

4224 FIRST AID KIT- 4224 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](#).

4224 First Aid Kit (Ammonia Inh, EW, Burn Jel, PVP Wipes, ASA- 35824CG)

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

Burn Jel***Active ingredient***

Lidocaine HCl 2.0%

Burn Jel***Purpose***

External analgesic

Burn Jel***Uses***

- temporarily relieves pain due to minor burns

Burn Jel***Warnings***

For external use only

Do not use

- on large areas of the body, particularly over raw surfaces or blistered areas

When using this product

- avoid contact with eyes

Stop use and ask a doctor if

- the condition gets worse
- symptoms persist for more than 7 days
- condition clears up and recurs within a few days

Keep out of reach of children

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

Burn Jel***Directions***

- adults and children 2 years of age and older; apply to affected area not more than 3 to 4 times daily
- children under 2 years of age: ask a doctor
- you may report a serious reaction to this product to 800-430-5490

Burn Jel***Other information***

- store at room temperature - do not use if opened or torn

Burn Jel***Inactive ingredients***

carbopol 940, carbopol 1342, diazolidinyl urea, glycerin, melaleuca alternifolia (tea tree) leaf oil, methylparaben, octoxynol-9, propylene glycol, propylparaben, triethylamine, water

Burn Jel***Questions***

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

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

4224

35824CG Kit Contents

1 AMMONIA INHALANTS 10 PER

2 GAUZE BANDAGE, 4" X 6 YD

1 TOURNIQUET, 1 PER

1 WIRE SPLINT 1 PER

2 GAUZE COMPRESS, 1728 SQ IN 1

2 BUFFERED EYE WASH 1 OZ BTL

2 ADHESIVE BDG, PLSTIC, 1"X3"16PER

2 BURN JEL 1/8 OZ, 6 PER

1 PVP IODINE WIPES 10 PER

2 BANDAGE COMP 2" W/TELFA PAD 4

3 BANDAGE COMP 4" W/TELFA PAD 1

LBL STOCK 6-3/8"X4"

1 LBL STOCK 6-3/8"X4"

1 LBL STOCK 3"x1-7/8"

4 BAYER 12 PACK PER ZIP BAG

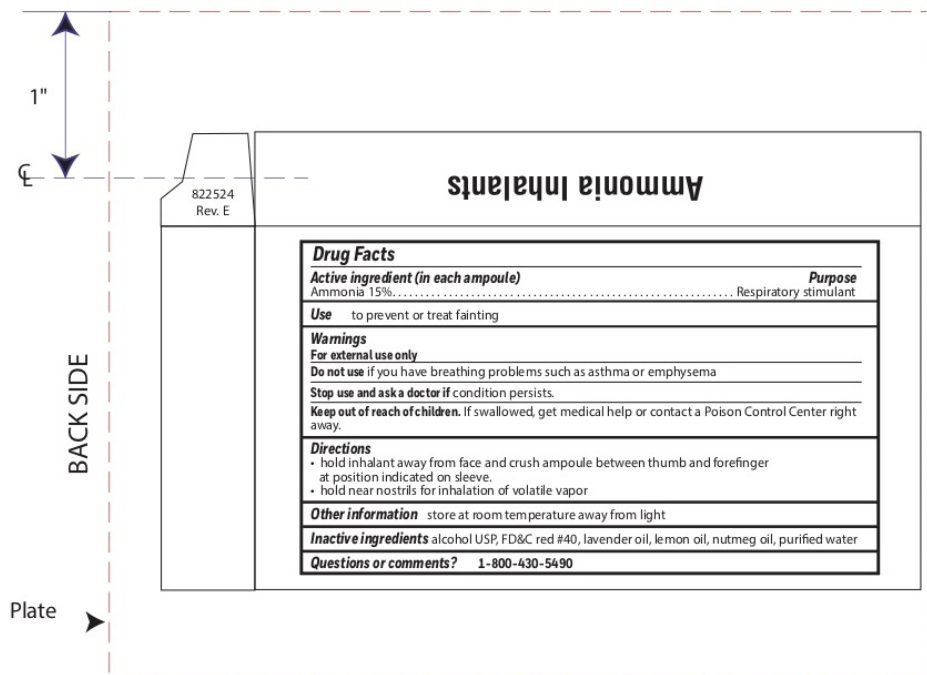
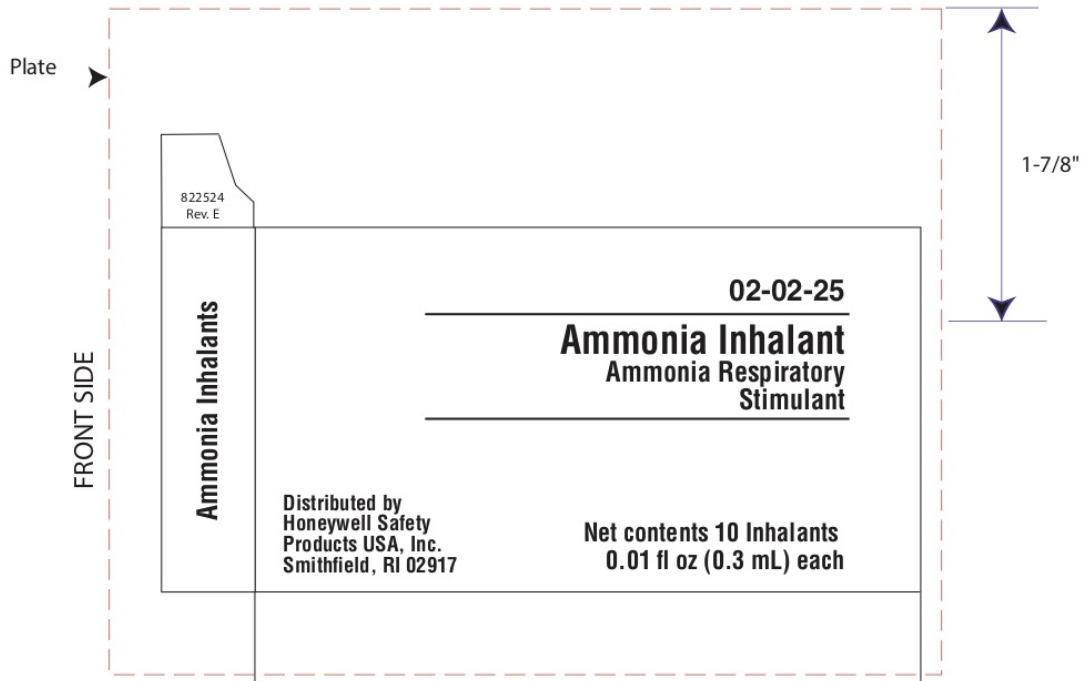
24 UNIT PLASTIC HIPS MT BLANK

