

4213 FIRST AID KIT- 4213 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](#).

4213 First Aid Kit (PVP wipes, alcohol wipes, Antiseptic Spray, ASA, ammonia- 340410F)

Povidone Iodine Swab

Active ingredient

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

Povidone Iodine Swab

Purpose

First aid antiseptic

Povidone Iodine Swab

Uses

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

Povidone Iodine Swab

Warnings

For external use only

Do not use

- 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

Povidone Iodine Swab

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

Povidone Iodine Swab

Other information

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

Povidone Iodine Swab

Inactive ingredients

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

Povidone Iodine Swab

Questions and comments

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 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 15⁰ to 25⁰ C (59⁰ to 77⁰F)

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 15⁰-30⁰ C (59⁰ -86⁰ 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

Ammonia Inhalant***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

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

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 breast-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 EVIDENT PACKETS - DO NOT USE IF OPEN OR TORN

Aspirin***Inactive ingredients***

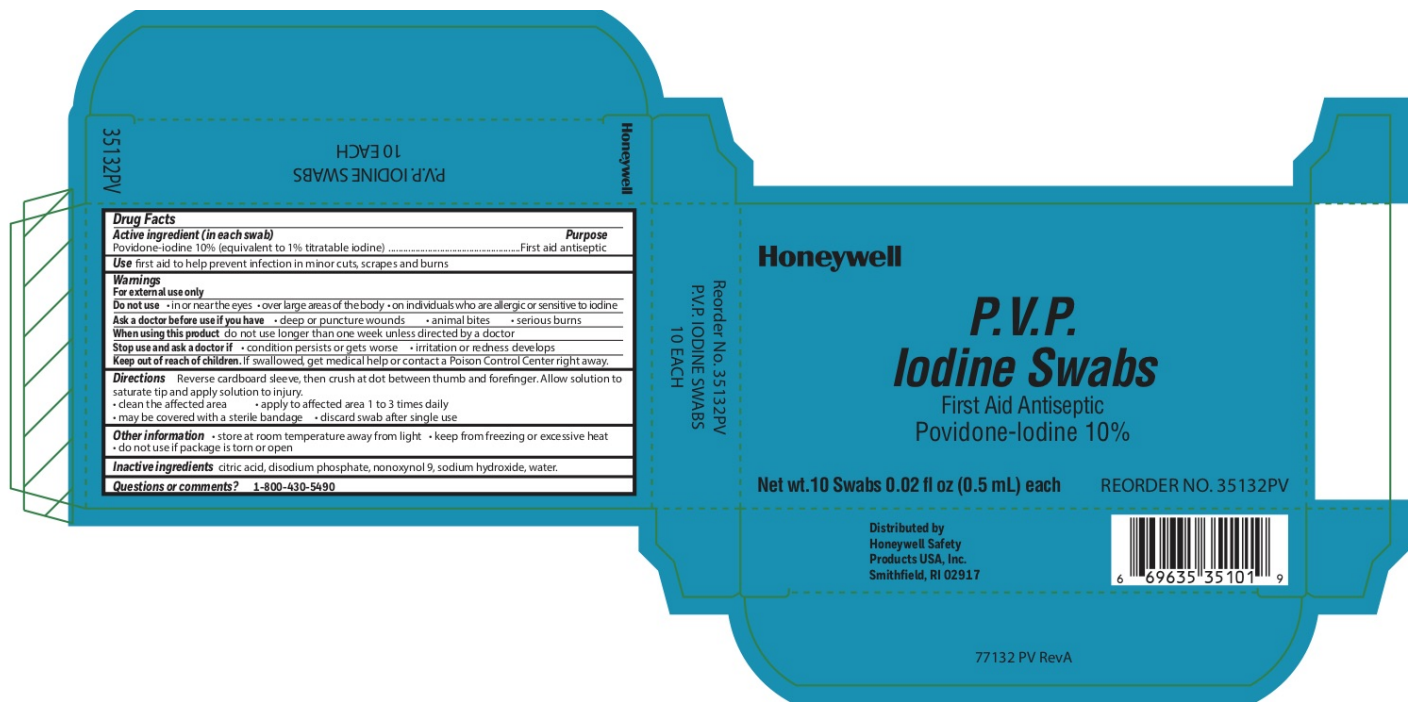
corn starch, croscarmellose sodium*, hypromellose*, microcrystalline cellulose*, mineral oil*, polyethylene glycol*, povidone, propylene glycol, silicon dioxide, stearic acid*, titanium dioxide*

