4291 FIRST AID KIT- 4291 first aid kit
4305 FIRST AID KIT- 4305 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.

4291, 4305 First Aid Kit (ammonia inh, EW, alcohol wipes, Burn Sray, Antiseptic Spray, BZK wipe, triple, ASA- SF00004026, SF00004363)

Eyesaline
Active ingredient

Sterile Water 99%

Eyesaline
Purpose

Eyewash

Eyesaline
Uses

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

Eyesaline
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.

Eyesaline
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

Eyesaline
Inactive ingredients

sodium chloride, sodium phosphate dibasic, sodium phosphate monobasic

Eyesaline
Questions

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

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 use only

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 burn

When using this product
- do not use longer than one 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 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 ^{0} to 25 ^{0} C (59 ^{0} to 77 ^{0}F)

Alcohol Wipe
Inactive ingredient

water

Alcohol Wipe
Questions

1-800-430-5490

Antiseptic Spray
Active ingredient

Benzalkonium chloride 0.13%

Antiseptic Spray
Purpose

First aid antiseptic

Antiseptic Spray
Uses
- first aid to help prevent infection in minor cuts, scrapes and burns

Antiseptic Spray
Warnings

For external use only

Do not use
- in or near 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

Stop use and ask a doctor if
- 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

Antiseptic Spray
Directions
- clean the affected area
- spray a small amount of this product on the area 1 to 3 times daily
- may be covered with a sterile bandage
- if bandaged, let dry first

Antiseptic Spray
Other information
- shake well
- store at room temperature 15 ^{0}-30 ^{0} C (59 ^{0} -86 ^{0} F)

Antiseptic Spray
Inactive ingredients

diazolidinyl urea, edetate disodium, glycerin, hypromellose, methylparaben, octoxynol 9, propylene glycol, propylparaben, trolamine, water

Antiseptic Spray
Questions

1-800-430-5490

Burn Spray
Active ingredient

Benzethonium chloride 0.2% w/w

Benzocaine 10% w/w

Menthol 0.33% w/w

Burn Spray
Purpose

Benzethonium chloride 0.2% w/w

Benzocaine 10% w/w

Menthol 0.33% w/w

Burn Spray

Uses

for the temporary relief of pain and itching and helps protect against infection in:

- minor cuts and scrapes
- burns
- sunburn
- insect bites
- minor skin irritations

Burn Spray
Warnings

For external use only

Flammable

- keep away from fire or flame
- contents under pressure
- do not puncture or incinerate container
- do not expose to temperatures above 120 0 F

Do not use

- in or near the eyes or other mucous membranes
- in case of serious burns
- in case of deep or puncture wounds
- for prolonged period of time
- on large portion of the body

Stop use and ask a doctor if

- condition worsens or symptoms persist for more than 7 days
- condition clears up and recurs within a few days
- redness, swelling, or irritation occurs

Keep out of the reach of children

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

Burn Spray
Directions

- clean the affected area
- shake can well before using
- hold 4 - 6 inches from surface and spray area until wet
- may be covered with a sterile bandage, if bandaged let dry first
- for adult institutional use only
- not intended for use on children

Burn Spray
Other information

- avoid inhaling
- use only as directed
- intentional misuse by deliberately concentrating or inhaling the contents may be harmful or fatal

Burn Spray

Inactive ingredients

dipropylene glycol, isobutane, n-butane, propane

Ammonia
Active ingredient

Ammonia 15%

Ammonia
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
Other information

- store at room temperature away from light

Ammonia
Inactive ingredients

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

Ammonia
Questions or Comments?

1-800-430-5490

BZK
Active ingredient

Benzalkonium chloride 0.13% w/v

BZK
Purpose

First aid antiseptic

BZK
Uses

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

BZK
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
Directions

- tear open packet and use as a washcloth

BZK
Other information

- store at room temperature 15 ^{0} to 30 ^{0} C (59 ^{0} - 8 ^{0}6 F)
- do not reuse towelette

BZK
Inactive ingredient

water

BZK
Questions

1-800-430-5490

Triple
Active ingredient (each gram contains)

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 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

Aspirin
Active ingredient

Aspirin 325 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Aspirin
Purpose

Pain reliever/fever reducer

Aspirin
Uses

temporarily reduces fever and relieves minor aches and pains associated with:

- a cold
- headache
- toothache
- muscular aches
- backache
- minor pain of arthritis
- premenstrual and menstrual periods

Warnings

Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a

rare but serious illness.

