4362 FIRST AID KIT- 4362 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.

4362 First Aid Kit (Triple, ammonia, EW, alcohol wipes, HC cr, PVP wipes, BZK wipes, SunX, sting relief- SF00001915)

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, trolamine, water

Burn Jel
Questions

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 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

Sting Relief
Active ingredient (in each wipe)

Ethyl alcohol 50.0%

Lidocaine HCl 2.0%

Sting Relief
Purpose

Antiseptic

Topical pain relief

Sting Relief
Uses

- prevent infection in minor scrapes, and temporary relief of itching of insect bites

Sting Relief
Warnings

For external use only

Flammable, keep away from open fire or flame

Do not use
- over large areas of the body
- in eyes
- over raw or blistered areas

Stop use and ask a doctor
- if conditions worsen or persist for more than 7 days or clear up and occur again within a few days

Keep out of reach of children.

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

Sting Relief
Directions
- adults and children 2 years and older: Apply to cleaned affected area not more than 3 times daily.
- children under 2 years of age: consult a doctor.

Sting Relief
Inactive ingredients

benzalkonium chloride, menthol, and purified water

Sting Relief
Questions or Comments?

1-800-430-5490

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

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

Hydrocortisone
Active ingredient (in each gram)

Hydrocortisone acetate (equivalent to Hydrocortisone 1%)

Hydrcortisone
Purpose

Anti-itch cream

Hydrocortisone
Uses

- for the temporary relief of itching associated with minor skin irritations and rashes

Hydrocortisone
Warnings

For external use only

Ask a doctor before use if
- you are using any other hydrocortisone product

When using the product

- avoid contact with eyes
- do not begin use of any other hydrocortisone product unless you have consulted a doctor
- do not use for the treatment of diaper rash

Stop use and ask a doctor if
- condition worsens
- condition persists 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.

Hydrocortisone
Directions
- adults and children 2 years and older:
- clean the affected area
- apply to the area not more than 3 to 4 times daily
- children under 2 years of age: consult a doctor

Hydrocortisone
Other information
- store at room temperature (do not freeze)

Hydrocortisone
Inactive ingredients

cetyl alcohol, citric acid, diazolidinyl urea, edetate disodium, glycerin, glyceryl monostearate, methylparaben, mineral oil, polyethylene glycol, propylene glycol, propylparaben, purified water, stearic acid, trolamine

Hydrocortisone
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 ingredients

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

Ammonia
Questions or Comments?

1-800-430-5490

Alcohol
Active ingredient

Isopropyl alcohol 70%

Alcohol
Purpose

First aid antiseptic

Alcohol
Uses

first aid to help prevent infection in
- minor cuts
- scrapes
- burns

Alcohol
Warnings

For external use only

Flammable, keep away from fire and flame

Do not use
- in or near 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 1 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
Directions
- clean the affected area
- may be covered with a sterile bandage
- apply wipe to affeted are 1 to 3 times daily
- discard wipe after single use

Alcohol
Other information
- store at room temperature 15^{0} to 25^{0} C (59^{0} to 77^{0} F)
- do not use if packet is torn or opened

Alcohol
Inactive ingredient

water

Alcohol
Questions

1-800-430-5490

PVP
Active ingredient

Povidone-iodine 10% (equivalent to 1% titratable iodine)

PVP
Purpose

First aid antiseptic

PVP
Uses

- first aid antiseptic to help prevent infection in minor cuts, scrapes and burns

PVP
Warnings

For external use only.

Ask a doctor before use if you have

- deep or puncture wounds
- animal bites
- serious burns

Stop use and ask a doctor if

- condition worsens or persists for more than 72 hours
- 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

- clean the affected area
- apply1 to 3 times daily
- may be covered with a sterile bandage
- if bandaged, let dry first
- discard wipe after single use

PVP
Other information

- do not use on individuals who are allergic or sensitive to iodine

- store at controlled temperature 59-86°F (15-30°C)
- do not use if pouch is open or torn

PVP

Inactive ingredients

nonoxynol 9, water

Sun X
Active ingredients

Avobenzone 1.0%

Homosalate 5.0%

Octinoxate 7.5%

Octisalate 5.0%

Oxybenzone 6.0%

Sun X
Purpose

Sunscreen

Sunscreen

Sunscreen

Sunscreen

Sunscreen

Sun X
Uses
- helps prevent sunburn
- If used as directed with other sun protection measures (see Directions) decreases the risk of skin cancer and early skin aging caused by the sun.

