# 4399 FIRST AID KIT- 4399 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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## 4399 First Aid Kit (Triple, alcohol wipes, PVP wipes, EW, PAWS- 68203)

### **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

#### 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

## Ask a doctor before use if you have

- a deep or puncture wounds
- animal bites

serious burns

## 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 15  $^{0}$  to 25  $^{0}$  C (59  $^{0}$  to 77  $^{0}$  F)
- tamper evident sealed packets
- do not use if packet is torn or opened

## Triple

## **Inactive ingredient**

petrolatum

## Triple

Questions?

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

# Eyewash

## Questions

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

#### **PAWS**

## Active ingredient

Ethyl alcohol 66.5%

#### **PAWS**

#### **Purpose**

Antiseptic

#### **PAWS**

#### Uses

• for handwashing to decrease bacteria on skin whenever soap and water is not readily available

#### **PAWS**

## **Warnings**

#### For external use only

## Flammable: keep away from fire or flame

#### Do not use

• in the eyes. If this happens, rinse thoroughly with water.

## Stop use and ask a doctor if

• irritation or redness develop and persists for more than 72 hours

## Keep out of reach of children

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

#### **PAWS**

#### Directions

- wet hands and wrists thoroughly for 15 seconds and allow to air dry
- always reseal after use
- children under 6 years of age should be supervised when using this product

#### **PAWS**

## **Inactive ingredients**

aloe vera, fragrance, purified water, triethanolamine

#### **Paws**

#### Questions

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 useonly

Flammable, keep away from fire or flame.

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 burns

## When using this product

• do not use longer than one week unless directed by a doctor

## Keep out of reach of children

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

## Stop use and ask a doctor

• if condition persists or gets worse

### **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 15 ° to 25 ° C (59 ° to 77 ° F)

# Alcohol Wipe *Inactive ingredients*

water

# Alcohol Wipe 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
- apply1 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

#### **PVP**

#### Questions

800-430-5490

#### 4399

#### 68203 Kit Contents

1 TRIPLE ANTIBIOTIC 10 PER

1 ALCOHOL PREP PADS 10P

- 1 PVP IODINE WIPES 10 PER
- 1 ADHESIVE TAPE W/P 1/2"X10YDS
- 1 ADHESIVE TAPE W/P 1" X 10YDS
- 2 BK GZ 4.5"X4.1YD6PLY RL ST MSO
- 1 FIRST AID GUIDE ASHI
- 1 EMERGENCY SURVIVAL BLANKET
- 2 GAUZE CLEAN-WRAP BDGE N/S 3"
- 2 GAUZE CLEAN-WRAP BDGE N/S 4"
- 2 BLOODSTOPPER
- 2 ABD COMBINE PAD 5" X 9"
- 1 MULTI-TRAUMA DRESSING 12"X30"
- 1 ELASTIC BANDAGE 3" X 4.5YD
- 1 ELASTIC BANDAGE 4" X 4.5YD
- 10 PAWS PERS ANTIMICRO WIPE
- 1 4OZ BFS EYEWASH TRILINGUAL BOTTLE
- LBL STOCK 3"x1-7/8"
- 1 LBL STOCK PLAIN 3.2"x7/8"
- 10 PR NITRILE GLVES ZIP BAG
- 1 1" X 3" PLASTIC BANDS 16/BAG
- 1 DRESSING PETROLATUM GAUZE
- 2 TRI BNDG NON WOVEN 40"X40"X56"
- 4 EYE PADS STD OVAL STERILE
- 10 GAUZE PADS 3"X3" 12PLY
- 20 GAUZE PADS 4"X4" 12PLY
- 1 ZIP LOCK BAG 13 X 15 1.5 MIL

## **Triple Antibiotic label**



## Eyewash

**EYESALINE** 

Solución

Isotónico Estéril

**EYEWASH** 

**LAVAGE OCULAIRE EYESALINE** 

La Solution Isotonique Stérile

Isotonic Solution 16 fl. oz. (473 mL)

