

**4149 FIRST AID KIT - 4149 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.*

-----

**4149 First Aid Kit (alcohol wipes, HC cr, PVP wipes, sting relief, EW- SF00003660)**

**Sting Relief**

***Active ingredient (in each wipe)***

Ethyl alcohol 50.0%

Lidocaine HCl 2.0%

**Sting Relief**

***Purposse***

Antiseptic

Topical pain relief

**Sting Relief**

***Uses***

- prevent infection in minor scrapes, and temporary relief of itching of insect bites

**Sting Relief**

***Warnings***

**For external use only**

**Flammable, keep away from open fire or flame**

**Do not use**

- over large areas of the body
- in eyes
- over raw or blistered areas

**Stop use and ask a doctor**

- if conditions worsen or persist for more than 7 days or clear up and occur again within a few days

**Keep out of reach of children.**

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

**Sting Relief**

***Directions***

- adults and children 2 years and older: Apply to cleaned affected area not more than 3 times daily.
- children under 2 years of age: consult a doctor.

**Sting Relief*****Inactive ingredients***

benzalkonium chloride, menthol, and purified water

**Sting Relief*****Questions or Comments?***

1-800-430-5490

**Eyewash*****Active ingredient***

Sterile Water 99%

**Eyewash*****Purpose***

Eyewash

**Eyewash*****Uses***

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

**Eyewash*****Warnings*****For external use only**

- Obtain immediate medical treatment for all open wounds in or near eyes.
- To avoid contamination, do not touch tip of container to any surface.
- Do not reuse.
- Once opened, discard.

**Do not use**

- if solution changes color or becomes cloudy
- if you have open wounds in or near the eyes, get medical help right away.

**Stop use and ask a doctor if**

- you experience eye pain
- changes in vision
- continued redness or irritation of the eye
- condition worsens or persists

**Keep out of reach of children**

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

**Eyewash*****Directions***

- remove contacts before using
- twist top to remove
- flush the affected area as needed

- control rate of flow by pressure on the bottle
- if necessary, continue flushing with emergency eyewash or shower

## **Eyewash**

### ***Inactive ingredients***

sodium chloride, sodium phosphate dibasic, sodium phosphate monobasic

## **Eyeash**

### ***Questions***

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

## **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

## **Alcohol**

### ***Active ingredient***

Isopropyl alcohol 70%

## **Alcohol**

### ***Purpose***

First aid antiseptic

## **Alcohol**

### ***Uses***

first aid to help prevent infection in

- minor cuts
- scrapes
- burns

## **Alcohol**

### ***Warnings***

**For external use only**

**Flammable, keep away from fire and flame**

### **Do not use**

- in or near eyes
- over large areas of the body

**Ask a doctor before use if you have**

- deep or puncture wounds
- animal bites
- serious burns

**When using this product**

- do not use longer than 1 week unless directed by a doctor

**Stop use and consult a doctor if**

- condition persists or gets worse

**Keep out of reach of children**

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

**Alcohol*****Directions***

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

**Alcohol*****Other information***

- store at room temperature 15<sup>0</sup> to 25<sup>0</sup> C (59<sup>0</sup> to 77<sup>0</sup> 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***

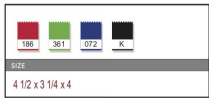
## **4149**

### **SF00003660 Kit Contents**

- 1 KNUCKLE BAND 8 PER
- 2 TRIANGULAR BDG, NON-STERILE
- 1 ADH TAPE, .5" X 2.5 YD, 2 PER
- 1 FORCEPS & SCISSORS, 1 EA
- 2 GAUZE BANDAGE, 2" X 6 YD, 2 PER
- 1 GAUZE COMP, 1 SQ YARD, 1 PER
- 1 INSTANT COLD PACK 4" X 6"
- 1 BANDAGE COMP, 2" OFFSET, 4 PER