Sun X
Warnings

For external use only

Do not use
- on damaged or broken skin

When using this product
- keep out of the eyes
- rinse with water to remove

Stop use and ask a doctor if
- rash occurs

Keep out of the reach of children

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

Sun X
Directions

- apply liberally and evenly 15 minutes before sun exposure

Sun Protection Measures: spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF value of 15 or higher and after sun protection measures including:

- limit time in the sun, especially from 10:00 a.m. - 2 p.m.
- wear long-sleeved shirts, pants, hats and sunglasses.
- reapply:
  - after 80 minutes of swimming or sweating
- immediately after towel drying
- at least every 2 hours

- children under 6 months of age: Ask a doctor

Sun X
Other information

- protect this product from excessive heat or direct sun

Sun x
Inactive ingredients

acrylates/C10-30 alkyl acrylate crosspolymer, aloe barbadensis leaf juice, butylparaben, calendula officinalis flower extract, carbomer, chamomile recutita extract, dimethicone, dimethyl capramide, ethylparaben, fragrance, glyceryl stearate, isobutylparaben, methylparaben, nasturtium officinale extract, peg-100 stearate, phenoxyethanol, propylparaben, symphytum officinale leaf extract, tetrasodium EDTA, triethanolamine, tocopherol, tocopherol acetate, water

Sun x
Questions

1-877-684-5774

4293
SF00004080 Kit Contents

1 FNGRTIP-5 PER, KNCKL BDG-4 PER

1 TRIPLE ANTIBIOTIC 10 PER

1 AMMONIA INHALANTS 10 PER

1 EYE DRESS PKT W/4 ADH STRIPS

1 TRIANGULAR BDG, NON-STERILE

1 FORCEPS & SCISSORS, 1 EA

1 GAUZE BANDAGE, 2" X 6 YD,2 PER

1 INSTANT COLD PACK 4" X 6"

1 ADH BDG W/NOADHR PAD,1X3 32PER

1 BURN JEL 1/8 OZ, 6 PER

1 ALCOHOL PREP PADS 10P

1 HYDROCORTISON,1.O%,1/32 OZ,10P

1 PVP IODINE WIPES 10 PER

1 STING RELIEF WIPES 10 PER BOX

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

1 FIRST AID GUIDE ASHI

1 1 OZ, BUFF EYEWASH

1 BANDAGE COMP 4" W/TELFA PAD 1

LBL STOCK 6-3/8"X4"