Allergy alert: Aspirin may cause a severe allergic reaction which may include:

- hives
- facial swelling
- asthma (wheezing)
- shock

Stomach bleeding warning:

This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher

- if you:are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Do not use

- if you are allergic to aspirin or any other pain reliever/fever reducer

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have a history of stomach problems such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis or kidney disease
- you are taking a diuretic
- you have asthma

Ask a doctor or pharmacist before use if you are

- taking a prescription drug for diabetes, gout or arthritis

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
- feel faint
- vomit blood
- have bloody or black stools
- have stomach pain that does not get better
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present in the painful area
- ringing in the ears or loss of hearing occurs
- any new symptoms appear

If pregnant or breast-feeding,

If pregnant or breat-feeding, ask a health professional before use. It is especially important not to use aspirin during the last three months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children.

In case of overdose, get medical help or contact Poison Control Center right away.

Aspirin
Directions

- drink a full glass of water with each dose
- adults and children 12 years of age and older: take 1 or 2 tablets every 4 hours while symptoms last, not more than 12 tablets in 24
- children under 12 years of age consult a doctor

Aspirin
Other information

- store at room temperature 15° - 30°C (59° - 86°F)
- TAMPER EVIDIENT PACKETS
- DO NOT USE IF OPEN OR TORN

Aspirin
Inactive ingredients

corn starch, croscarmellose sodium*, hypromellose*, microcrystalline cellulose*, mineral oil*, polyethylene glycol*, povidone, propylene glycol, silicon dioxide, stearic acid*, titanium ...

Aspirin
Questions or comments?

1-800-430-5490

4291
SF00004026 Kit Contents

1 3/4 X 3 PLAS 100/BOX

1 1X3 PLASTIC 100/BOX

1 FINGERTIP "T" WOVEN 40/BOX

1 1X3 WOVEN SING 50/BOX

1 SWIFT KNUCKLE 40/BX

1 AMMONIA INHALANTS 10 PER

1 INSTANT COLD PACK 4" X 6"

1 BIOHAZARD BAGS

1 ELASTIC TAPE 1" X 5YD

1 O/H TAPE ADHESIVE TRI-CUT

1 O/H PUMP ANTISEPTIC 2 OZ ID F

1 O/H PUMP BURN RELIEF 2 OZ ID G

1 FIRST AID GUIDE ASHI

4 GAUZE CLEAN-WRAP BDGE N/S 2"

2 BLOODSTOPPER

1 NON ADHERENT PADS 2"X3" 50'S

2 GZE PADS STERILE 2"X 2" 25'S

1 GZE PADS STERILE 4"X 4" 25'S
1 CO-FLEX BANDAGE 2"X 5YDS TAN
1 COTTON TIPS 100 PER VIAL
2 ANTISEPTIC WIPES BZK CHL 20'S
1 ALCOHOL WIPES 50'S
1 ASPIRIN IND PK 5 GR 2/ENV 250
1 TRIPLE BIOTIC .5 GRAM PKT 20
1 4OZ BFS EYEWASH TRILINGUAL BOTTLE
1 SCISSOR BDGE 4" RED PLS HDL
1 KIT TWEEZER 3 1/2" SLANTED
1 180 EMPTY BLANK NO LOGO
1 POCKET INSERT RED #180 KIT 4R
1 TONGUE BLADES SR WRAPPED 6'S
1 LBL STOCK 6-3/8"X4"
1 LBL STOCK 4"X2-7/8"
2 PR LRG NITRILE GLVES ZIP BAG
2 TRI BNDG NON WOVEN 40"X40"X56"

4305
SF00004363 kit contents
1 3/4 X 3 PLAS 100/BOX
1 1X3 PLASTIC 100/BOX
1 FINGERTIP "T" WOVEN 40/BOX
1 1X3 WOVEN SING 50/BOX
1 SWIFT KNUCKLE 40/BX
1 AMMONIA INHALANTS 10 PER
1 INSTANT COLD PACK 4" X 6"
1 ELASTIC TAPE 1" X 5YD
1 O/H TAPE ADHESIVE TRI-CUT
1 O/H PUMP ANTISEPTIC 2 OZ ID F
1 O/H PUMP BURN RELIEF 2 OZ ID G
1 FIRST AID GUIDE ASHI
4 GAUZE CLEAN-WRAP BDGE N/S 2"
2 BLOODSTOPPER
1 NON ADHERENT PADS 2"X3" 50'S
2 GZE PADS STERILE 2"X 2" 25'S
1 GZE PADS STERILE 4"X 4" 25'S