*may contain these ingredients

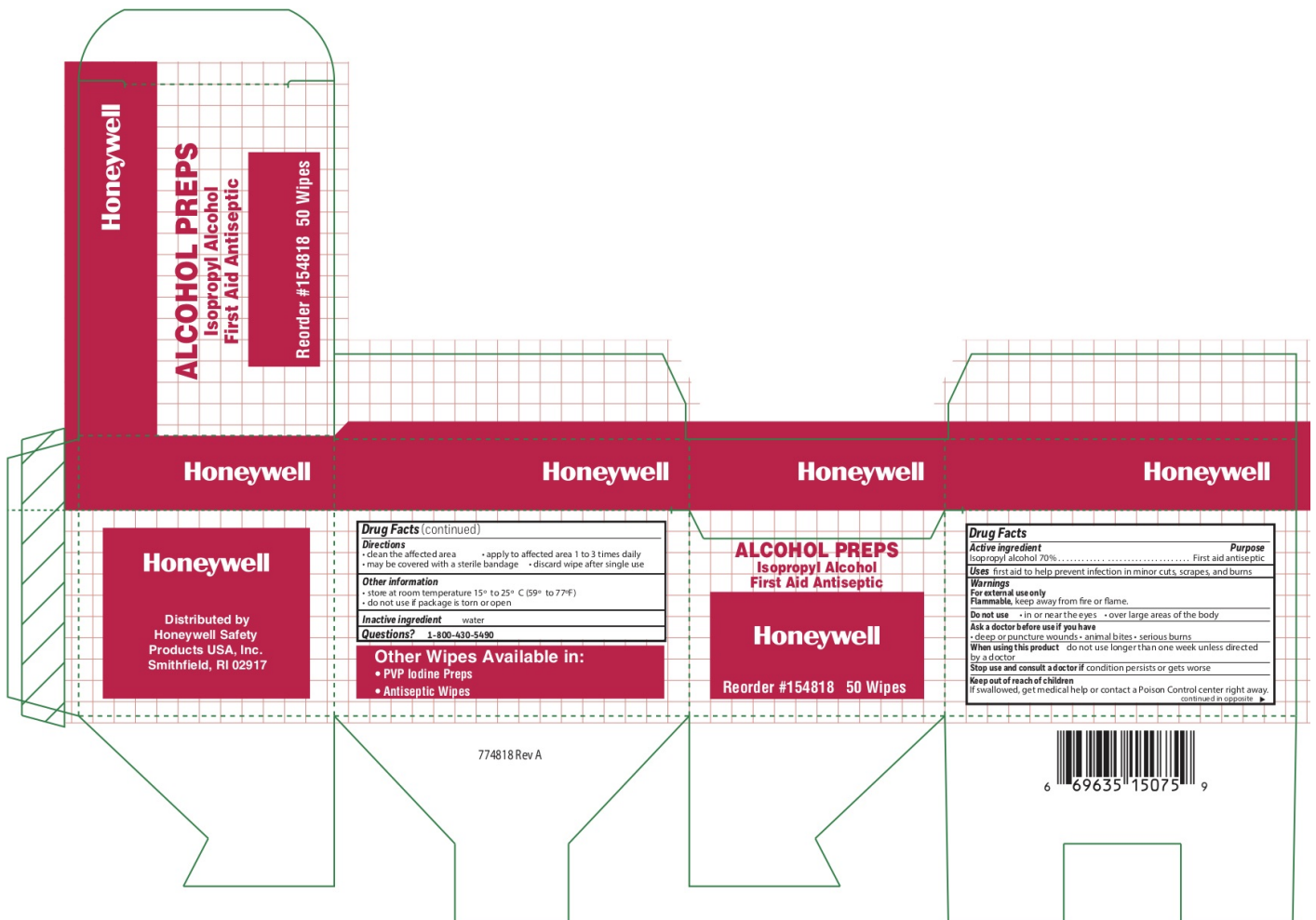
Aspirin***Questions or Comments?***

1-800-430-5490

Povidone Iodine Swab***Principal Display Panel***