1 ADHES TAPE EYE STRIPS 2'S

2 TRI BNDG NON WOVEN 40"X40"X56"

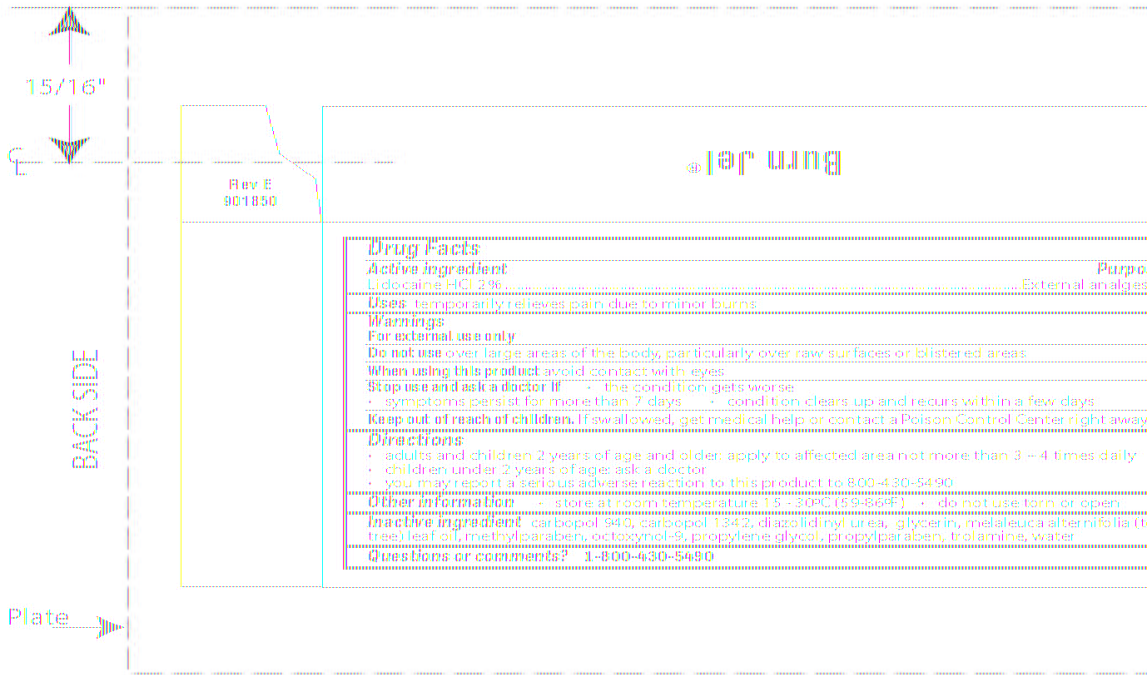
Principal Display Panel

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

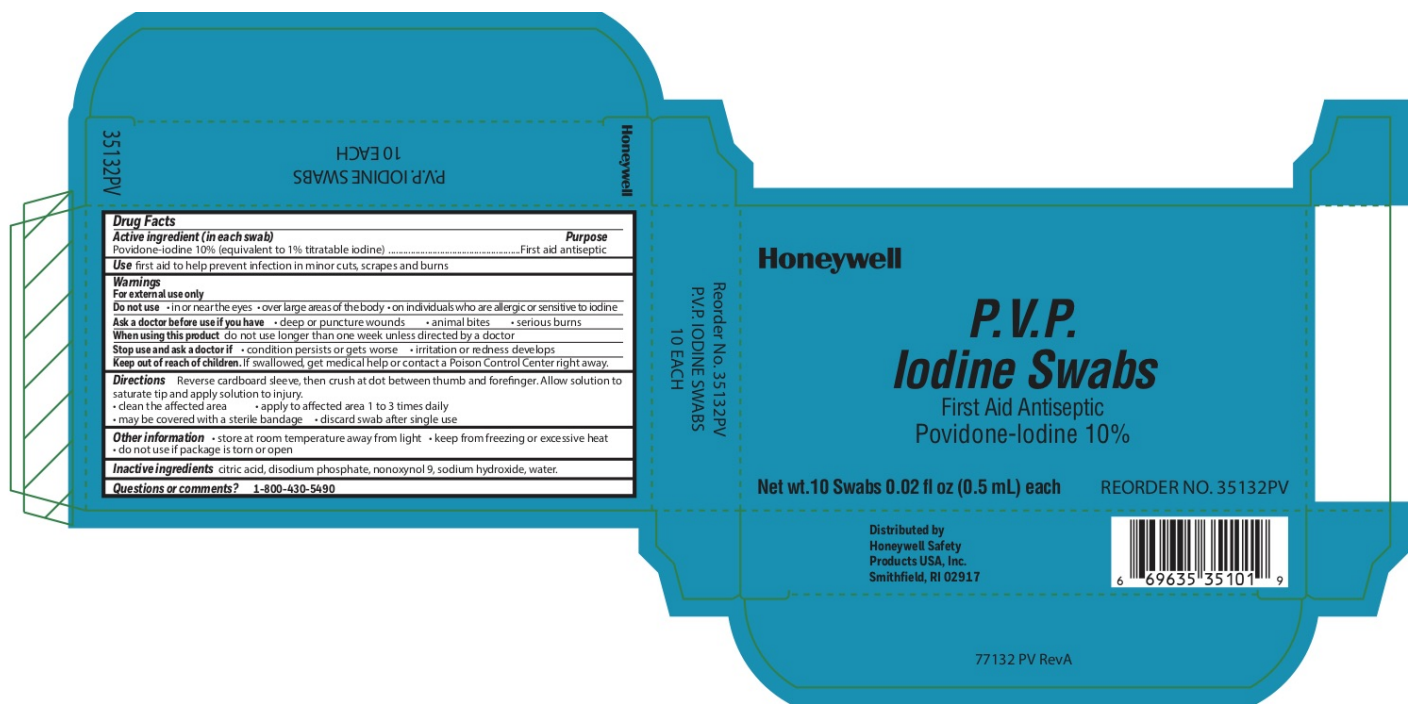


Principal Display Panel

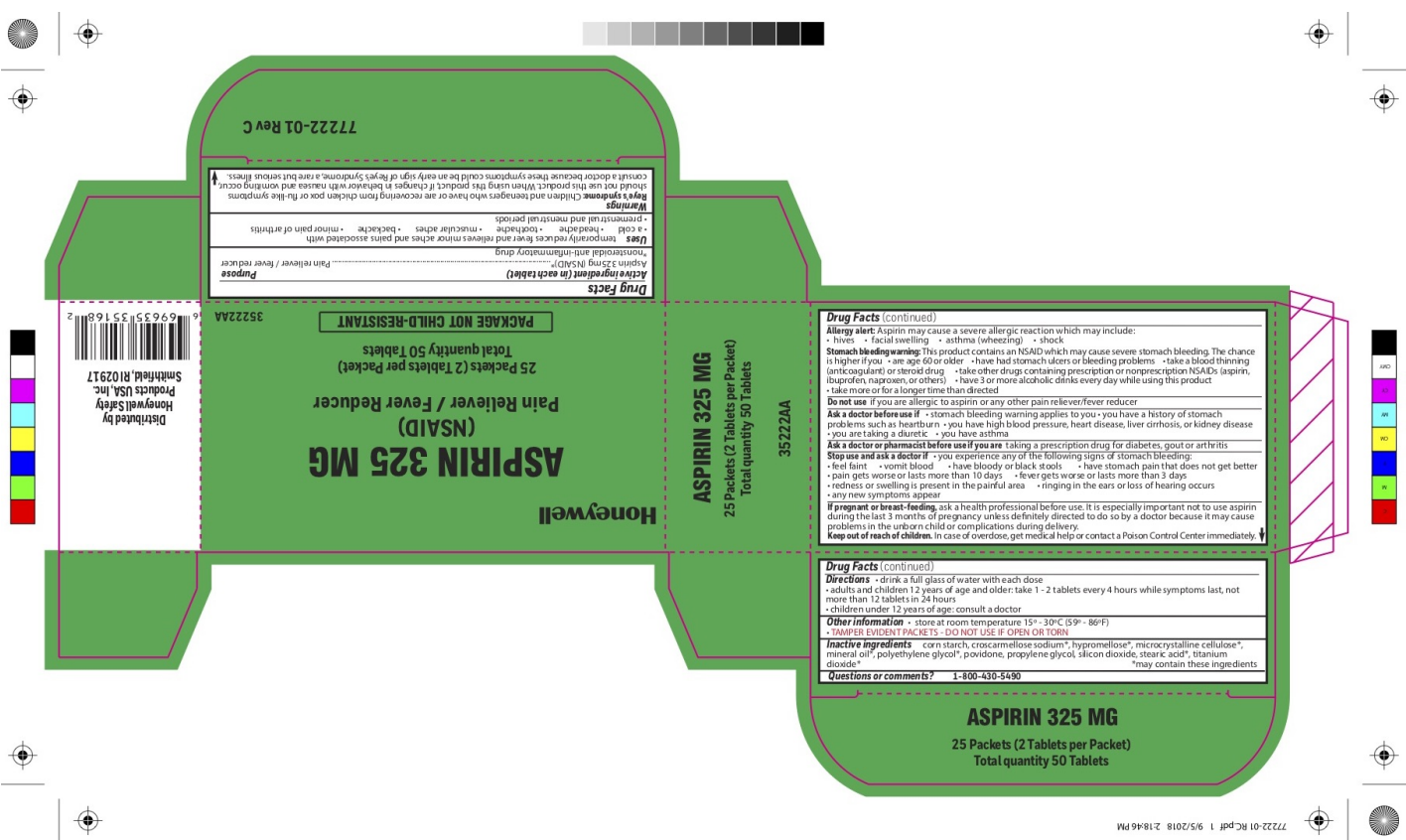
796353 Rev. E Unit Carton Printing Plate for "B" size cartor



PVP
Principal Display Panel



Aspirin
Principal Display Panel



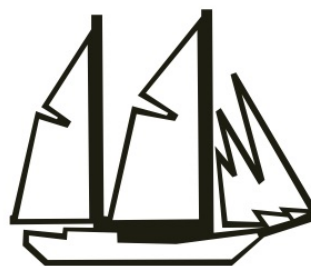
4224 Kit Label
35824CG



FIRST AID KIT

FOR LIFEBOATS

USCG NUMBER 160.041/22/0



by Honeywell

Model #35824CG-4838

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

4224 first aid kit				
Product Information				
Product Type		HUMAN OTC DRUG	Item Code (Source)	
			NDC:0498-4224	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-4224-01	1 in 1 KIT	09/13/2018	
Quantity of Parts				
Part #	Package Quantity		Total Product Quantity	
Part 1	24 PACKET		48	
Part 2	10 AMPULE		3 mL	
Part 3	12 PACKET		42 g	
Part 4	10 POUCH		3 mL	
Part 5	2 BOTTLE		60 mL	
Part 1 of 5				
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)				
STARCH, CORN (UNII: O8232NY3SJ)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)				
MINERAL OIL (UNII: T5L8T28FGP)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				

TITANIUM DIO XIDE (UNII: 15FIX9V2JP)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POVIDONE (UNII: FZ989GH94E)	

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 2 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 3 of 5

BURN JEL

gel for burns gel

Product Information

Item Code (Source)	NDC:0498-0203
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
TEA TREE OIL (UNII: VIF565UC2G)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
OCTOXYNOL-9 (UNII: 7JPC6Y25QS)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0203-00	3.5 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
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OTC monograph not final	part348	09/19/2018	
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Part 4 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 5 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	

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
Honeywell Safety Products USA, Inc		079287321	pack(0498-4224)

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(0498-0203)
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Establishment			
Name	Address	ID/FEI	Business Operations
Honeywell Safety Products USA, Inc.		167518617	manufacture(0498-0100)

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