### 4396 FIRST AID KIT- 4396 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.

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#### 4396 First Aid Kit (PVP, First Aid Burn Cr, Ammonia- 011798-1494)

# PVP Wipes Active ingredient

Povidone-iodine 10%

(equivalent to 1% titratable iodine)

## **PVP Wipes**

**Purpose** 

First aid antiseptic

#### **PVP Wipes**

Uses

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

## **PVP Wipes**

**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 Wipes**

#### Directions

- clean the affected area
- apply1 to 3 times daily
- may be covered with a sterile bandage
- if bandaged, let dry first
- discard wipe after single use

#### 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 Wipes Inactive ingredients

nonoxynol 9, water

## PVP Wipes Questions

800-430-5490

## Burn Cream Active ingredient

Benzalkonium chloride 0.13%

Lidocaine hydrochloride 0.5%

# Burn Cream *Purpose*

First aid antiseptic

External analgesic

#### **Burn Cream**

#### Uses

- prevent skin infection
- for temporary relief of pain associated with miinor burns

## Burn Cream

Warnings

#### For external use only

#### Do not use

- in or near the eyes
- if you are allergic to any of the ingredients
- in large areas of the body particularly over raw surfaces or blistered areas
- for more than 10 days

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

- deep or puncture wounds
- animal bites
- serious burns

#### Stop use and ask a doctor if

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

### Keep out of reach of chidren

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

#### **Burn Cream**

#### Directions

- adults and children 2 years of age and older:
- clean the affected area
- apply a small amount of this product (equal to the area of the tip of finger) onto the affected area 1 to 3 times daily
- may be covered with a sterile bandage
- children under 2 years of age: ask a doctor

#### **Burn Cream**

### Other information

- tamper evident sealed packets
- do not use if packet is opened or torn

#### **Burn Cream**

### **Inactive ingredients**

aloe barbadensis juice, cetyl alcohol, diazolidinyl urea, edetate disodium, glycerin, glyceryl stearate SE, methylparaben, mineral oil, PEG-100, propylene glycol, propylparaben, stearic acid, trolamine, water

#### **Burn Cream**

**Questions** 

1-800-430-5490

### Active ingredient

Ammonia 15%

#### **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

#### Otheer information

• store at room temperature away from light

#### Ammonia

#### **Innactive ingredients**

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

#### Ammonia

#### **Questions or Comments?**

1-800-430-5490

#### 4396

#### 011798-1494 Kit Contents

- 1 43 LBL KIT BOX 011798-1494
- 1 44 LBL BOEING WARNING
- 1 237 LBL INNER 011798-1494
- 1 201 LBL OUTER 011798-1494
- 1 FIRST AID BURN CREAM 6 PER
- 1 AMMONIA INHALANTS 10 PER
- 4 GAUZE BANDAGE, 4" X 6 YD
- 5 TRIANGULAR BDG, NON-STERILE
- 2 WIRE SPLINT 1 PER
- 1 ADHESIVE TPE 1"X2-1/2 YD 2 PER
- 8 BANDAGE COMP, 4" OFFSET, 1 PER
- 1 ADHESIVE BDG,PLSTIC,1"X3"16PER
- 2 PVP IODINE WIPES 10 PER
- 1 SCISSOR BDGE 4" RED PLS HDL
- LBL STOCK 6-3/8"X4"
- 1 LBL STOCK 6-3/8"X4"
- 1 LBL STOCK 3"x1-7/8"