1 CO-FLEX BANDAGE 2"X 5YDS TAN

1 COTTON TIPS 100 PER VIAL

1 ANTISEPTIC WIPES BZK CHL 20'S

1 ALCOHOL WIPES 50'S

1 ASPIRIN IND PK 5 GR 2/ENV 250

1 TRIPLE BIOTIC .5 GRAM PKT 20

1 4OZ BFS EYEWASH TRILINGUAL BOTTLE

1 SCISSOR BDGE 4" RED PLS HDL

1 KIT TWEEZER 3 1/2" SLANTED

1 180 EMPTY BLANK NO LOGO

1 TONGUE BLADES SR WRAPPED 6'S

1 LBL STOCK 4"X2-7/8"

1 LBL STOCK 3"x1-7/8"

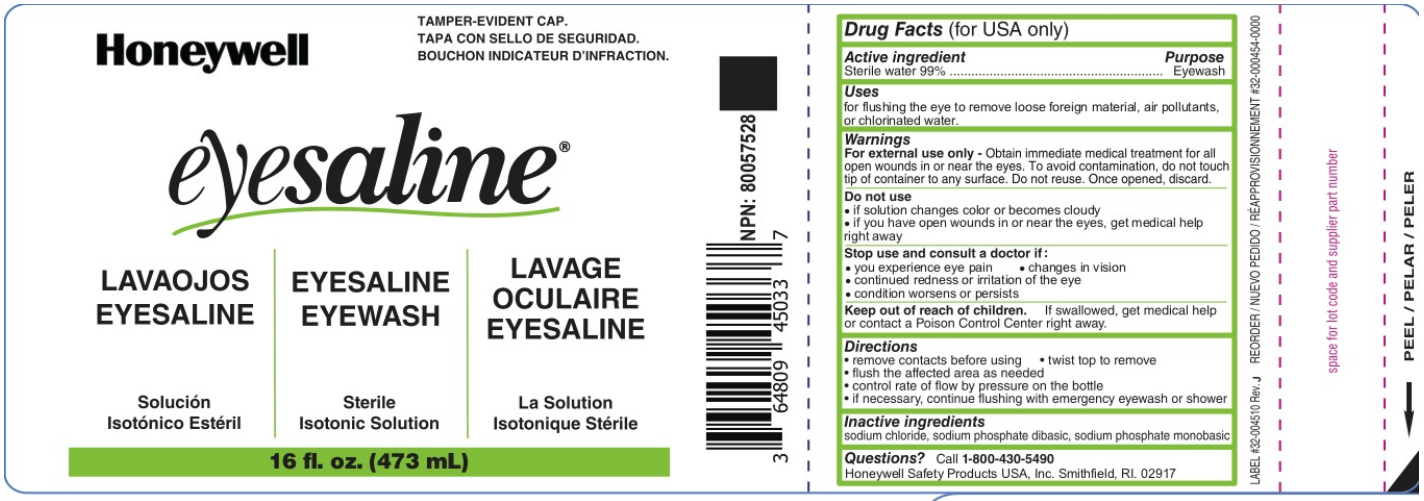
2 PR LRG NITRILE GLVES ZIP BAG

1 LBL CONTENTS ANSI Z308.1-2009 REV B

2 TRI BNDG NON WOVEN 40"X40"X56"

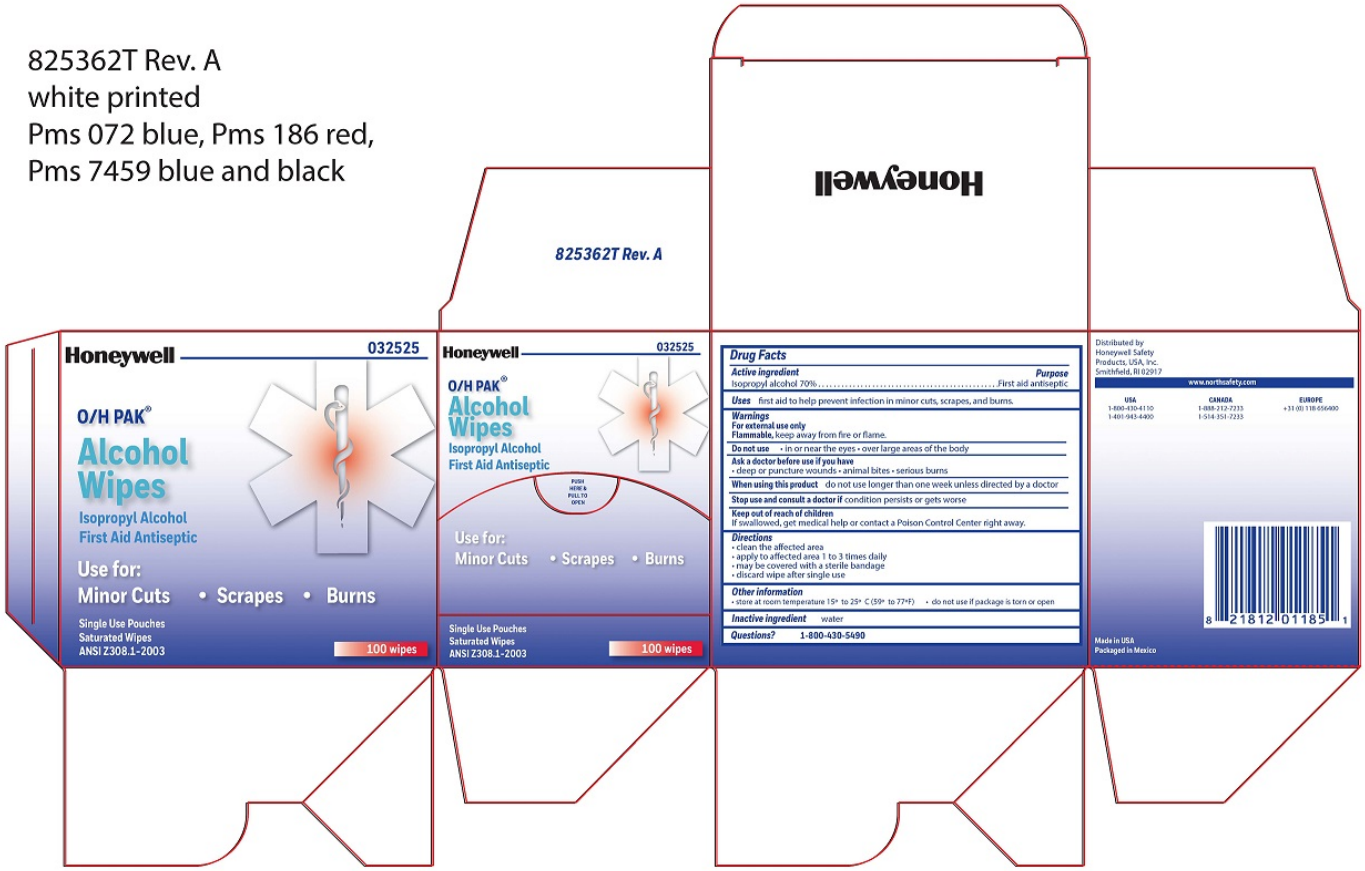
1 RED BIO BAGS 2/BX