1 BANDAGE COMP, 4" OFFSET, 1 PER  
1 FINGERTIP BANDAGE, 10 PER  
1 1 OZ EYE WASH W/PADS & STRIPS  
2 WATER JEL DRESSING, 2" X 2"  
2 WATER JEL DRESSING, 2" X 6"  
1 ALCOHOL PREP PADS 10P  
1 HYDROCORTISON, 1.0%, 1/32 OZ, 10P  
3 PVP IODINE WIPES 10 PER  
1 IVYX CLEANSER TOWEL 5 PER  
1 NITRILE GLOVES 2PR BBP  
2 ADH BDG, CLOTH, 1"X3", 16 PER  
1 CPR FILTERSHIELD 77-100  
1 4OZ BFS EYEWASH TRILINGUAL BOTTLE  
LBL STOCK 6-3/8"X4"  
LBL STOCK 4"X2-7/8"  
1 LBL STOCK 3"x1-7/8"  
1 KIT 36 UNIT PLASTIC  
1 LBL 36U CVR NORTH ID C.  
1 STING Relief WIPES 10

**Sting Relief**  
***Principal Display Panel***



**Eyewash**  
**Principal Display Panel**



Honeywell

TAMPER-EVIDENT CAP.  
TAPA CON SELLO DE SEGURIDAD.  
BOUCHON INDICATEUR D'INFRACTION.

eyesaline®

LAVAOJOS  
EYESALINE

EYESALINE  
EYEWASH

LAVAGE  
OCULAIRE  
EYESALINE

Solución  
Isotónico Estéril

Sterile  
Isotonic Solution

La Solution  
Isotonique Stérile

16 fl. oz. (473 mL)

NPN: 80057528  
64809 1 45033 117

Drug Facts (for USA only)

**Active ingredient** Sterile water 99% **Purpose** Eyewash  
**Uses** for flushing the eye to remove loose foreign material, air pollutants, or chlorinated water.  
**Warnings** For external use only - Obtain immediate medical treatment for all open wounds in or near the eyes. To avoid contamination, do not touch tip of container to any surface. Do not reuse. Once opened, discard.  
**Do not use** if solution changes color or becomes cloudy  
if you have open wounds in or near the eyes, get medical help right away  
**Stop use and consult a doctor if:**  
• you experience eye pain • changes in vision  
• continued redness or irritation of the eye  
• condition worsens or persists  
**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.  
**Directions**  
• remove contacts before using • twist top to remove  
• flush the affected area as needed  
• control rate of flow by pressure on the bottle  
• if necessary, continue flushing with emergency eyewash or shower  
**Inactive ingredients** sodium chloride, sodium phosphate dibasic, sodium phosphate monobasic  
**Questions?** Call 1-800-430-5490  
Honeywell Safety Products USA, Inc. Smithfield, RI. 02917

