

**4348 FIRST AID KIT- 4348 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](#).*

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**4348 First Aid Kit (HC cr, PVP wipes, sting relief- 013058-4344)**

**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

**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

## **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***

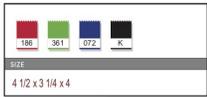
## **4348**

### **013058-4344 Kit Contents**

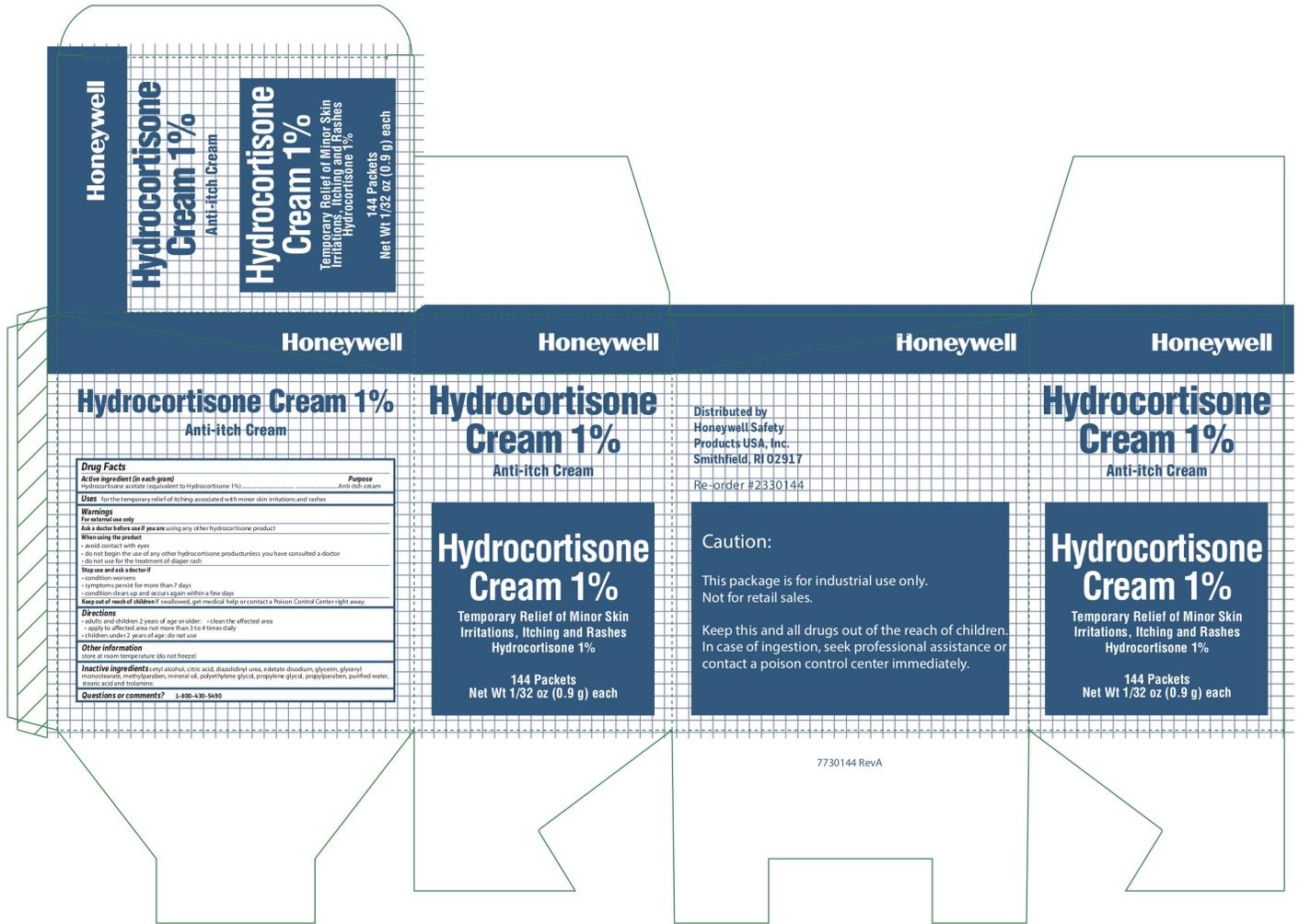
1 TRIANGULAR BDG, NON-STERILE  
1 GAUZE COMPRESS, 1728 SQ IN 1  
1 ADHESIVE BDG, PLSTIC, 1"X3"16PER  
1 TOPICAL COOLING JEL  
1 HYDROCORTISON, 1.0%, 1/32 OZ, 10P  
1 PVP IODINE WIPES 10 PER  
LBL STOCK 6-3/8"X4"  
1 LBL STOCK 3"x1-7/8"  
1 PR LRG NITRILE GLVES ZIP BAG  
1 KIT STL 10 UN WHITE 01  
1 STING Relief WIPES 10