Eyesaline
Principal Display Panel



Alcohol Wipe
Principal Display Panel

825362T Rev. A
white printed
Pms 072 blue, Pms 186 red,
Pms 7459 blue and black

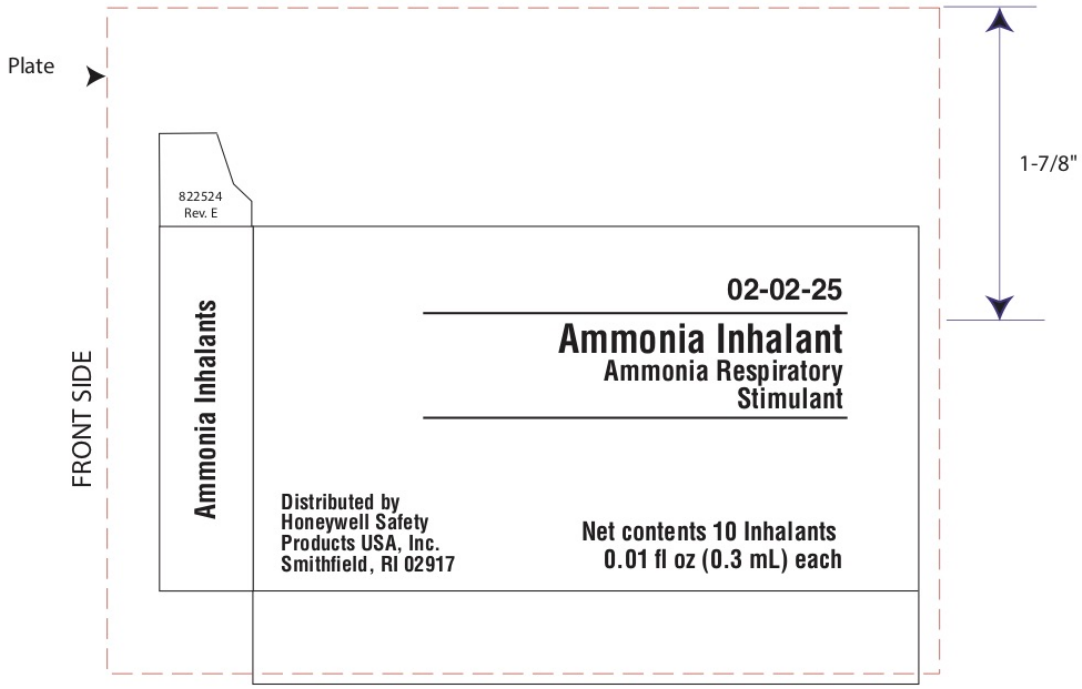


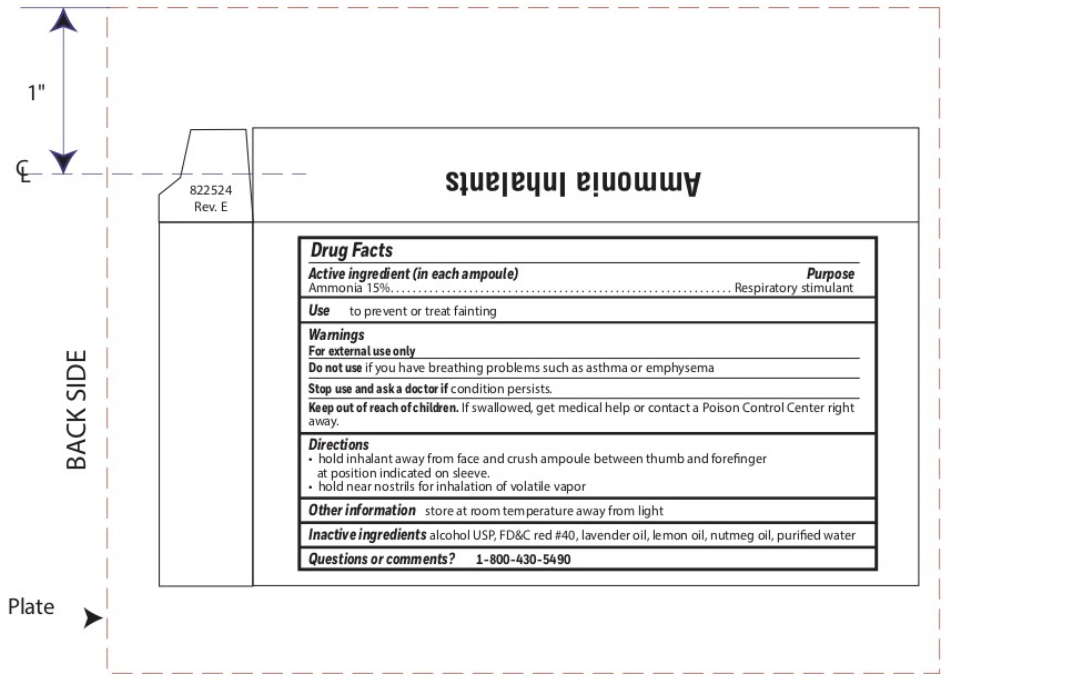
Antiseptic Spray
Principal Display Panel

