

**4135 FIRST AID KIT- 4135 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.

4135 First Aid Kit (Triple, Ammonia Inh, EW, PVP Wipes, BZK wipe- SF00001642)

Active ingredient

Ammonia 15%

Purpose

Respiratory stimulant

Uses

to prevent or treat fainting

Warnings

For external use only

Do not use

- if you have 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.

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

Other information

store at room temperature away from light

Inactive ingredients

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

Questions or Comments

1-800-430-5490

PVP***Active ingredient***

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

PVP***Purpose***

First aid antisepti

PVP***Uses***

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

PVP***Warnings*****For external use only****Do not use**

- in 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

- 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

PVP***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

PVP

Other information

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

PVP**Inactive ingredients**

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

PVP**Questions and Comments?**

1-800-430-5490

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
- Ask a doctor before use if you have
- a deep or puncture wounds
- animal bites

- serious burns

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

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 15⁰ to 25⁰ C (59⁰ to 77⁰ F)
- tamper evident sealed packets
- do not use if packet is torn or opened

Triple***Inactive ingredient***

petrolatum

Triple***Questions?***

1-800-430-5490

BZK Wipe***Active ingredient***

Benzalkonium chloride 0.13% w/v

BZK Wipe***Purpose***

First aid antiseptic

BzK Wipe***Uses***

Antiseptic cleansing of face, hands, and body without soap and water

BZK Wipe

Warnings

For external use only

Do not use

- in the eyes or over large areas of the body
- on mucous membranes
- on irritated skin
- in case of deep puncture wounds, animal bites or serious burns, consult a doctor
- longer than 1 week unless directed by a doctor

Stop use and ask a doctor if

- if irritation, redness or other symptoms develop
- the condition persists or gets worse

