4209 FIRST AID KIT- 4209 first aid kit
4211 FIRST AID KIT- 4211 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.

4209, 4211 First Aid Kit (Pyrocaine Sp, EW, ASA, 1st aid Pack: triple, amm. Inh, BZK wipe-340001F, 340002F)

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

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 (in each tablet)

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

Aspirin
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 hours
- 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 dioxide*

*may contain these ingredients

Aspirin
Questions or Comments

1-800-430-5490

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 ingredient

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

Ammonia
Questions or Comments?

1-800-430-5490

Pyrocaine
Active ingredient

Benzocaine 20%

Benzethonium chloride 0.2%

Pyrocaine
Purpose

Topical anesthetic

Topical antiseptic

Pyrocaine
Uses

For the temporary relief of pain and itching, and to help protect against skin infection in:

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

Do not use

- in or near the eyes or over large portions of the body

- in case of deep or puncture wounds or on:
- raw surfaces
- blistered areas
- animal bites
- serious burns

Keep out of reach of children
- If swallowed, get medical help or contact a Poison Control Center right away

Pyrocaine
Warnings

For external use only

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

Stop use and ask a doctor if
- If condition persists or worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days

Pyrocaine
Directions
- clean the affected area
- shake can well before using
- hold can 6 to 12 inches away from the affected area and spray liberally
- apply to affected area not more than 3 times daily
- for adult institutional use only
- not intended for use on children

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

Pyrocaine
Inactive ingredients

butane,dipropylene glycol, isobutane, propane

BZK Wipes
Active ingredient

Benzalkonium chloride 0.13% w/v

BZK Wipe
Purpose

First aid antiseptic

BZK Wipes
Uses

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

BZK Wipes
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 15 ^{0} to 30 ^{0} C (59 ^{0} - 86 ^{0} F)
- do not reuse towelette

BZK Wipe
Inactive ingredient

water

BZK Wipe
Questions

1-800-430-5490

4209
340001F Kit Contents

1 3/4X3 PLAS SING 50/BOX

1 GAUZE BANDAGE, 4" X 6 YD

1 ADH TAPE W/P 1/2"X 2 1/2 YD

1 GAUZE CLEAN-WRAP BDGE N/S 2"

1 PYRO-CAINE AEROSOL 1/2 OZ

1 1 OZ, BUFF EYEWASH

1 SCISSOR BDGE 4" RED PLS HDL

1 KIT TWEEZER 3 1/2" SLANTED

1 F. A. INST CHART SM (INDIVIDUAL LBL)

LBL STOCK 6-3/8"X4"

1 LBL STOCK 3"x1-7/8"

2 BAYER 12 PACK PER ZIP BAG

1 1ST AID PK 0001 0002 110 amm,bzk, triple

1 KIT, PP 10 UNIT FA

4211
340002L Kit Contents

1 3/4X3 PLAS SING 50/BOX

1 ADH TAPE W/P 1/2"X 2 1/2 YD

1 GAUZE CLEAN-WRAP BDGE N/S 2"

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

1 PYRO-CAINE AEROSOL 1/2 OZ

1 1 OZ, BUFF EYEWASH

1 SCISSOR BDGE 4" RED PLS HDL

1 KIT TWEEZER 3 1/2" SLANTED

1 F. A. INST CHART SM (INDIVIDUAL LBL)

LBL STOCK 6-3/8"X4"

