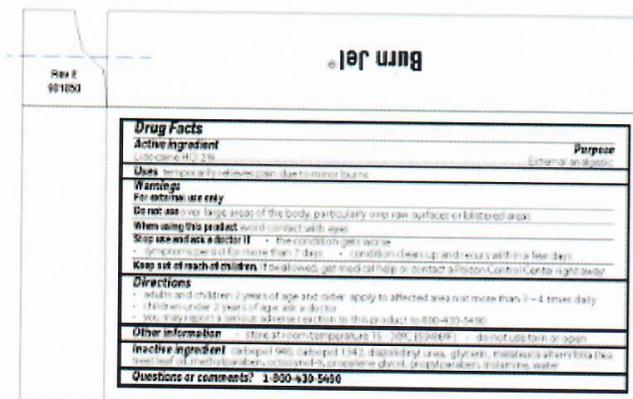
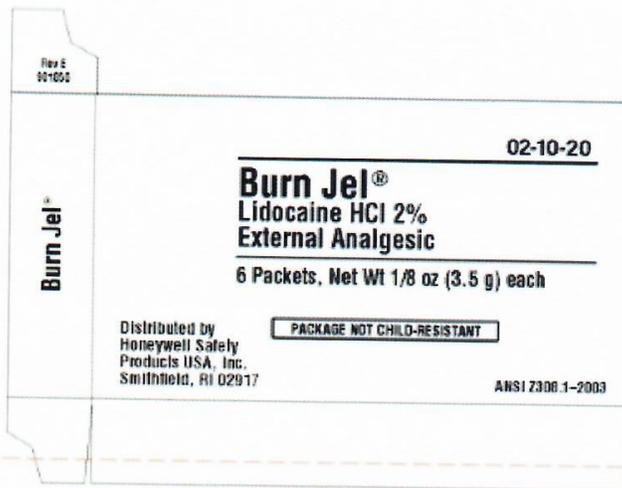
Ammonia inhalent
Principal Display Panel