### **Sting Relief**

#### ***Principal Display Panel***



**Hydrocortisone**  
*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** Povidone-iodine 10% (equivalent to 1% titrable iodine) ..... **Purpose** 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)

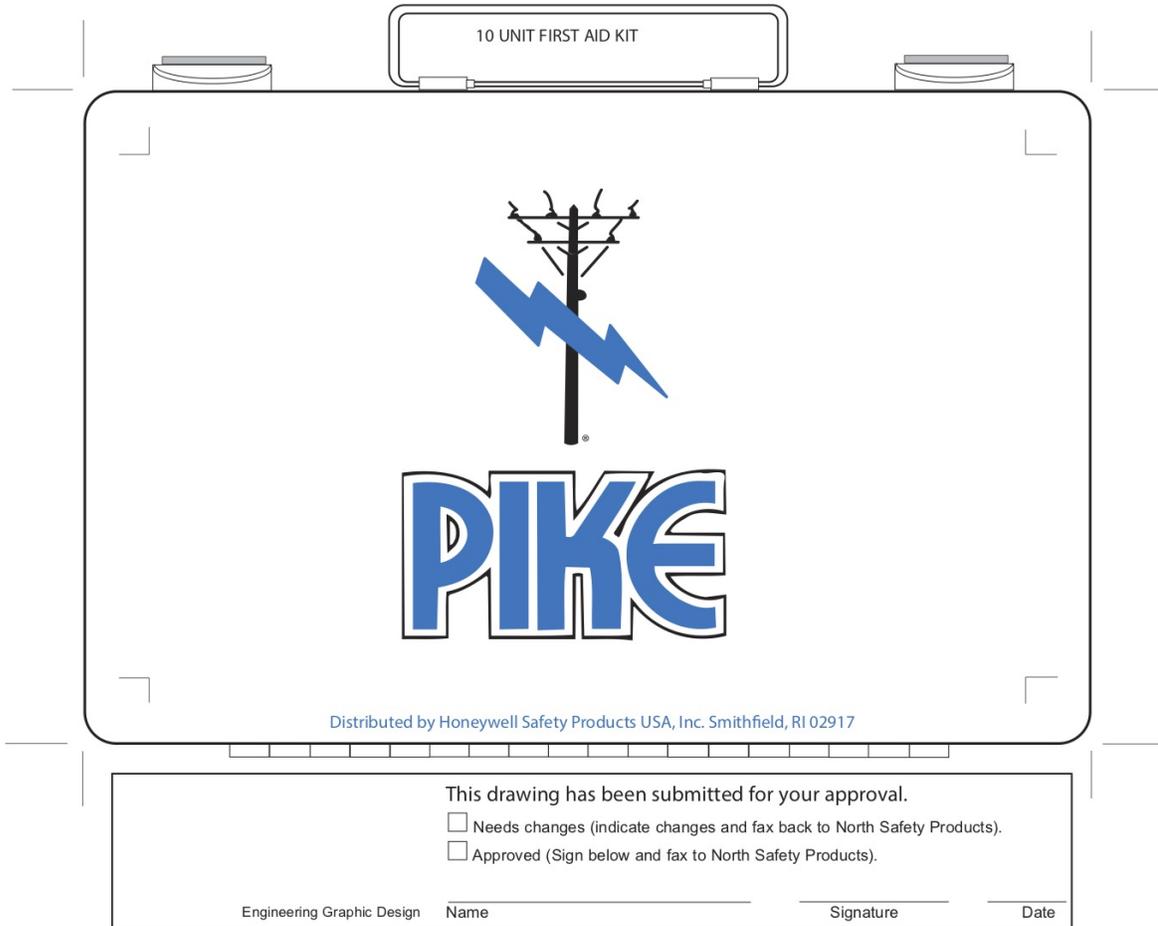
• do not use if package is torn or open • do not use on individuals who are allergic or sensitive to iodine

**Inactive ingredients** nonoxonyl-9, water

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



4348 Kit Label  
013058-4344



## 4348 FIRST AID KIT

4348 first aid kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0498-4348
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-4348-01	1 in 1 KIT	09/13/2018	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	10 POUCH	4 mL
Part 2	10 PACKET	9 g
Part 3	10 POUCH	3 mL
Part 4	10 PACKET	9 g

## Part 1 of 4

### 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 2 of 4

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

## 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 mono graph not final	part348	03/06/2013	10/15/2019

## Part 3 of 4

### 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 4 of 4****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
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)
CETYL ALCOHOL (UNII: 936JST6JCN)
METHYLPARABEN (UNII: A2I8C7H9T)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
EDETATE DISODIUM (UNII: 7FLD91C86K)
STEARIC ACID (UNII: 4ELV7Z65AP)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
TROLAMINE (UNII: 9O3K93S3TK)

### 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
Honeywell Safety Products USA, Inc		079287321	pack(0498-4348)

### Establishment

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

### 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)