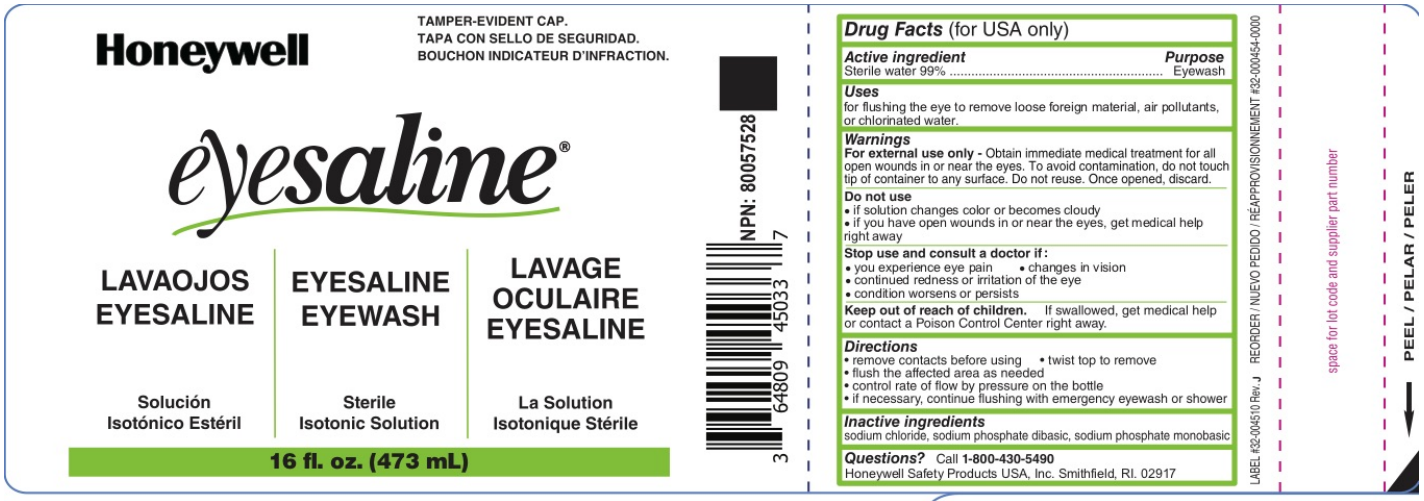
1 LBL STOCK 3"x1-7/8"