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

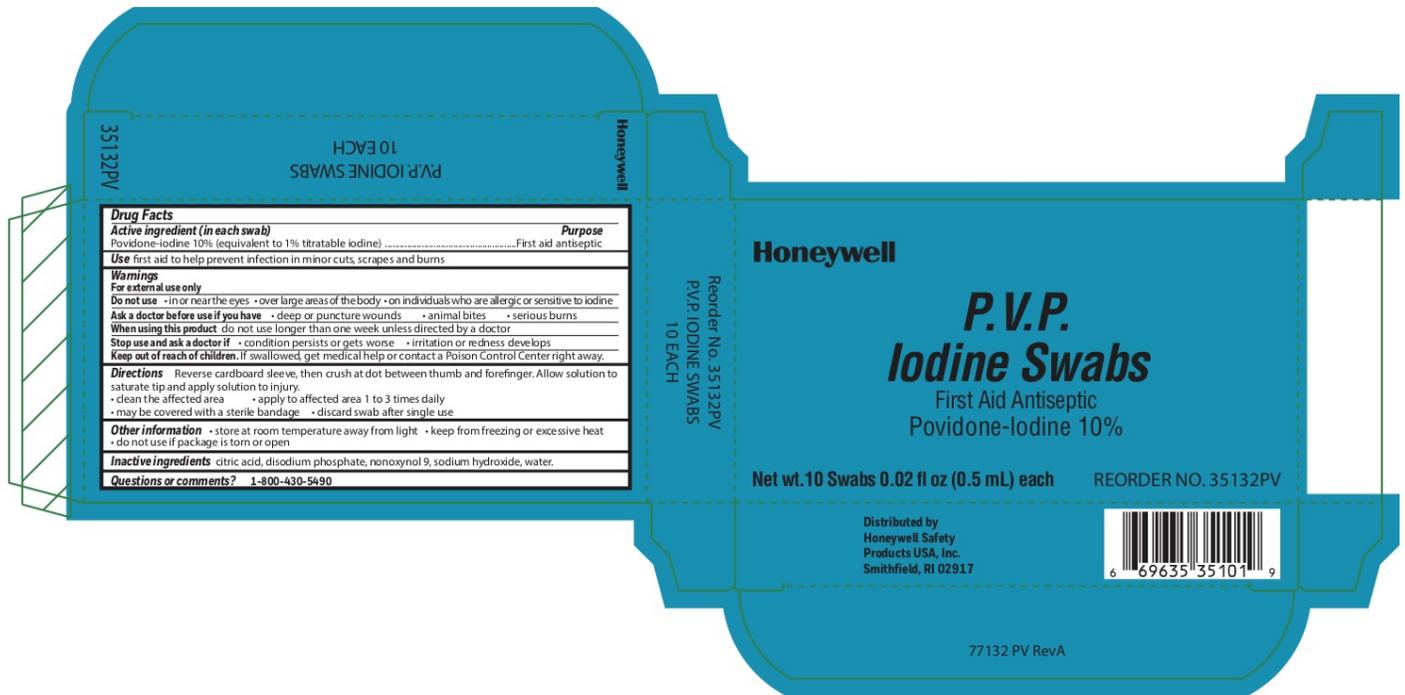


796006 Rev. E (page 3 of 3)

Principal Display Panel

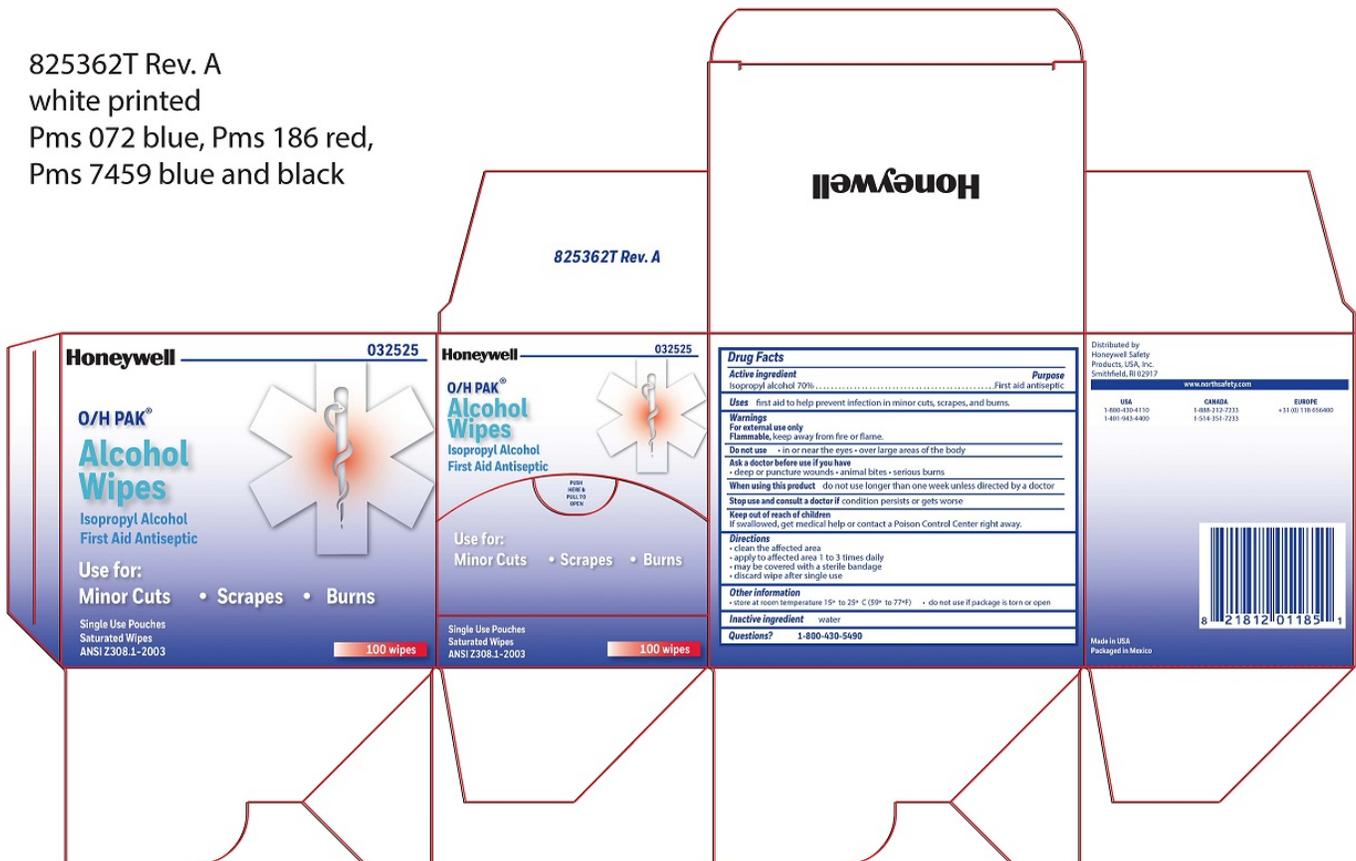


**Povidone Iodine Swab
Principal Display Panel**



**Alcohol Wipe
Principal Display Panel**

825362T Rev. A
 white printed
 Pms 072 blue, Pms 186 red,
 Pms 7459 blue and black



4301 Kit Label

SF00004247

Cover Size: 9.25"w x 6.5"h
TYPE OF KIT: Metal 16 Unit Kit Horizontal
SCREEN NUMBER: SF00002928-5100
LOGO SIZE: 8.30" x 5.49"
PRINTED IN: PMS Red 187



FIRST AID KIT

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

If distributor is signing for end user approval of logo, distributor assumes responsibility.

This drawing has been reviewed and approved for the following: kit size, ink color(s), kit part number and logo being printed on the kit

Needs changes

Approved

(A digital signature or response via email with attached approval are both accepted as an approval to this form. Please indicate any changes needed)

Name

Signature

Date

FRM-03-050 Rev. *

(8/18/10)

1/1

4301 FIRST AID KIT

4301 first aid kit kit

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:0498-4301

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-4301-01	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	4 POUCH	1.6 mL
Part 4	10 POUCH	3 mL
Part 5	6 PACKET	21 g

Part 1 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 CHLORIDE (UNII: 451W47IQ8X)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)	

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 2 of 5

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 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

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
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unapproved drug other	09/18/2018
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Part 5 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
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
OCTOXYNOL-9 (UNII: 7JPC6Y25QS)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
TEA TREE OIL (UNII: VIF565UC2G)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

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	

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
James Alexander		040756421	manufacture(0498-3334)

Establishment

Name	Address	ID/FEI	Business Operations
Honeywell Safety Products USA, INC		079287321	pack(0498-4301)

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 Biotech Medical		532775194	manufacture(0498-0121)

Revised: 5/2019

Honeywell Safety Products USA, INC