Alcohol Principal Display Panel



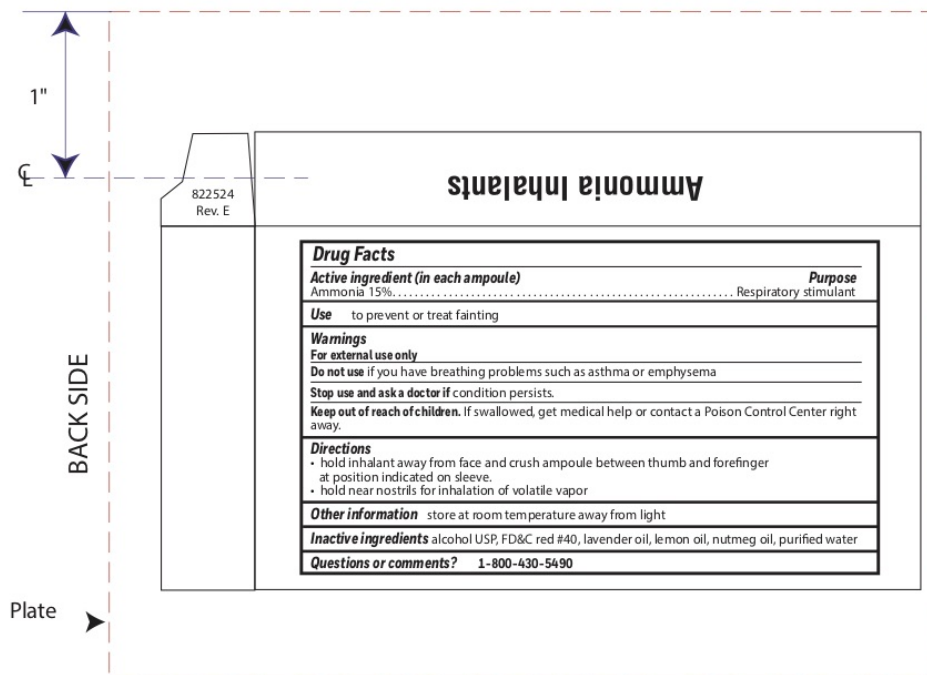
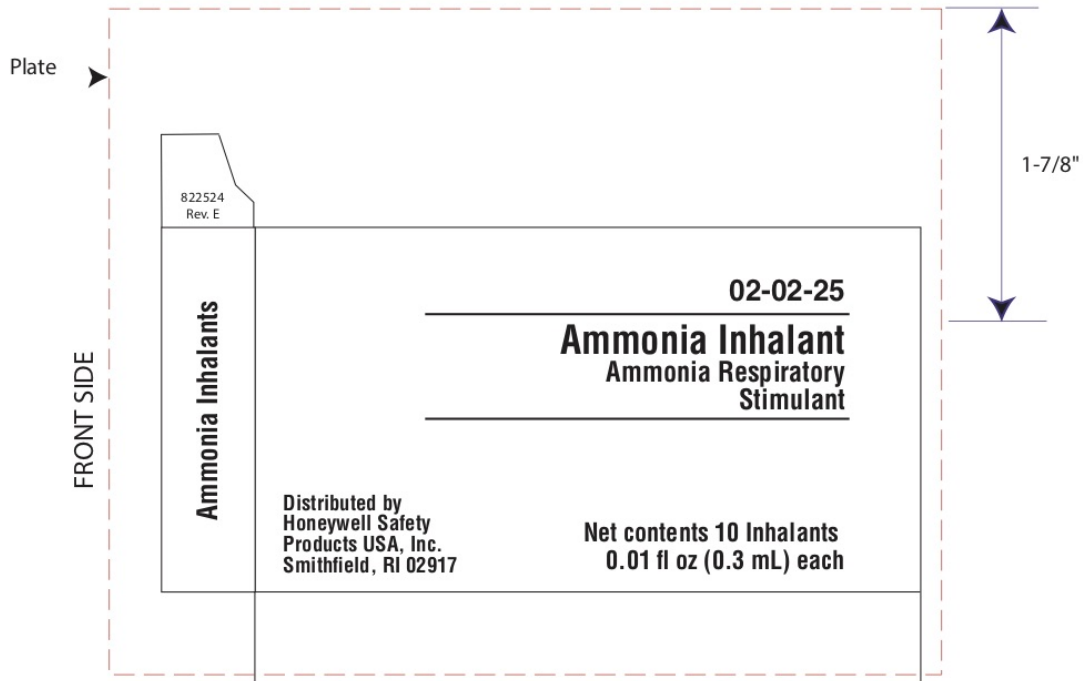
Antiseptic Spray