2 BAYER 12 PACK PER ZIP BAG

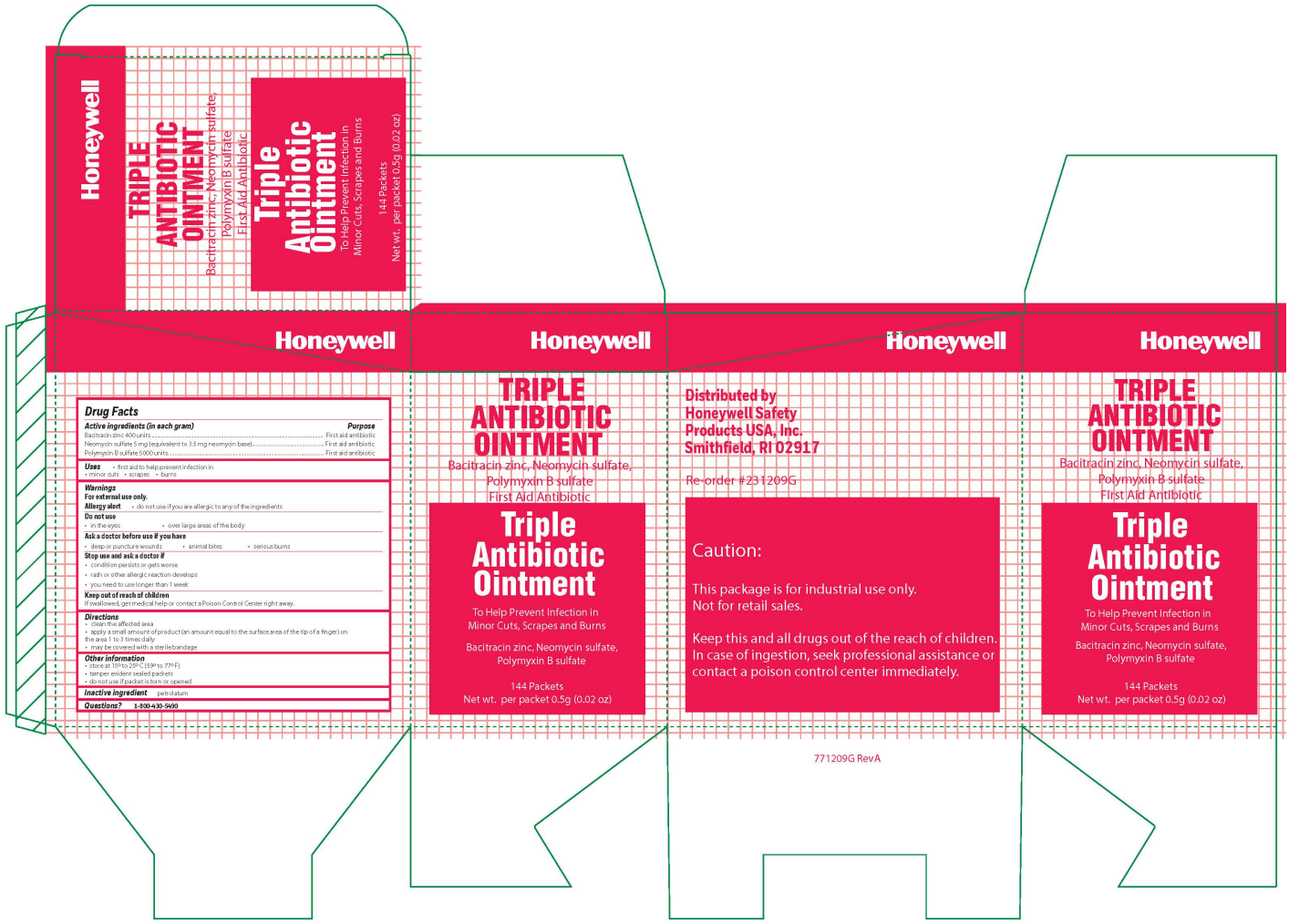
1 1ST AID PACK FOR 0001 0002 110

1 KIT, PP 10 UNIT FA

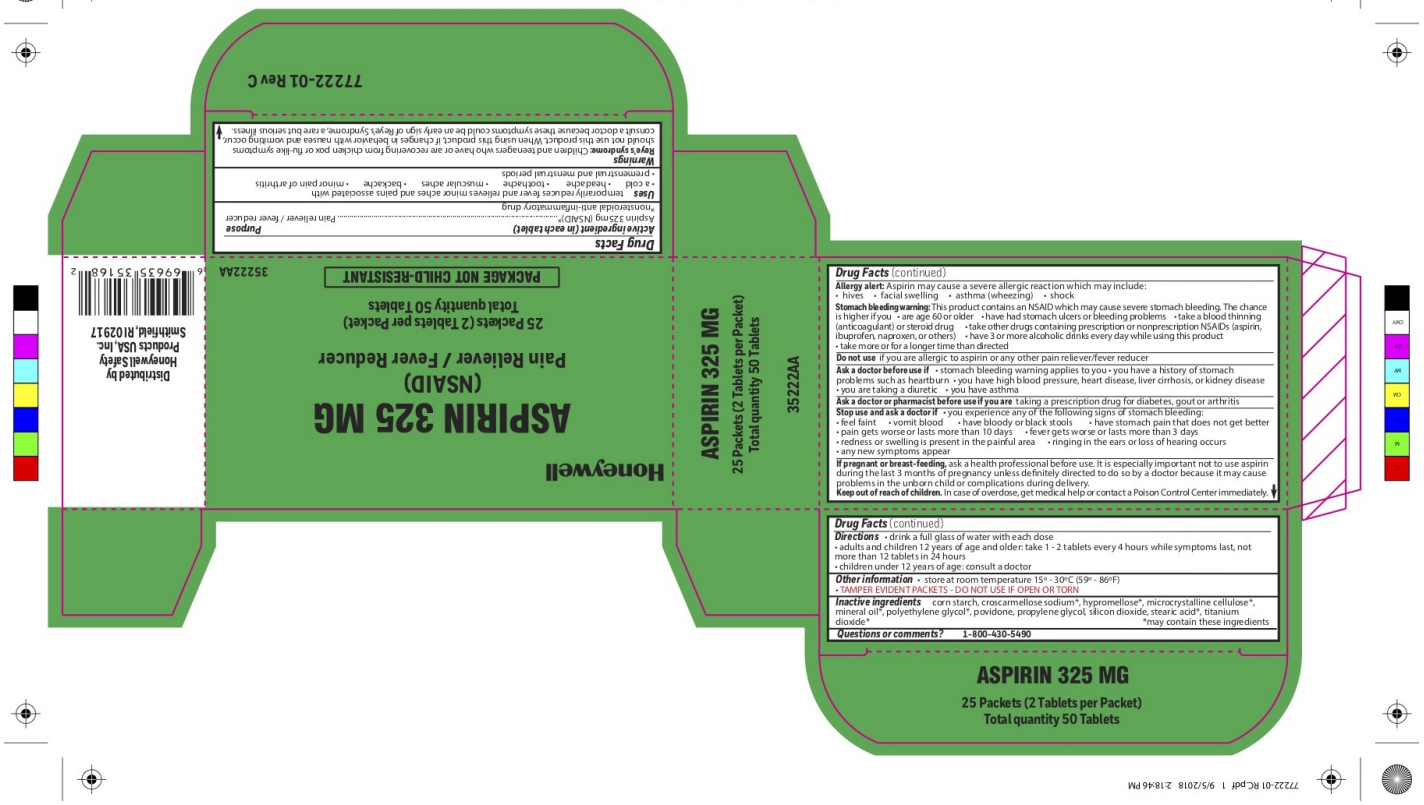
Eyewash
Principal Display Panel



Triple
Principal Display Panel

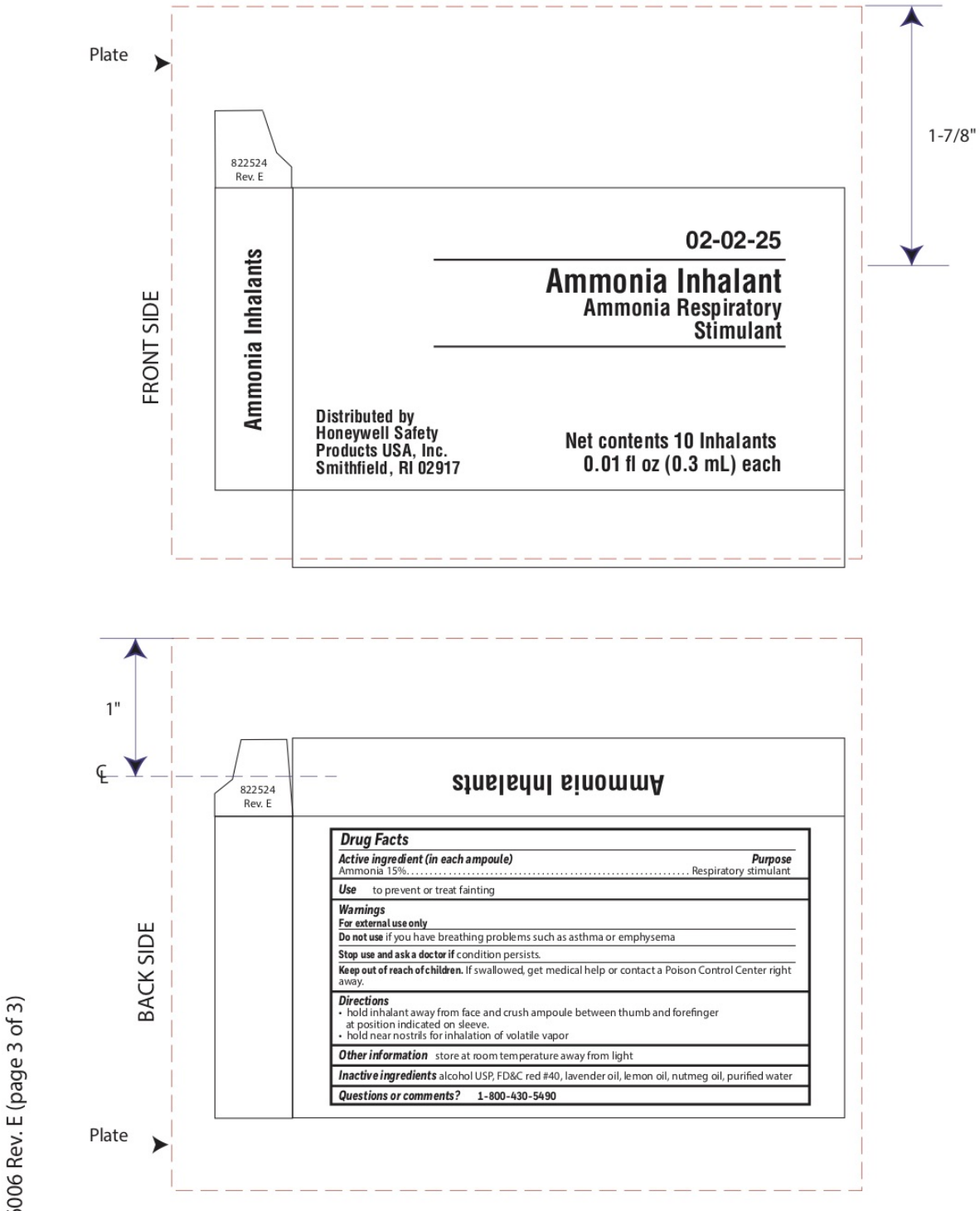


Aspirin
Principal Display Panel



Ammonia
Principal Display Panel

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



Pyrocaine

Principal Display Panel

BZK Wipe
Principal Display Panel

4209 Kit Label
340001F

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

4211 Kit Label
340002F

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

4209 FIRST AID KIT

4209 first aid kit kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0498-4209

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0498-4209-01	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	30 mL
Part 2	6 PACKET	8.4 mL
Part 3	12 PACKET	24
Part 4	4 PACKET	3.6 g
Part 5	2 AMPULE	0.6 mL
Part 6	1 CAN	14.2 g

Part 1 of 6

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

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 2 of 6

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 3 of 6

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

Product Characteristics			
Color	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	

Part 4 of 6

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**
BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN	400 [iU] in 1 g