Keep out of reach of children

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

BZK Wipe

Directions

tear open packet and use as a washcloth

BZK Wipe

Other information

- store at room temperature 15⁰ to 30⁰ C (59⁰ - 86⁰ F)
- do not reuse towelette

BZK Wipe

Other information

water

BZK Wipe

Questions

1-800-430-5490

4135

SF00001642 Kit Contents

1 3/4 X 3 PLAS 100/BOX

1 TRIPLE ANTIBIOTIC 10 PER

2 INSTANT COLD PACK 4" X 6"

1 1 OZ EYE WASH W/PADS & STRIPS

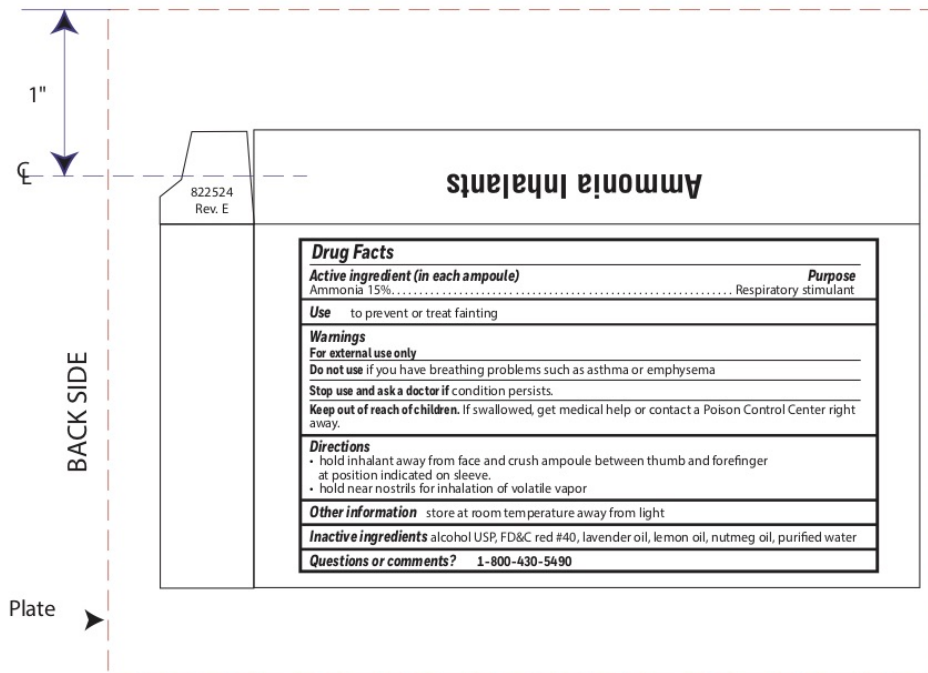
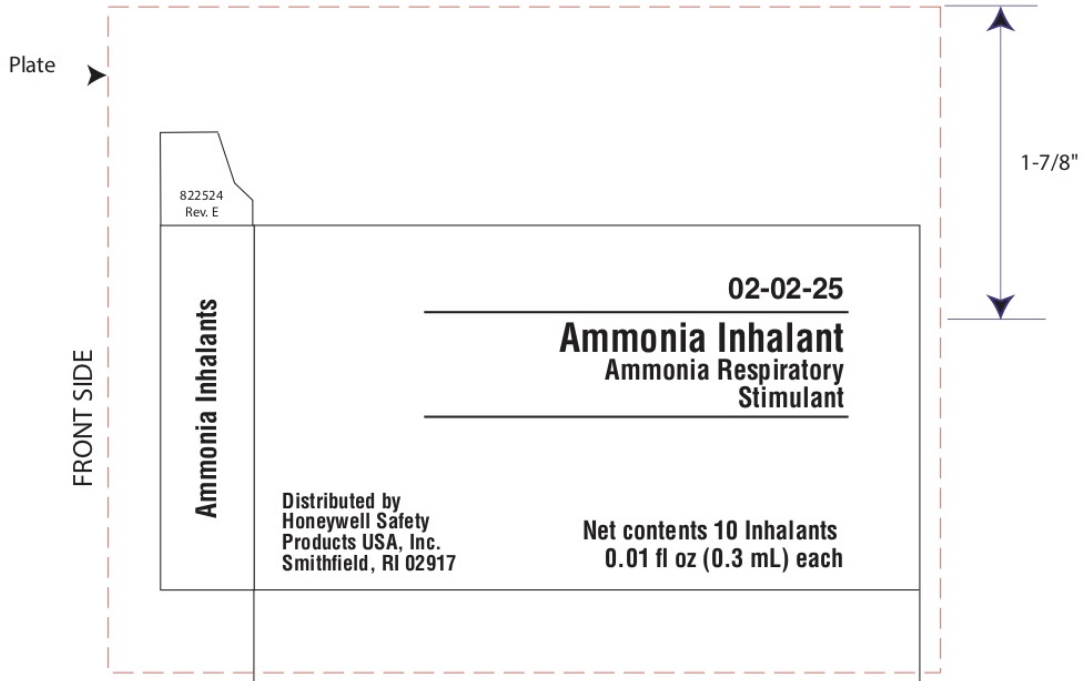
4 PVP IODINE WIPES 10 PER

1 ANTIMCRBL ANTSPCTC TWLETTTS

1 ADHESIVE TAPE W/P 1/2"X 5 YD
1 FIRST AID GUIDE ASHI
6 GAUZE CLEAN-WRAP BDGE N/S 2"
2 ABD COMBINE PAD 5" X 9"
1 GZE PADS STERILE 2"X 2" 25'S
1 SCISSOR BDGE 4" RED PLS HDL
1 KIT TWEEZER 3 1/2" SLANTED
LBL STOCK 6-3/8"X4"
LBL STOCK 4"X2-7/8"
1 LBL STOCK 3"x1-7/8"
1 ZIP BAG FOR 50 ECONO
1 KIT STL BULK MEDIUM
1 TRI BNDG NON WOVEN 40"X40"X56"