Principal Display Panel

Honeywell 032203	Drug Facts
ANTISEPTIC SPRAY <i>Benzalkonium chloride</i> First Aid Antiseptic	Active ingredient Benzalkonium chloride 0.13% Purpose First aid antiseptic
	Uses first aid to help prevent infection in minor cuts, scrapes and burns
Net contents 2 fl oz (59 mL)	Warnings For external use only
ANSI Z308.1-2003	Do not use • in or near the eyes • over large areas of the body
 8 21812 01498 2	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 condition persists or gets worse
	Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away.
	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
	Other information • shake well • store at room temperature, 15° to 30°C (59° to 86°F)
	Inactive ingredients diazolidinyl urea, edetate disodium, glycerin, hypromellose, methylparaben, octoxynol 9, propylene glycol, propylparaben, triethylamine, water
	Questions or comments? 1-800-430-5490
	Mfg. for: Honeywell Safety Products USA, Inc. Smithfield, RI 02917 032203 Rev. G

Ammonia Principal Display Panel

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



Principal Display Panel



4213 Kit Label
340410F

First Aid

4213 Kit Contnets
340410F

- 1 INSTANT COLD PACK 4" X 6"
- 1 PVP IODINE WIPES 10 PER
- 1 ADH TAPE W/P 1/2"X 2 1/2 YD
- 1 FIRST AID GUIDE ASHI
- 1 GAUZE CLEAN-WRAP BDGE N/S 2"
- 1 FIRST AID SPRAY AEROSOL 3 OZ
- 1 ASPIRIN 5 GR BTL OF 100'S
- LBL STOCK 6-3/8"X4"
- LBL STOCK 4"X2-7/8"
- 1 LBL STOCK 3"x1-7/8"
- 1 PR LRG NITRILE GLVES ZIP BAG
- 1 1" X 3" PLASTIC BANDS 16/BAG
- 4 WIPE ALCOHOL PREP IPA 70% (DUKAL)
- 1 KIT STL 10 UN WHITE 01
- 4 NON ADHERENT PAD 2" X 3"
- 2 AMMONIA INHALANT, BULK

4213 FIRST AID KIT

4213 first aid kit kit

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:0498-4213

Packaging

#

Item Code

Package Description

Marketing Start Date

Marketing End Date

1

NDC:0498-4213-01

1 in 1 KIT; Type 0: Not a Combination Product

10/18/2018

Quantity of Parts

Part #

Package Quantity

Total Product Quantity

Part 1

4 POUCH

1.6 mL

Part 2

10 POUCH

3 mL

Part 3

1 BOTTLE, SPRAY

59 mL

Part 4

2 AMPULE

0.6 mL

Part 5

50 PACKET

100

Part 1 of 5

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 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
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 4 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		Strength
AMMONIA (UNII: 5138Q19F1X) (AMMONIA - UNII:5138Q19F1X)		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 5 of 5	
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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
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE (UNII: FZ989GH94E)	
MINERAL OIL (UNII: T5L8T28FGP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

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	09/19/2018	

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(0498-4213)

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

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

Establishment			
Name	Address	ID/FEI	Business Operations
Changzhou Maokang Medical		421317073	manufacture(0498-0143)

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

Revised: 3/2019

Honeywell Safety Products USA, INC