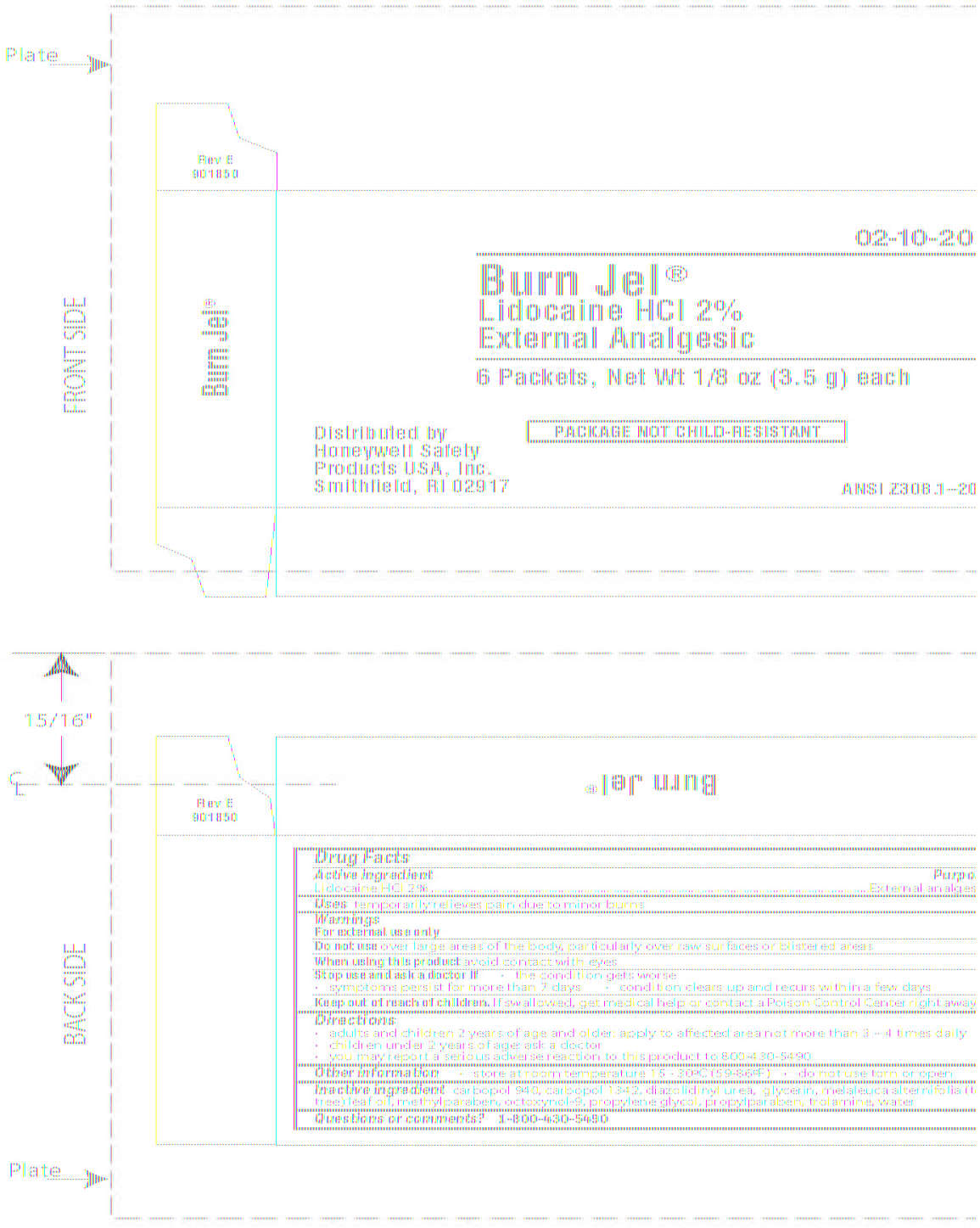
LBL STOCK 4"X2-7/8"