Burn Spray
Principal Display Panel

Ammonia
Principal Display Panel

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

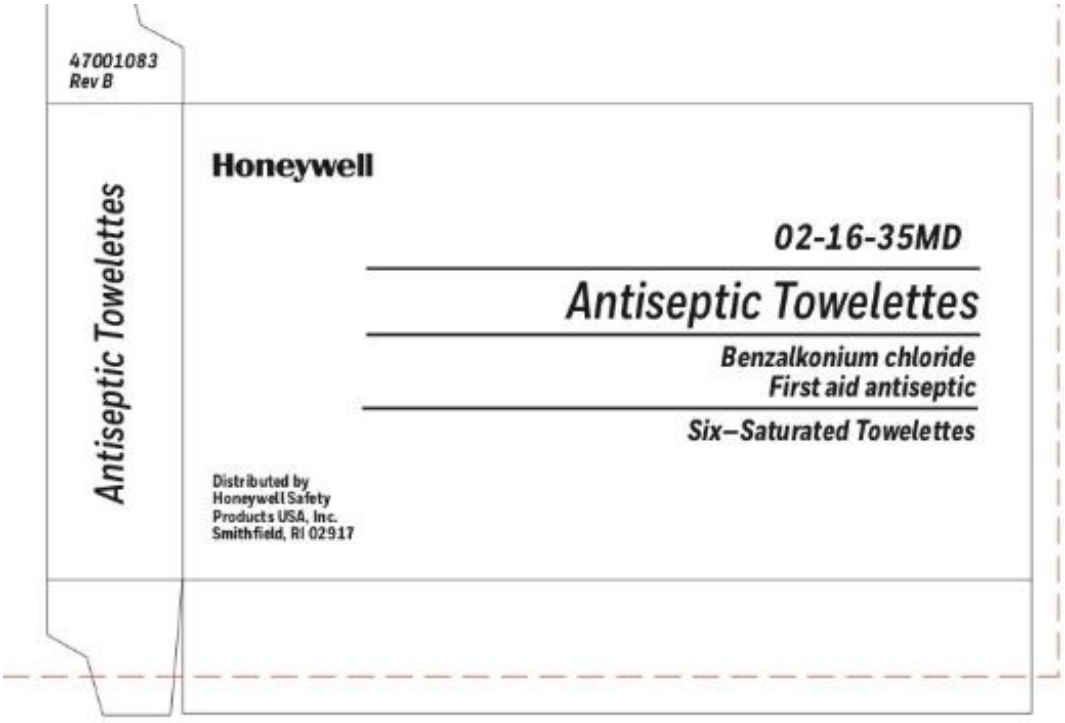


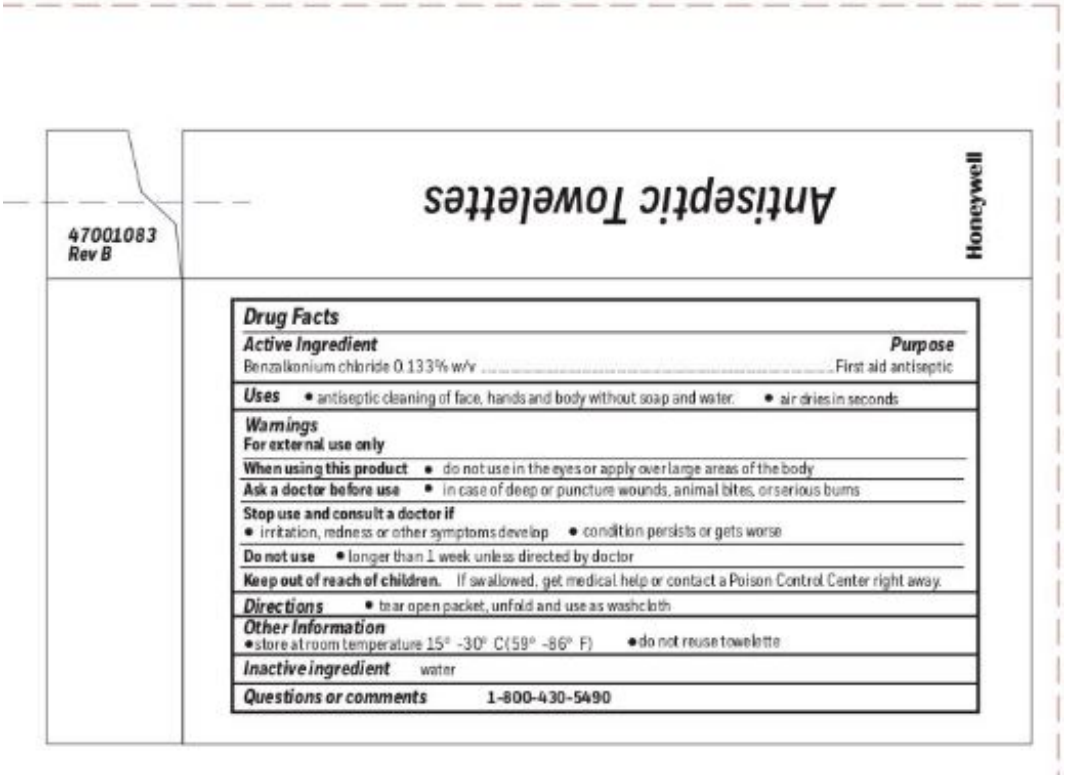


796006 Rev. E (page 3 of 3)

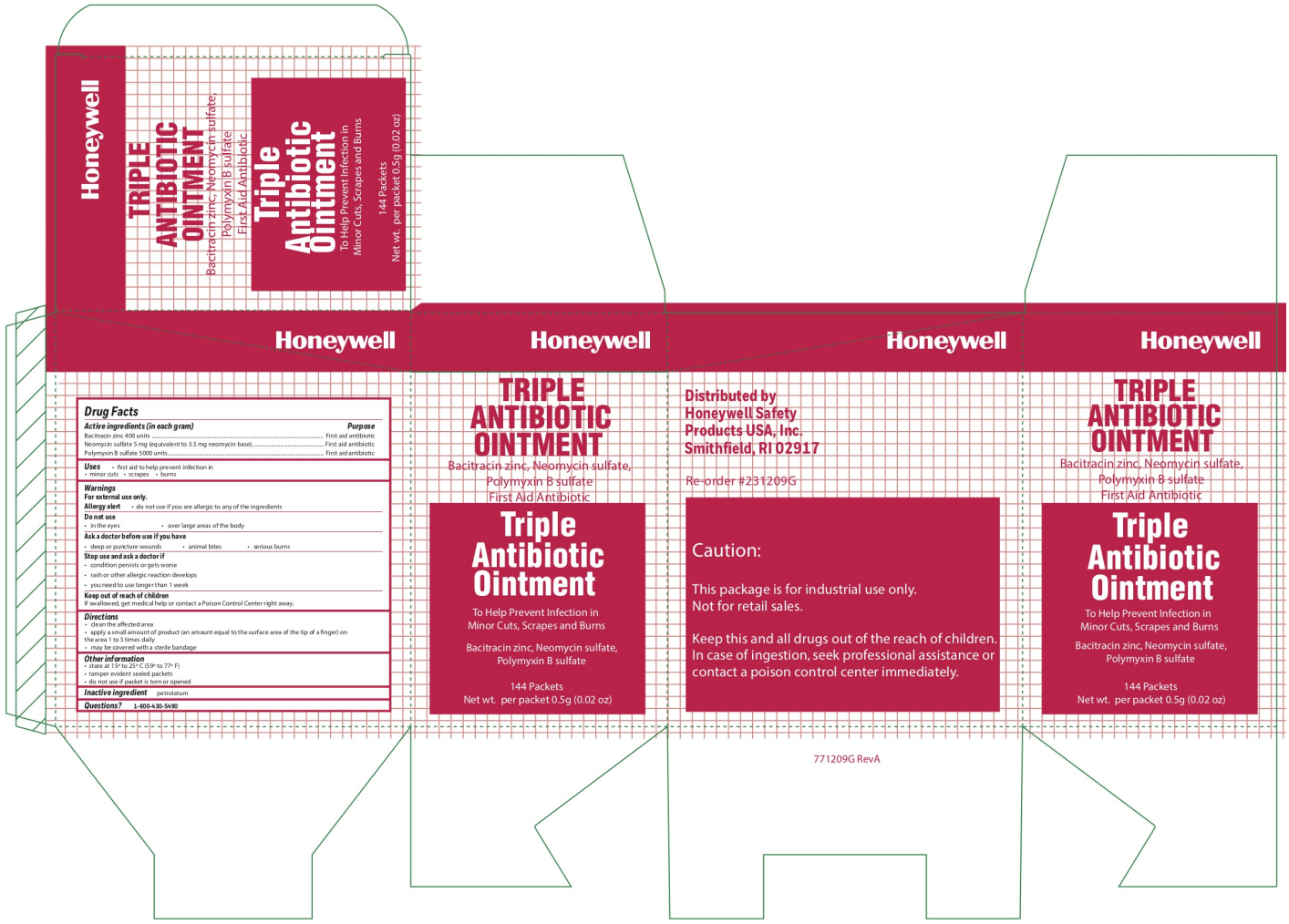
BZK

Principal Display Panel





Triple
Principal Display Panel



Aspirin
Principal Display Panel

4291 Kit Label
SF00004026

Swift 3 Shelf Cabinet Size 180 15″x 17″
printed in Pantone BLACK, RED 185

actual logo size: 13.3″ x 3″
Part Number: SF00001129-SW163

If distributor is signing for end user approval of logo, distributor assumes responsibility.

This drawing has been reviewed and approved for the following: Model type of kit, size of logo, PMS color of logo and placement of the logo on the first aid kit.