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

space for lot code and supplier part number

PEEL / PELAR / PELEL

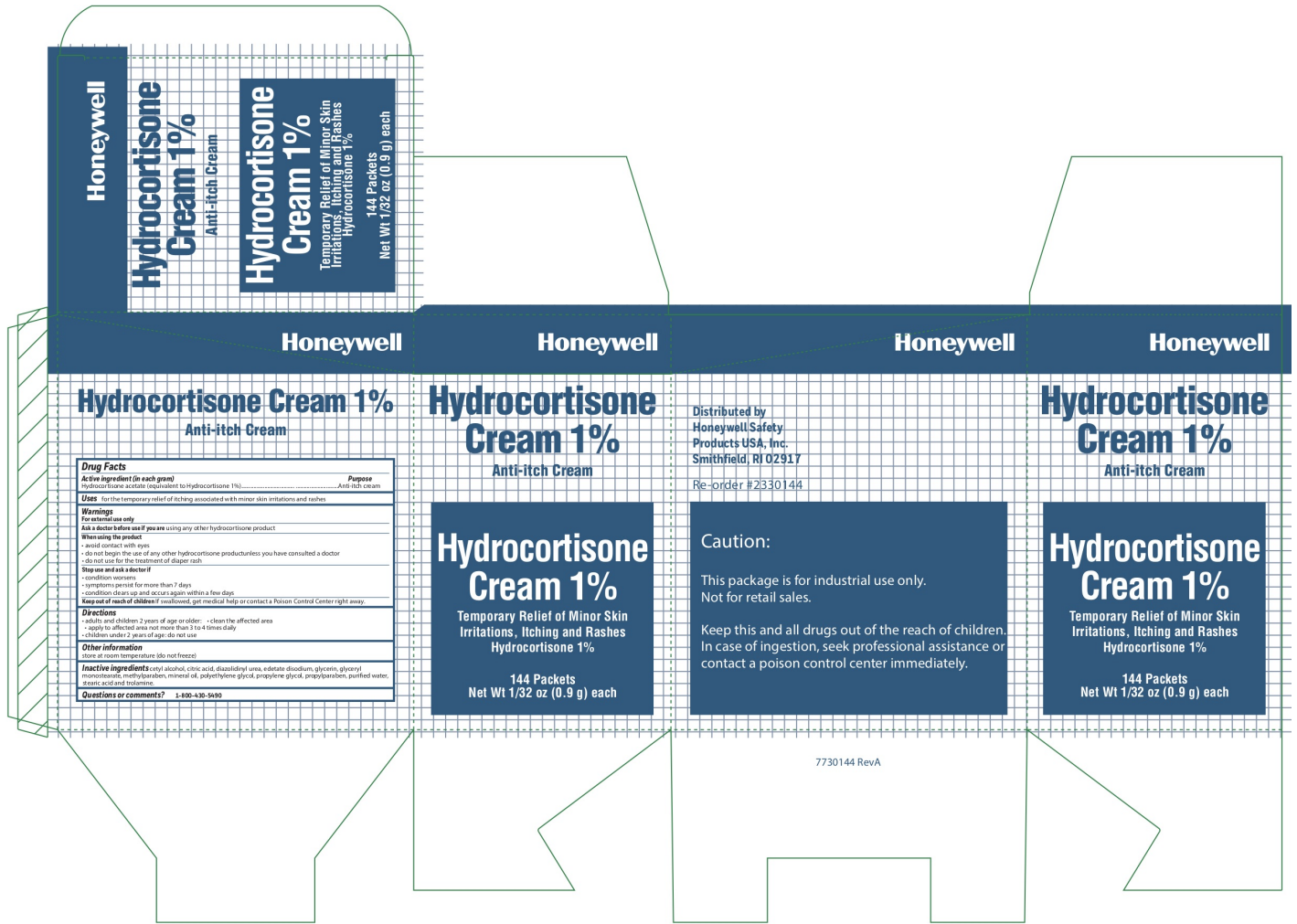
Datos de medicamento (Para EE.UU. solamente)

**Ingrediente Activo** Agua estéril 99% **Propósito** Lavaojos  
**Usos** para el lavado de ojo para quitar las partículas sueltas y extrañas, los contaminantes aeros, o agua de cloruro  
**Advertencias** Para el uso externo sólo - Obtenga tratamiento médico inmediato para todas las heridas abiertas en o cerca de los ojos. Para evitar la contaminación, no toque la punta del envase con ninguna superficie. No vuelva a usar. Vez abierto, descarte.  
**No se use** si la solución se enturbia o cambia de color  
si tiene heridas abiertas en o cerca del ojo, obtenga ayuda medica de inmediato  
**Deje de usar y consulte a un médico si:**  
• experimenta dolor de ojo • cambio de visión  
• rojez continuo o irritación del ojo  
• la condición empeora o persiste  
**Manténgase fuera del alcance de los niños.** En caso de ingestión accidental, obtenga atención médica o llame a un Centro de control de envenenamiento inmediatamente.  
**Instrucciones**  
• quite los lentes de contacto antes de usar la solución  
• tuerza la tapa para quitar  
• enjuague el área afectada según se necesite  
• controle el chorro haciendo presión el la botella  
• si es necesario, sigue enjuagado con un lavaojos o ducha de emergencia  
**Ingredientes inactivos** cloruro de sodio, fosfato de sodio dibásico, fosfato de sodio monobásico  
**¿Preguntas?** Llame al 1-800-430-5490  
Honeywell Safety Products USA, Inc. Smithfield, RI. 02917

Information

**Usages** Pour le rinçage des yeux afin d'enlever un corps étranger, des polluants atmosphériques ou de l'eau chlorée.  
**Advertissements** Pour usage externe seulement - Obtenir immédiatement des soins médicaux pour toutes les plaies ouvertes dans ou près des yeux. Pour éviter toute contamination, ne pas toucher la pointe du récipient à n'importe quelle surface. Ne pas réutiliser. Une fois ouvert, jetez-le.  
**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