1 LBL STOCK 3"x1-7/8"

1 KIT STL 24 UN WHITE 01

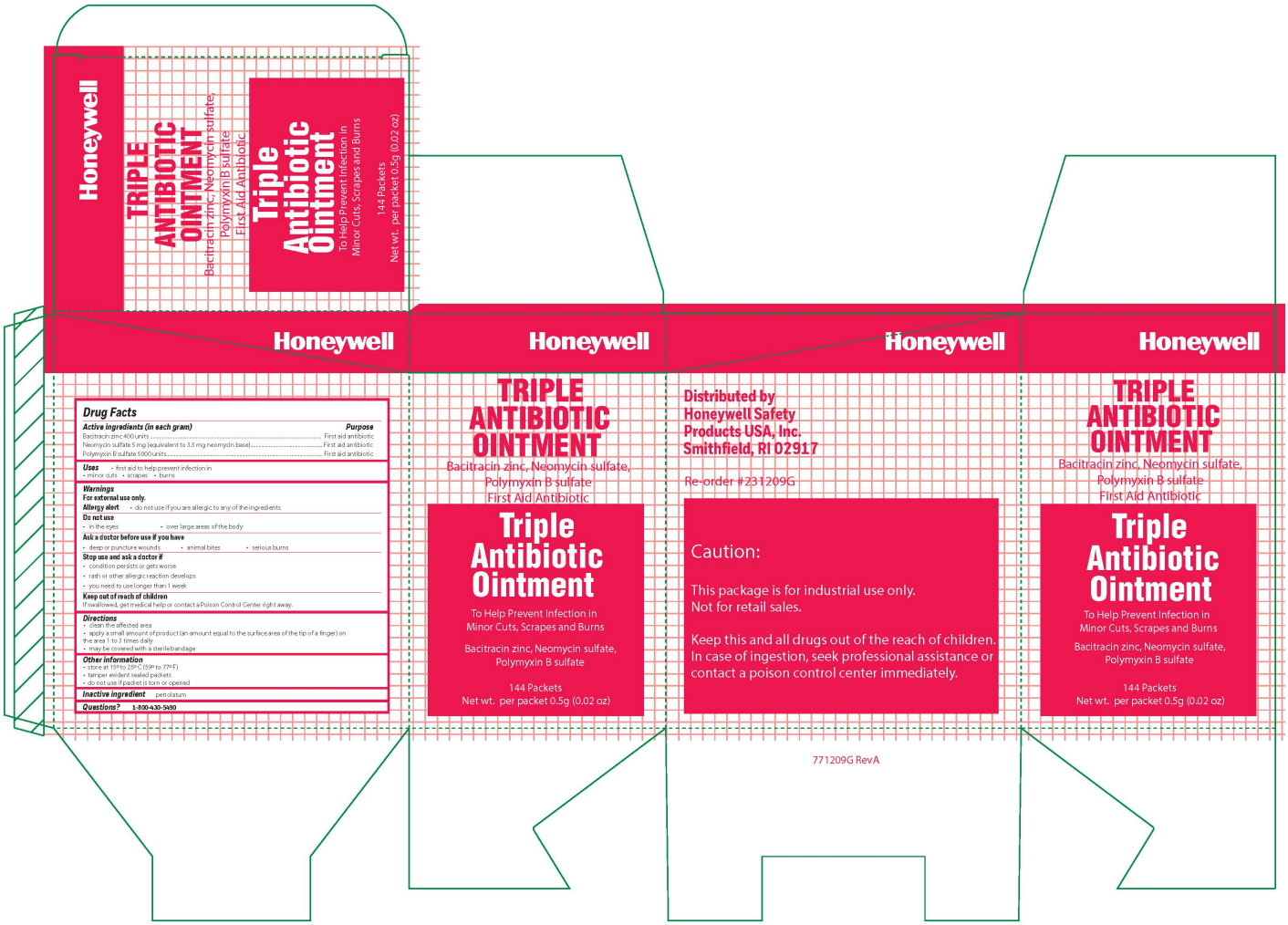
Burn Jel
Principal Display Panel