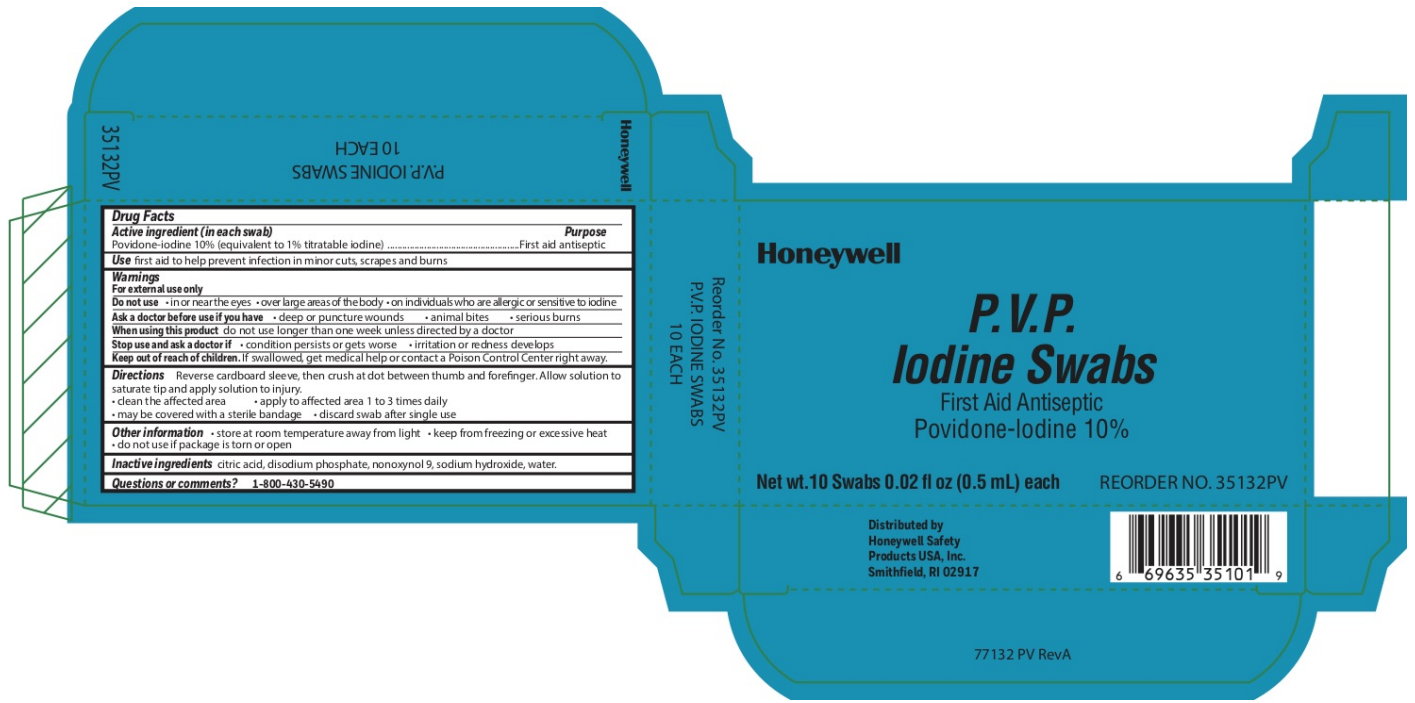
Principal Display Panel

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

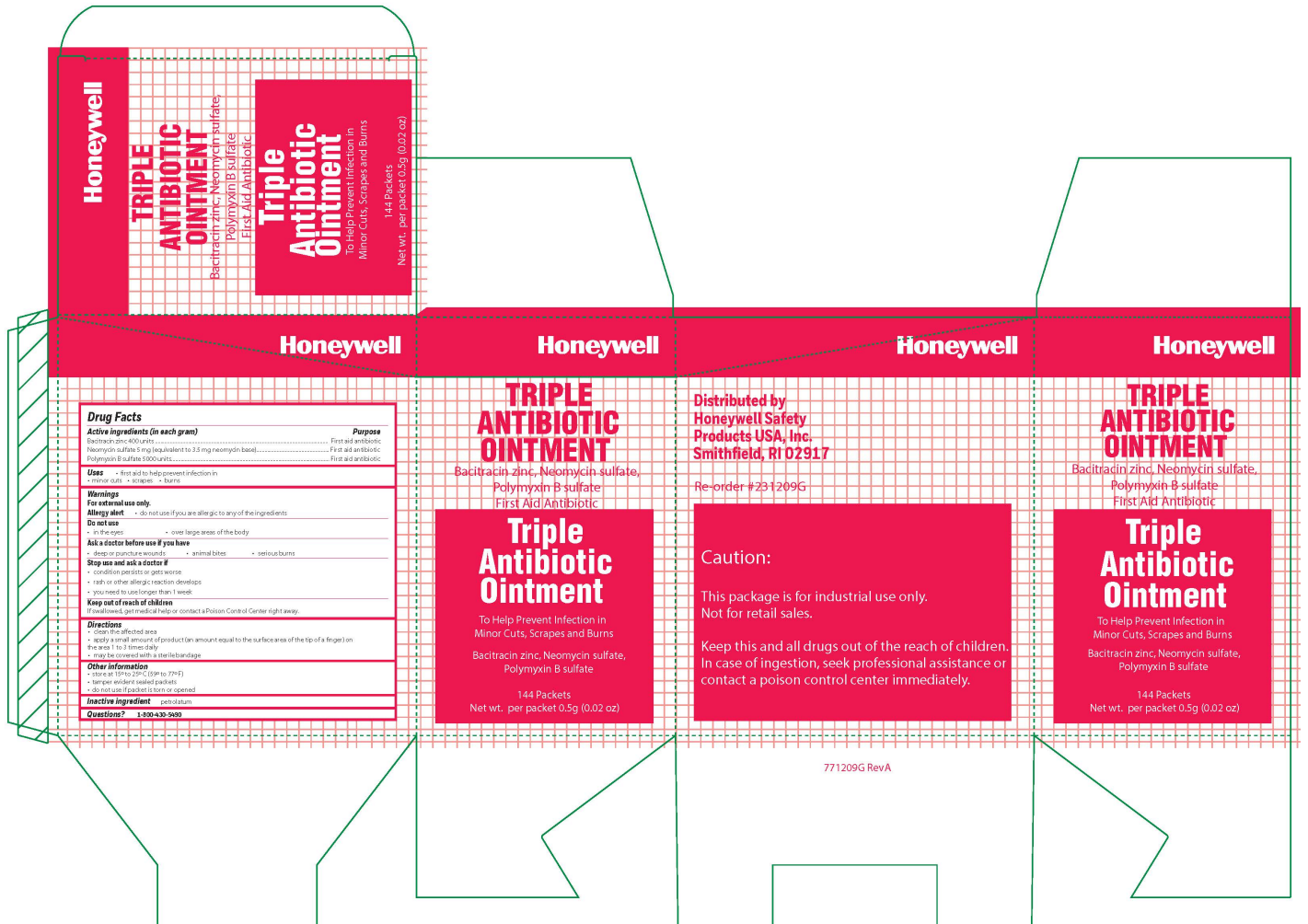


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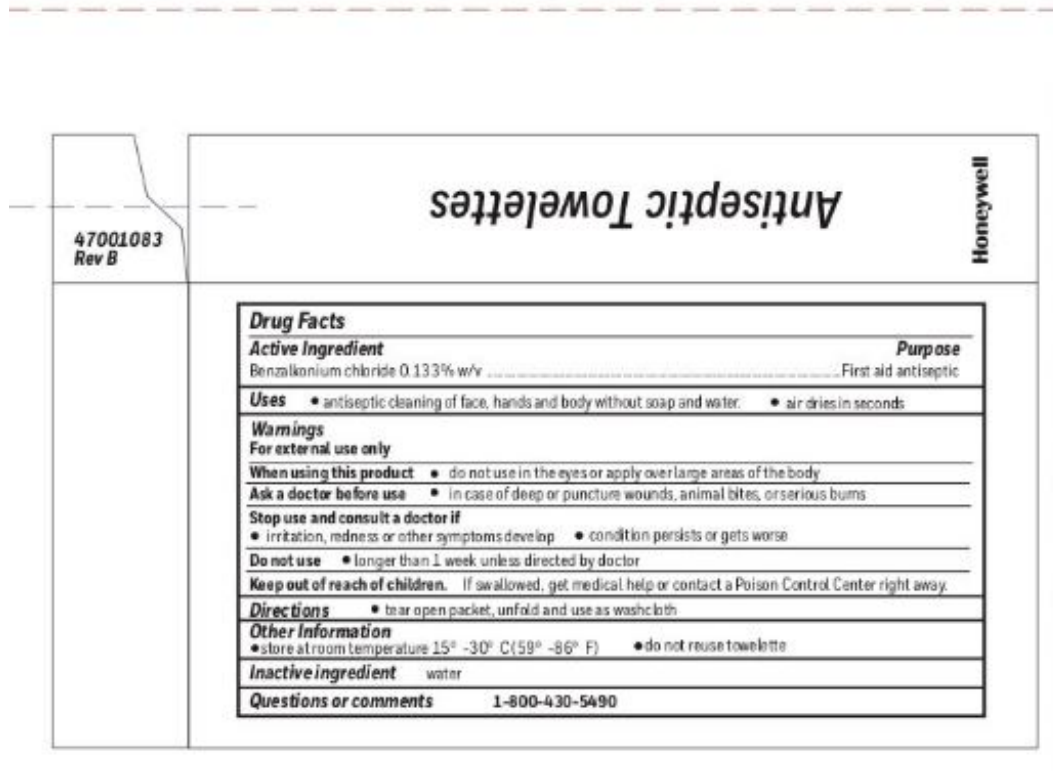
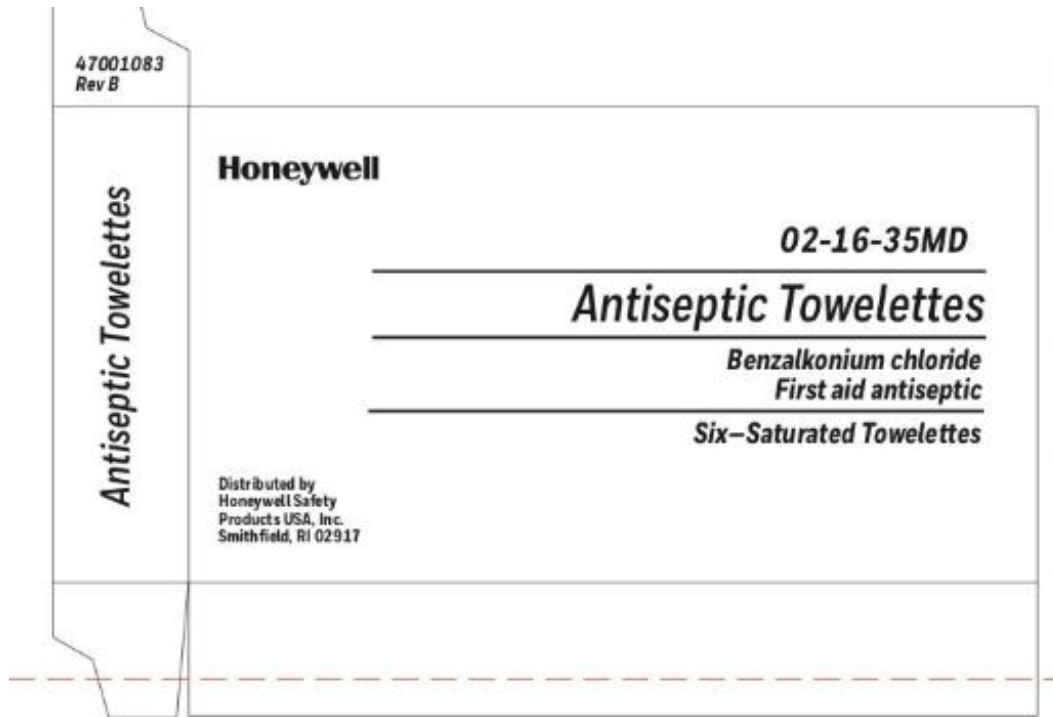
Principal Display Panel



Triple Principal Display Panel



**BZK Wipe
Principal Display Panel**



**4135 Kit Label
SF0001642**



FIRST AID KIT

Red Rooster® – Professional Tools
Toll Free (866) 725-3627
www.redroosterag.com

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

4135 FIRST AID KIT

4 135 first aid kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0498-4135
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-4135-01	1 in 1 KIT	09/13/20 18	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	4 AMPULE	1.2 mL
Part 2	40 POUCH	12 mL
Part 3	1 BOTTLE	30 mL
Part 4	10 PACKET	9 g
Part 5	1 PACKET	1.4 mL

Part 1 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 2 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: 059QF0KO0R)	

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 3 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 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 4 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	Strength
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B	5000 [iU] in 1 g
BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN	400 [iU] in 1 g
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:H6QD7X297)	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			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0750-35	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 final	part333B	09/19/2018	

Part 5 of 5

ANTISEPTIC TOWELETTE

benzalkonium chloride liquid

Product Information

Item Code (Source) NDC:0498-0501

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0501-00	1.4 mL 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	part333E	12/22/2017	

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
James Alexander		040756421	manufacture(0498-3334)

Establishment

Name	Address	ID/FEI	Business Operations
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Honeywell Safety Products USA, Inc		079287321	pack(0498-4135)
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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(0498-0501)

Establishment

Name	Address	ID/FEI	Business Operations
Sion Biotext Medical		532775194	manufacture(0498-0121)

Revised: 5/2019

Honeywell Safety Products USA, Inc.