1 STOCK LABEL 1 7/8" X 1/2"

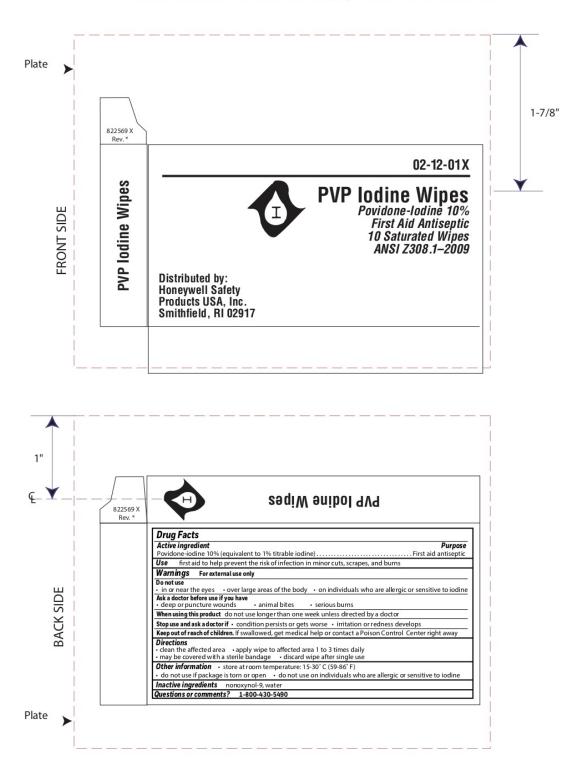
1 PR LRG NITRILE GLVES ZIP BAG

1 KIT STL 24 UN WHITE 01

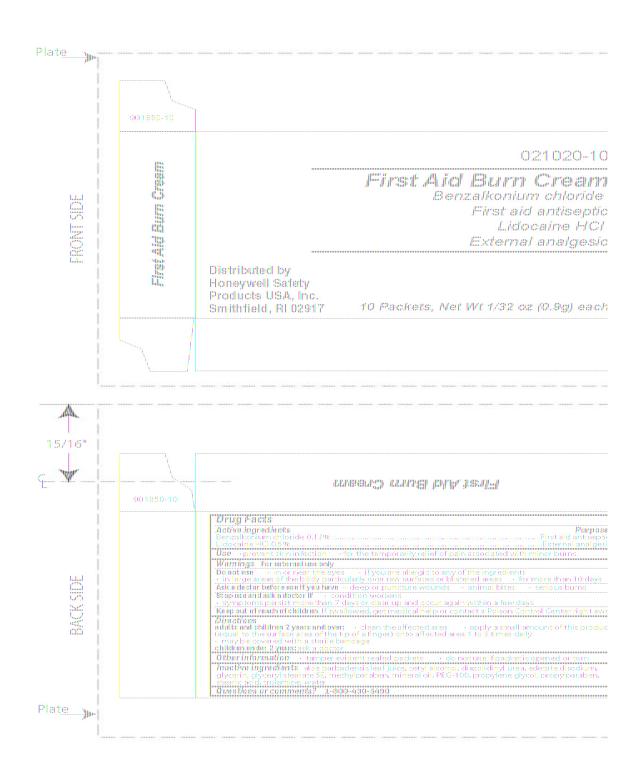
1 LABL INSTR 24 & 36 UNIT KITS

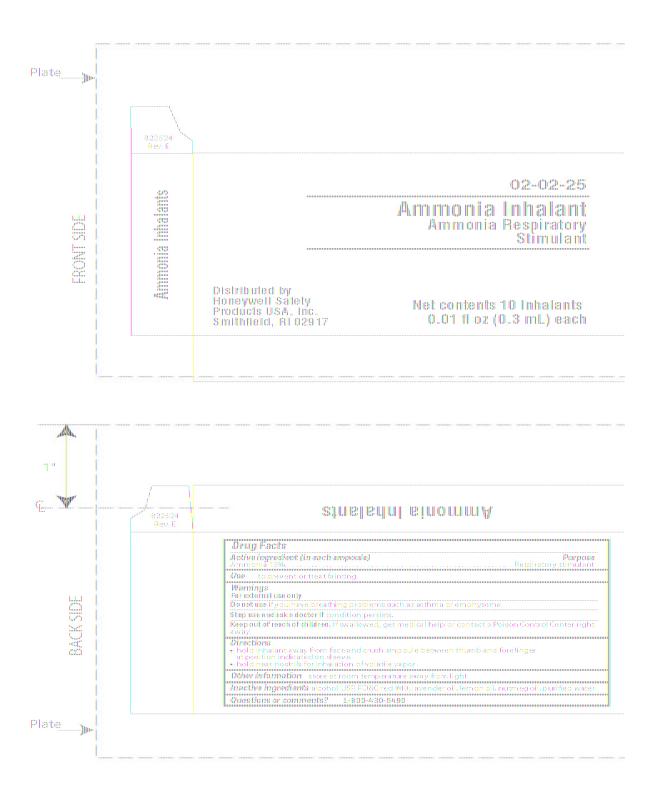
## **Honeywell PVP Wipes**

796042 Rev. B Unit Carton Printing Plate for "A" size carton.

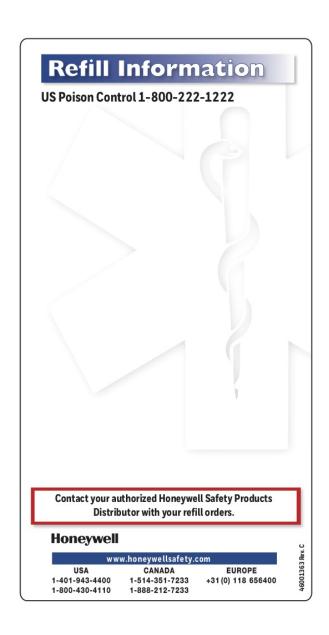


796353-10 Rev. A Unit Carton Printing Plate for "B" size





46001363 Rev.C Prints 3 colors Black, Red (PMS 186) and Blue (PMS 072)



## 4396 FIRST AID KIT

4396 first aid kit kit

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:0498-4396

## Packaging

# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:0498-4396-01	1 in 1 KIT	11/21/2018	

## Quantity of Parts

Quan	Quantity of 1 arts		
Part #	Package Quantity	Total Product Quantity	
Part 1	10 AMPULE	3 mL	
Part 2	20 POUCH	6 mL	
Part 3	6 PACKET	5.4 g	

## Part 1 of 3

#### **AMMONIA INHALENT**

ammonia inhalent inhalant

## **Product Information**

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

## Active Ingredient/Active Moiety

ı	Active ingredictionactive wronery		
l	Ingredient Name	Basis of Strength	Strength
ı	<b>AMMO NIA</b> (UNII: 5138 Q 19 F1X) (AMMO NIA - UNII:5138 Q 19 F1X)	AMMONIA	0.045 g in 0.3 mL

## **Inactive Ingredients**

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	

l	P	ackaging			
ı	#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
ı	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				
unapproved drug other		09/18/2018		

#### Part 2 of 3

#### **PVP IODINE WIPE**

povidone-iodine 10% swab

#### **Product Information**

Item Code (Source)NDC:0498-0121Route of AdministrationTOPICAL