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



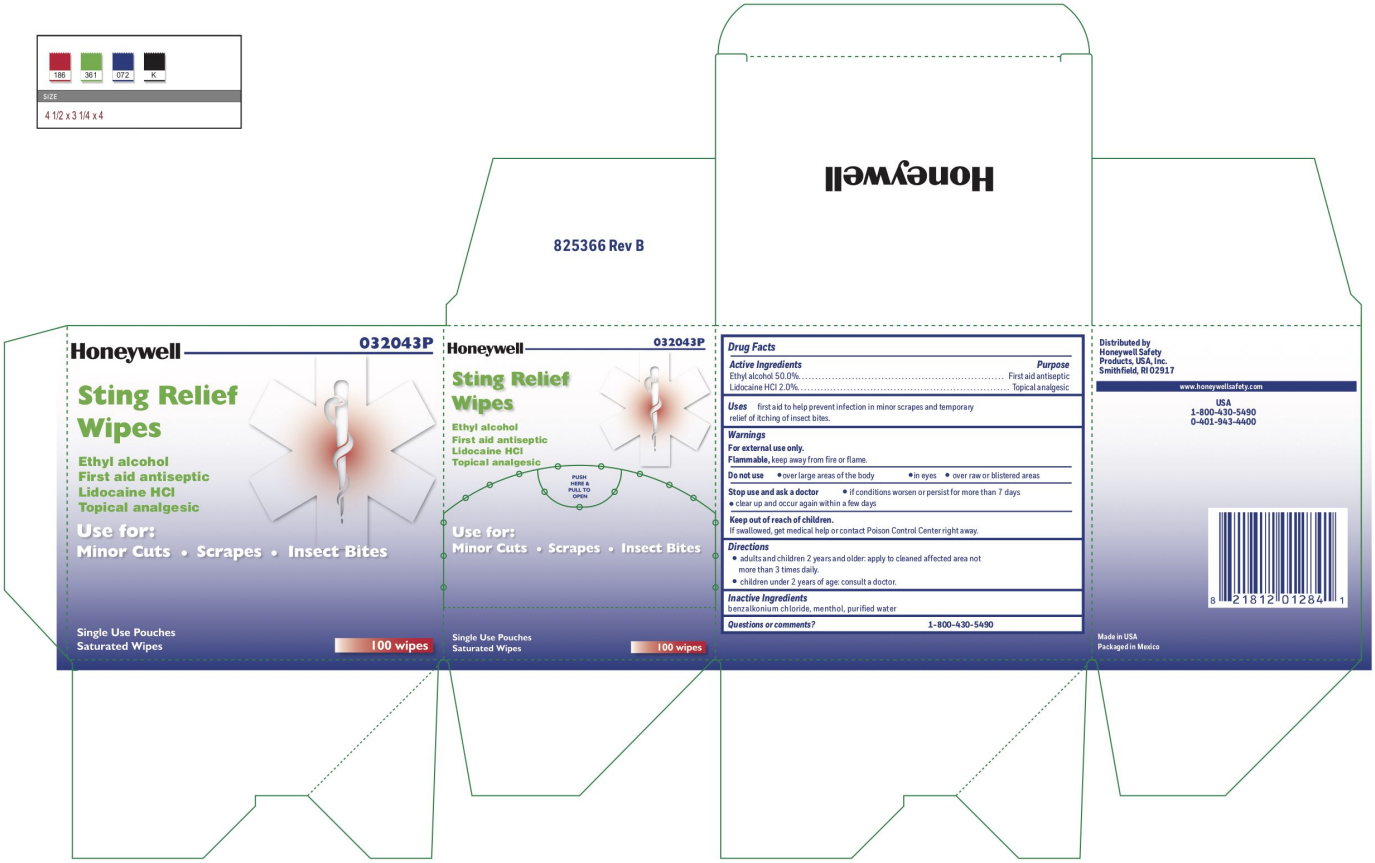
Triple

Principal Display Panel