Hydrocortisone  
Principal Display Panel



**Hydrocortisone Cream 1%**  
Anti-itch Cream

Drug Facts	Purpose
<b>Active ingredient (in each gram)</b> hydrocortisone acetate (equivalent to hydrocortisone 1%)	Anti-itch cream
<b>Uses:</b> For temporary relief of itching associated with minor skin irritations and rashes.	
<b>Warnings:</b> For external use only. Ask a doctor before use if you are using any other hydrocortisone product.	
<b>When using the product:</b> - avoid contact with eyes - do not begin the use of any other hydrocortisone product unless you have consulted a doctor - do not use for the treatment of diaper rash	
<b>Stop use and ask a doctor if:</b> - condition worsens - symptoms persist for more than 7 days - condition clears up and occurs again within a few days	
<b>Keep out of reach of children:</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions:</b> - adults and children 2 years of age or older: - clean the affected area - apply to affected area not more than 3 to 4 times daily - children under 2 years of age: do not use	
<b>Other information:</b> Store at room temperature (do not freeze)	
<b>Inactive ingredients:</b> cetyl alcohol, citric acid, disodium urea, edetate disodium, glycerin, glyceryl monostearate, methylparaben, mineral oil, polyethylene glycol, propylene glycol, propylparaben, purified water, stearic acid and tosilamine	
<b>Questions or comments?</b> 1-800-430-5430	

**Hydrocortisone Cream 1%**  
Anti-itch Cream

**Hydrocortisone Cream 1%**  
Temporary Relief of Minor Skin Irritations, Itching and Rashes  
Hydrocortisone 1%  
144 Packets  
Net Wt 1/32 oz (0.9 g) each

Distributed by  
Honeywell Safety  
Products USA, Inc.  
Smithfield, RI 02917  
Re-order #2330144

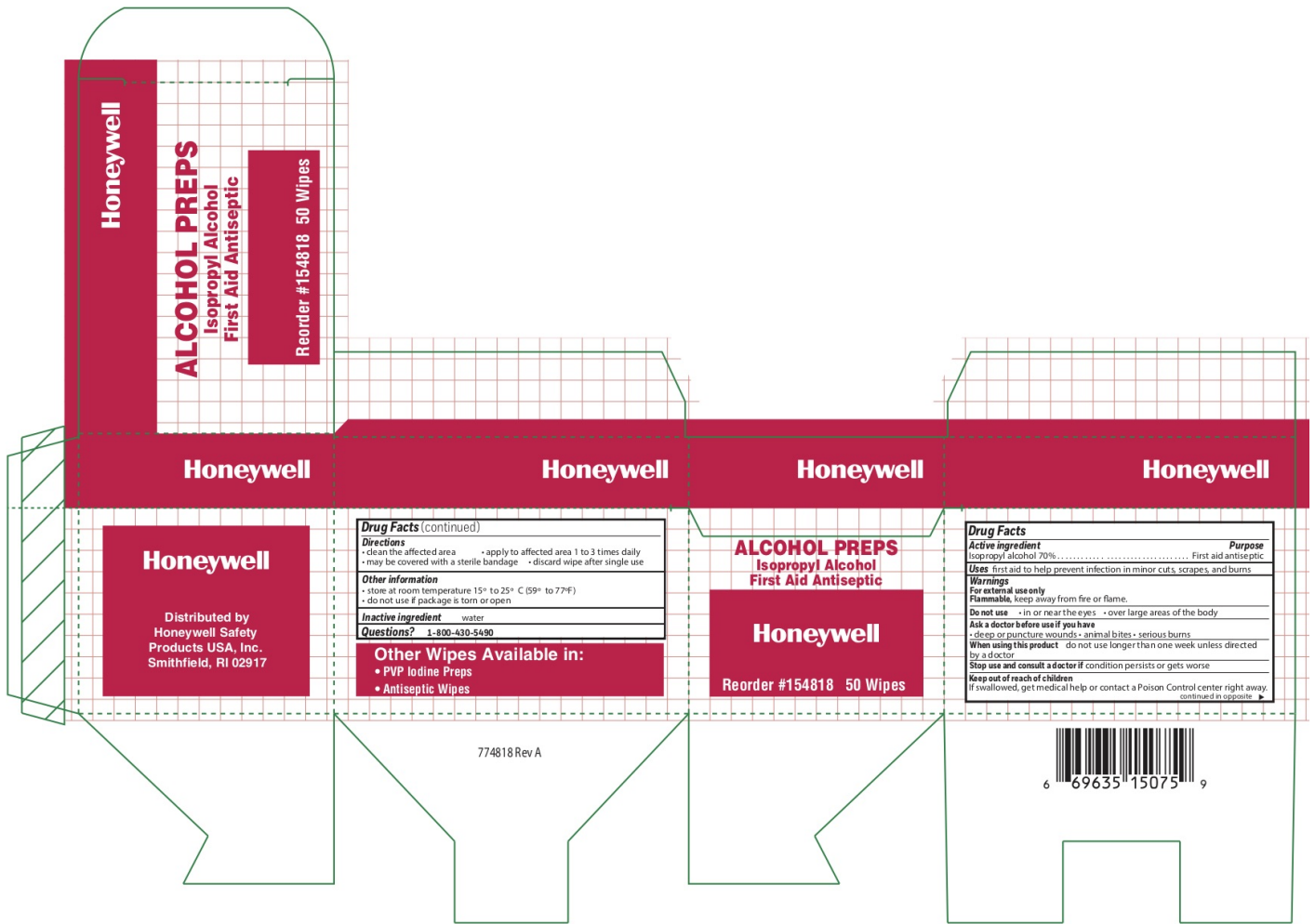
**Caution:**  
This package is for industrial use only.  
Not for retail sales.  
Keep this and all drugs out of the reach of children.  
In case of ingestion, seek professional assistance or  
contact a poison control center immediately.