### Active Ingredient/Active Moiety

Ingredient Name
Basis of Strength
POVIDONE-IO DINE (UNII: 85H0 HZU99M) (IO DINE - UNII:9679TC07X4)
IO DINE
10 mg in 1 mL

## **Inactive Ingredients**

Ingredient Name
Strength
NONOXYNOL-9 (UNII: 48Q180SH9T)
WATER (UNII: 059QF0K00R)

## Packaging

	1 uckuşing			
3	# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
	NDC:0498-0121-34	10 in 1 CARTON		
	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 3 of 3

#### FIRST AID BURN

benzalkonium chloride, lidocaine hydrochloride cream

#### **Product Information**

Item Code (Source)	NDC:0498-0903
Route of Administration	TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
LIDO CAINE HYDRO CHLO RIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE	0.5 g in 100 g	
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 g	

Inactive Ingredients	
Ingredient Name	Strength
GLYCERIN (UNII: PDC6 A3C0 OX)	
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
METHYLPARABEN (UNII: A2I8 C7HI9 T)	
PEG-100 STEARATE (UNII: YD01N1999R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
EDETATE DISO DIUM (UNII: 7FLD9 1C8 6 K)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	

Packaging					
II	# 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	part333A	12/20/2017		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
unapproved drug other		11/21/2018			

## 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(0498-4396)	

Establishment				
Name	Address	ID/FEI	Business Operations	
Water-Jel Technologies		155522589	manufacture(0498-0903)	

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