☐ Needs changes ☐ Approved

(A digital signature or response via email with attached approval are both accepted as an approval to this form. Please indicate any changes needed)

Name _____ Signature _____ Date _____

4305 Kit Label
SF00004363

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

4291 FIRST AID KIT

4291 first aid kit kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0498-4291

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-4291-01	1 in 1 KIT; Type 0: Not a Combination Product	10/18/2018	

Quantity of Parts		
Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	118 mL
Part 2	50 POUCH	20 mL
Part 3	1 BOTTLE, SPRAY	59 mL
Part 4	1 BOTTLE, SPRAY	59 mL
Part 5	20 PACKET	10 g
Part 6	10 AMPULE	3 mL
Part 7	40 PACKET	56 mL
Part 8	250 PACKET	500

Part 1 of 8

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 CHLORIDE (UNII: 451W47IQ8X)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)	

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 2 of 8

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: 059QF0KO0R)	

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 8

BURN RELIEF

lidocaine hydrochloride spray

Product Information	
Item Code (Source)	NDC:0498-0221
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	24.64 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
OCTOXYNOL-9 (UNII: 7JPC6Y25QS)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
TEA TREE OIL (UNII: VIF565UC2G)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0498-0221-59	59 mL in 1 BOTTLE, SPRAY; 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	09/18/2018	

Part 4 of 8

ANTISEPTIC

benzalkonium chloride spray

Product Information	
Item Code (Source)	NDC:0498-0402
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
OCTOXYNOL 9 (UNII: 7JPC6Y25QS)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
TROLAMINE (UNII: 9O3K93S3TK)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0498-0402-59	59 mL in 1 BOTTLE, SPRAY; 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	09/18/2018	

Part 5 of 8

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:I16QD7X297)	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:0498-0750-36	0.5 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 6 of 8

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 7 of 8

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	12/21/2017	

Part 8 of 8

ASPIRIN

aspirin tablet

Product Information	
Item Code (Source)	NDC:0498-0114
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg

Inactive Ingredients	
Ingredient Name	**Strength**
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	
MINERAL OIL (UNII: T5L8T28FGP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POVIDONE (UNII: FZ989GH94E)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Product Characteristics			
Color	white (white)	**Score**	2 pieces
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	FR21
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0498-0114-01	2 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	part343	09/18/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/18/2018	

4305 FIRST AID KIT

4305 first aid kit kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0498-4305

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0498-4305-01	1 in 1 KIT; Type 0: Not a Combination Product	10/18/2018	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BOTTLE	118 mL
Part 2	50 POUCH	20 mL
Part 3	1 BOTTLE, SPRAY	59 mL
Part 4	1 BOTTLE, SPRAY	59 mL
Part 5	20 PACKET	10 g
Part 6	10 AMPULE	3 mL
Part 7	20 PACKET	28 mL
Part 8	250 PACKET	500

Part 1 of 8

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 CHLORIDE (UNII: 451W47IQ8X)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)	

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 2 of 8

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: 059QF0KO0R)	

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 8

BURN RELIEF

lidocaine hydrochloride spray

Product Information	
Item Code (Source)	NDC:0498-0221
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	24.64 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
OCTOXYNOL-9 (UNII: 7JPC6Y25QS)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
TEA TREE OIL (UNII: VIF565UC2G)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0498-0221-59	59 mL in 1 BOTTLE, SPRAY; 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	09/18/2018	

Part 4 of 8

ANTISEPTIC

benzalkonium chloride spray

Product Information	
Item Code (Source)	NDC:0498-0402
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
OCTOXYNOL 9 (UNII: 7JPC6Y25QS)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
TROLAMINE (UNII: 9O3K93S3TK)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0498-0402-59	59 mL in 1 BOTTLE, SPRAY; 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	09/18/2018	

Part 5 of 8

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:I16QD7X297)	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:0498-0750-36	0.5 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 6 of 8

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 7 of 8

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	12/21/2017	

Part 8 of 8

ASPIRIN

aspirin tablet

Product Information	
Item Code (Source)	NDC:0498-0114
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg

Inactive Ingredients	
Ingredient Name	**Strength**
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	
MINERAL OIL (UNII: T5L8T28FGP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POVIDONE (UNII: FZ989GH94E)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Product Characteristics			
Color	white (white)	**Score**	2 pieces
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	FR21
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0498-0114-01	2 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	part343	09/18/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/18/2018	

Labeler - 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(0498-4291, 0498-4305)

Establishment

Name	Address	ID/FEI	Business Operations
Ultra Seal Corportion		085752004	manufacture(0498-0114)

Establishment

Name	Address	ID/FEI	Business Operations
Water-Jel Technologies		155522589	manufacture(0498-0750, 0498-0402, 0498-0221)

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, 0498-0501)