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B	5000 [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:0498-0750-35	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 6

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 6 of 6

PYROCAINE BURN

benzocaine, benzethonium chloride aerosol, spray

Product Information	
Item Code (Source)	NDC:0498-0011
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	20 g in 100 g
BENZETHONIUM CHLORIDE (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP)	BENZETHONIUM CHLORIDE	0.2 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
1,1,3-TRI(3-TERT-BUTYL-4-HYDROXY-6-METHYLPHENYL)BUTANE (UNII: BF6E9O0XJN)	
ISOBUTANE (UNII: BXR49TP611)	
1,1,3-TRIS(2-CHLOROETHOXY)PROPANE (UNII: 4FEX9N888E)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0498-0011-77	14.2 g in 1 CAN; 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	01/01/2018	

Marketing Information

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

4211 FIRST AID KIT

4211 first aid kit kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0498-4211

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-4211-01	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	30 mL
Part 2	6 PACKET	8.4 mL
Part 3	12 PACKET	24
Part 4	4 PACKET	3.6 g
Part 5	2 AMPULE	0.6 mL
Part 6	1 CAN	14.2 g

Part 1 of 6

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

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 2 of 6

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 3 of 6

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

Product Characteristics			
Color	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	

Part 4 of 6

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**
BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN	400 [iU] in 1 g
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B	5000 [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:0498-0750-35	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 6

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 6 of 6

PYROCAINE BURN

benzocaine, benzethonium chloride aerosol, spray

Product Information

Item Code (Source)	NDC:0498-0011
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	20 g in 100 g
BENZETHONIUM CHLORIDE (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP)	BENZETHONIUM CHLORIDE	0.2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
1,1,3-TRI(3-TERT-BUTYL-4-HYDROXY-6-METHYLPHENYL)BUTANE (UNII: BF6E9O0XJN)	
ISOBUTANE (UNII: BXR49TP611)	
1,1,3-TRIS(2-CHLOROETHOXY)PROPANE (UNII: 4FEX9N888E)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0011-77	14.2 g in 1 CAN; 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	01/01/2018	

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(0498-4209, 0498-4211)

Establishment

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

Establishment

Name	Address	ID/FEI	Business Operations
Dixon Investments		115315822	manufacture(0498-0011)

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)