**Hydrocortisone Cream 1%**  
Anti-itch Cream

**Hydrocortisone Cream 1%**  
Temporary Relief of Minor Skin Irritations, Itching and Rashes  
Hydrocortisone 1%  
144 Packets  
Net Wt 1/32 oz (0.9 g) each

7730144 RevA

**Alcohol**  
**Principal Display Panel**



**PVP**  
*Principal Display Panel*

FRONT SIDE

822569 X  
Rev. \*

PVP Iodine Wipes

02-12-01X



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

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

BACK SIDE

822569 X  
Rev. \*



PVP Iodine Wipes

**Drug Facts**

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

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

**Warnings** For external use only

**Do not use**  
• in or near the eyes • over large areas of the body • on individuals who are allergic or sensitive to iodine  
**Ask a doctor before use if you have**  
• deep or puncture wounds • animal bites • serious burns

**When using this product** do not use longer than one week unless directed by a doctor

**Stop use and ask a doctor if** • condition persists or gets worse • irritation or redness develops

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

**Directions**

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

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

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

**Inactive ingredients** nonoxonyl-9, water

**Questions or comments?** 1-800-430-5490



4149 Kit Label  
SF0003660

**Honeywell**  
**First Aid Kit**  
 Unitized

ANSI Z308.1-2009  
 COMPLIANT

Latex Free

For Up To 36 People

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

777027 Rev. D

## 4149 FIRST AID KIT

4149 first aid kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0498-4149
---------------------	----------------	---------------------------	---------------

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-4149-01	1 in 1 KIT	09/13/2018	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	30 mL
Part 2	10 POUCH	4 mL
Part 3	10 POUCH	4 mL
Part 4	10 PACKET	9 g
Part 5	30 POUCH	9 mL
Part 6	1 BOTTLE	118 mL
Part 7	10 PACKET	9 g

## Part 1 of 7

### 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, 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 2 of 7

### 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 3 of 7

### 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: 059QF0K00R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0733-00	0.4 mL in 1 POUCH; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/23/2017	

## Part 4 of 7

### 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 5 of 7

### 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: 059QF0K00R)	
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 6 of 7

### EYESALINE EMERGENCY EYEWASH

purified water liquid

**Product Information****Item Code (Source)** NDC:0498-0100**Route of Administration** OPTHALMIC**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, 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:0498-0100-02	118 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 7 of 7****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: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: 059QF0K00R)
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 mono graph not final	part348	03/06/2013	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/13/2018	

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

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

### Establishment

Name	Address	ID/FEI	Business Operations
Honeywell Safety Products USA, Inc		079287321	pack(0498-4149)

### Establishment

Name	Address	ID/FEI	Business Operations
Water-Jel Technologies		155522589	manufacture(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 Biotech		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.