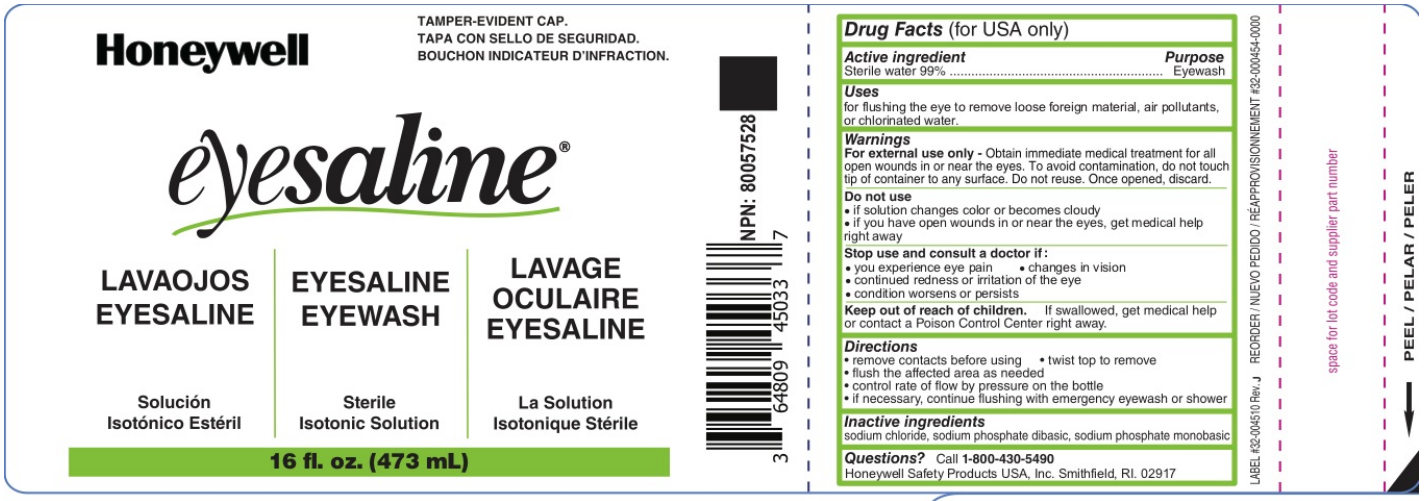


Sting Relief

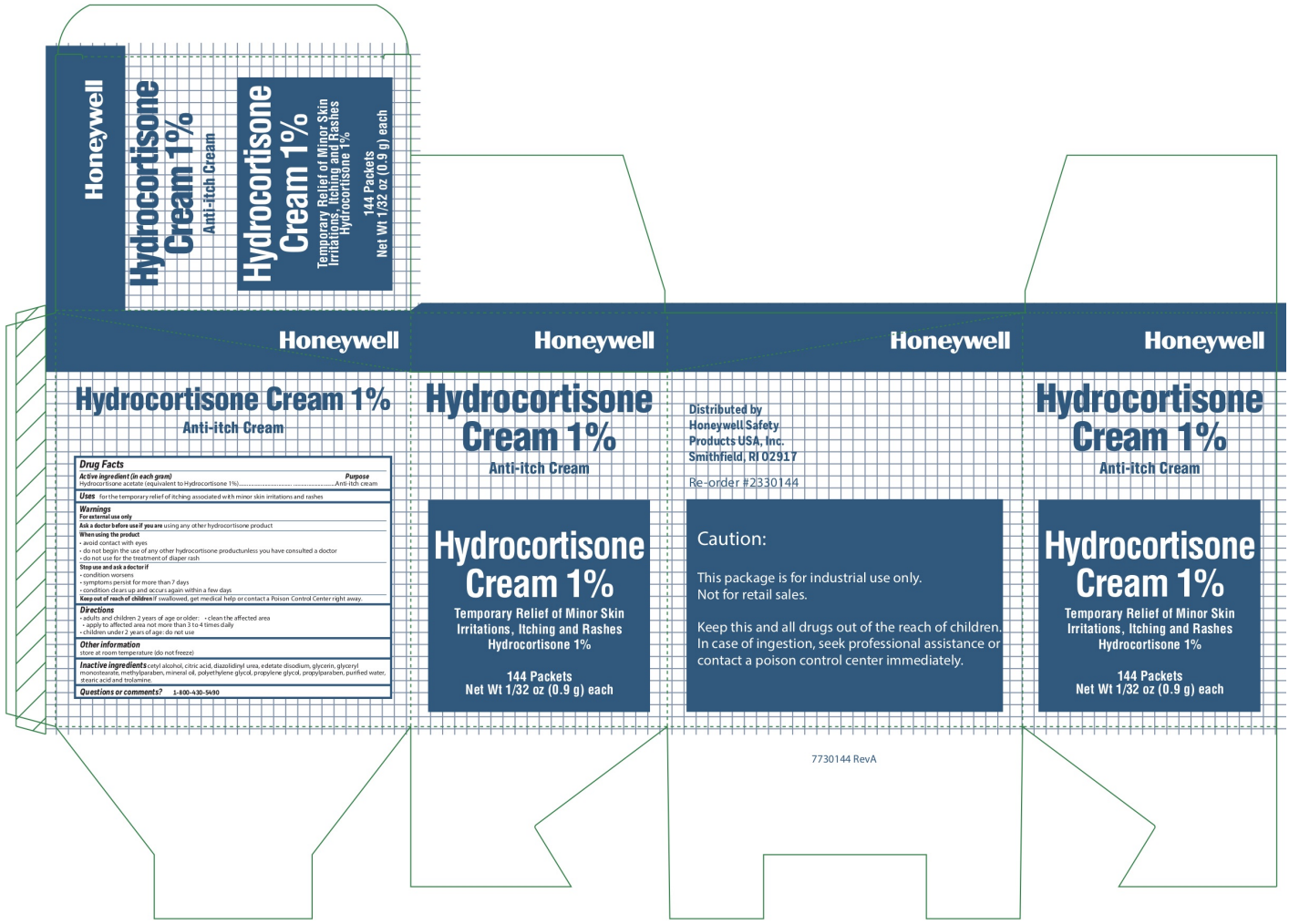
Principal Display Panel