Sterile



Drug Facts (for USA only) Active ingredient Stop use and consult a doctor if: 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

#32-000454-0000 Purpose Uses for flushing the eye to remove loose foreign material, air pollutants, RÉAPPROVISIONNEMENT 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 NUEVO PEDIDO /

Inactive ingredients

sodium phosphate dibasic, sodium phosphate monobasic

Questions? Call 1-800-430-5490

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

Datos de medicamento (Para EE.UU. solamente)

REORDER

#32-004510 Rev. J

Ingrediente Activo Agua estéril 99% .......

Propósito

PEEL / PELAR / PELER

Usos para el lavado de ojo para quitar las particulas 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
inguna 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

de immediato

Deje de usar y consulte a un médico si:

• experimenta dolor de ojo

• cambio de visión

• rojez continuo o intilación del ojo

· la condición empedra 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

- quitese 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 atmospheriques où de l'eau chlorée.

Advertissements

Pour usage externs 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-les.

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 infaliation persistante des yeux

• condition empire ou persiste

Garder hors de la portée des enfants.
En cas d'ingestion, communiquer immédiatement avec un médecir ou avec un centre antipoison.

Mode d'emploi

• enlever les verres de contact avant l'utilisation • dévisser le bouchon pour l'enlever • incer la zone touchée selon les besoins • ajuster le debt d'écoulement de la solution en partier le continent de la solution en contenant et inécessaire, continuer de rincer avec une solution de rinçage oculaire d'urgence ou une douche

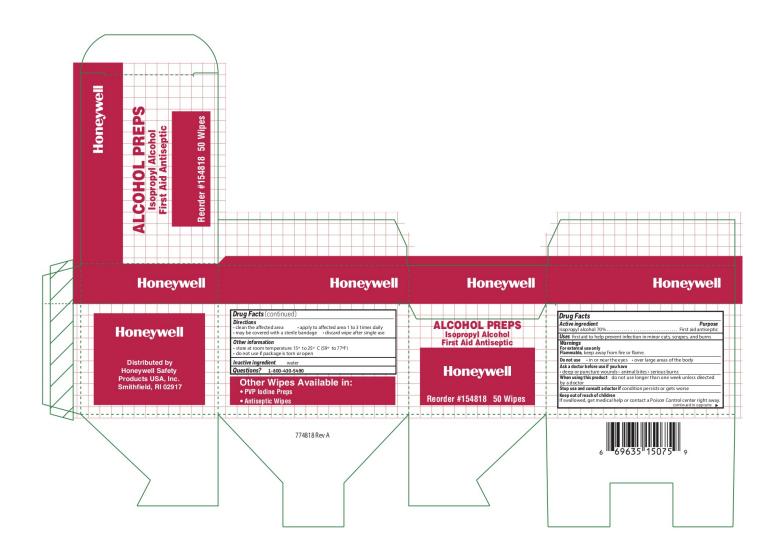
Ingrédients eau stérile, chlorure de sodium, phosphate dibasique de sodium, phosphate monobasique de sodium

Des questions? Faites le 1-800-430-5490 Honeywell Safety Products USA, Inc. Smithfield, RI. 02917

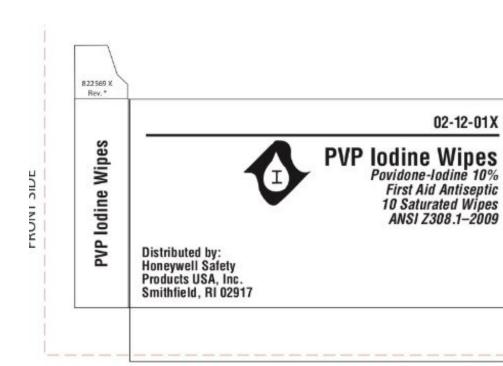
**PAWS** label

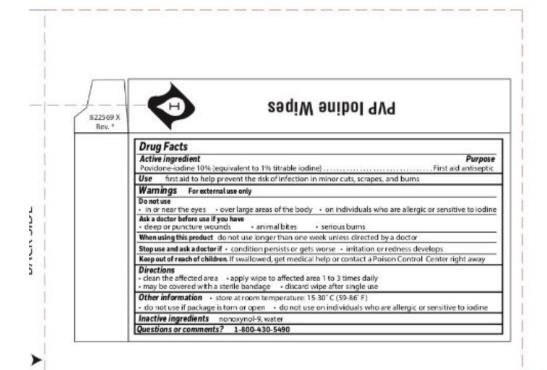


Alcohol Wipe Principal Display Panel



PVP Principal Display Panel





4399 kit label 68203 46001363 Rev.C Prints 3 colors Black, Red (PMS 186) and Blue (PMS 072)



#### **Product Information**

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:0498-4399

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:0498-4399-01	1 in 1 KIT	09/13/2018		

Quant	Quantity of Parts			
Part #	Package Quantity	Total Product Quantity		
Part 1	10 POUCH	3 mL		
Part 2	1 BOTTLE	118 mL		
Part 3	10 PACKET	9 g		
Part 4	10 POUCH	4 mL		
Part 5	10 PACKET	0.019 L		

## Part 1 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
ı	PO VIDO NE-IO DINE (UNII: 85H0 HZU99 M) (IO DINE - UNII:9679 TC07X4)	IODINE	10 mg in 1 mL

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
NONOXYNOL-9 (UNII: 48Q180SH9T)		

Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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 2 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 PHO SPHATE, DIBASIC (UNII: GR686LBA74)		
SO DIUM PHO SPHATE, MO NO BASIC, MO NO HYDRATE (UNII: 593YOG76RN)		
SODIUM CHLORIDE (UNII: 451W47IQ8X)		

Packaging					
I	#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
I	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	12/18/20 18	

# Part 3 of 5

# 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 Strengt			
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B	5000 [iU] in 1 g	
BACITRACIN ZINC (UNII: 89 Y4M234ES) (BACITRACIN - UNII:58 H6 RWO 52I)	BACITRACIN	400 [iU] in 1 g	
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:116QD7X297)	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				

ı	Packaging	g				
	# Item	Code	Package Description	Marketing Sta	art Date	<b>Marketing End Date</b>
	1 NDC:0498	-0750-35 0.9 g in	1 PACKET; Type 0: Not a Combination Pro	oduct		

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 5

# **ALCOHOL WIPE**

isopropyl alcohol swab

<b>Product Information</b>	
Item Code (Source)	NDC:0498-0143
Route of Administration	TOPICAL

# Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
	ISOPROPYL ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

	Packaging			
I	# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
l	1 NDC:0498-0143-0	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 5 of 5

# **PAWS**

ethyl alcohol liquid

<b>Product Information</b>	
Item Code (Source)	NDC:0498-3111
Route of Administration	TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	665 mL in 1 L		

Inactive Ingredients			
Ingredient Name	Strength		
TROLAMINE (UNII: 903K93S3TK)			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			
WATER (UNII: 059QF0KO0R)			

P	ackaging			
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1		0.0019 L in 1 PACKET; Type 0: Not a Combination Product		

Marketing Infor	mation				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333E	12/21/2017			
Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		

09/13/2018

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

unapproved drug other

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

Establishment			
Name	Address	ID/FEI	Business Operations
Honeywell Safety Products USA, Inc		079287321	pack(0498-4399)

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

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 mewdical Biotext		532775194	manufacture (0498-0121)

Establishment					
Name	Address	ID/FEI	Business Operations		
Safetec of America Inc		874965262	manufacture(0498-3111)		

Revised: 10/2019 Honeywell Safety Products USA, Inc.