Eyewash
Principal Display Panel

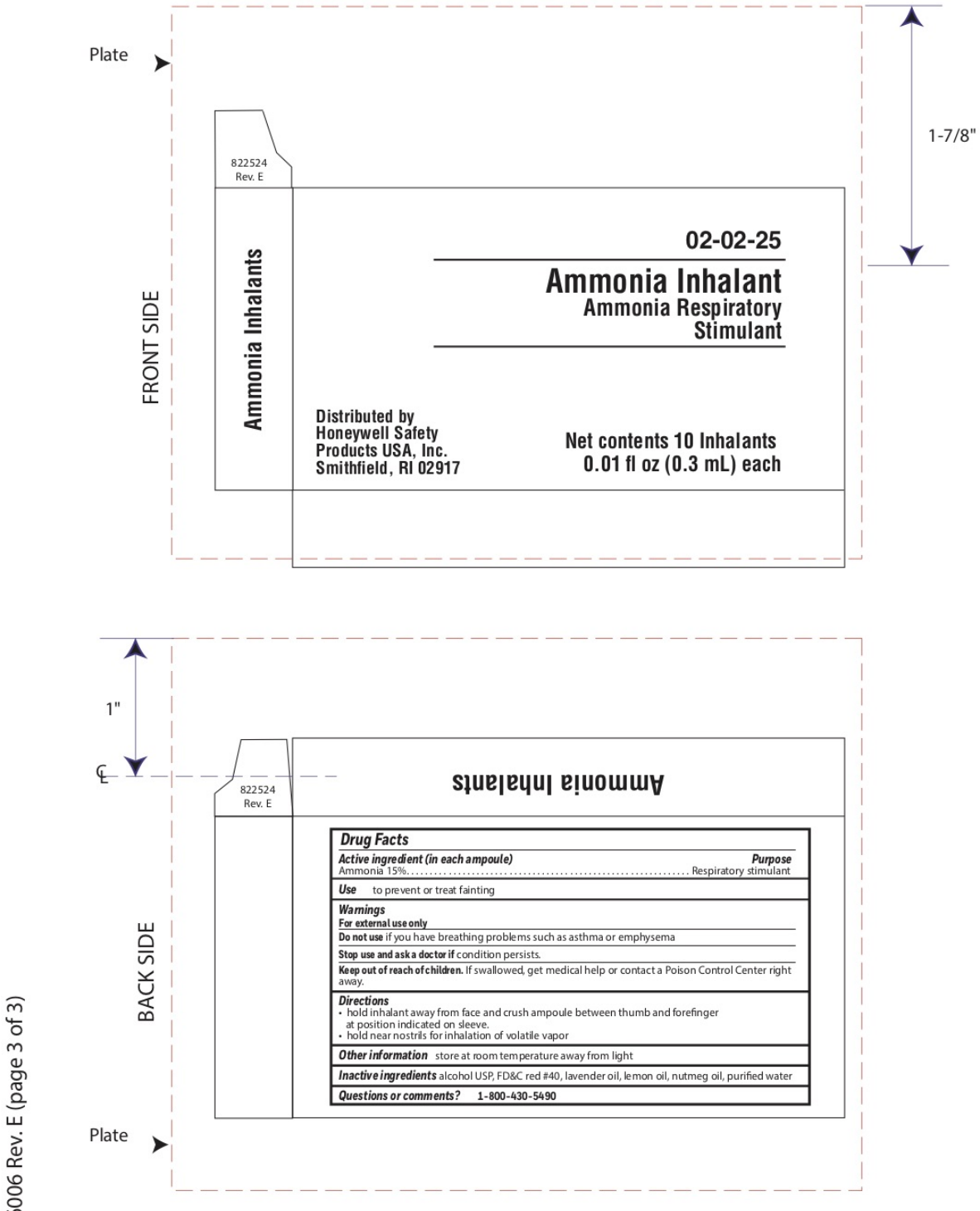


Hydrocortisone
Principal Display Panel



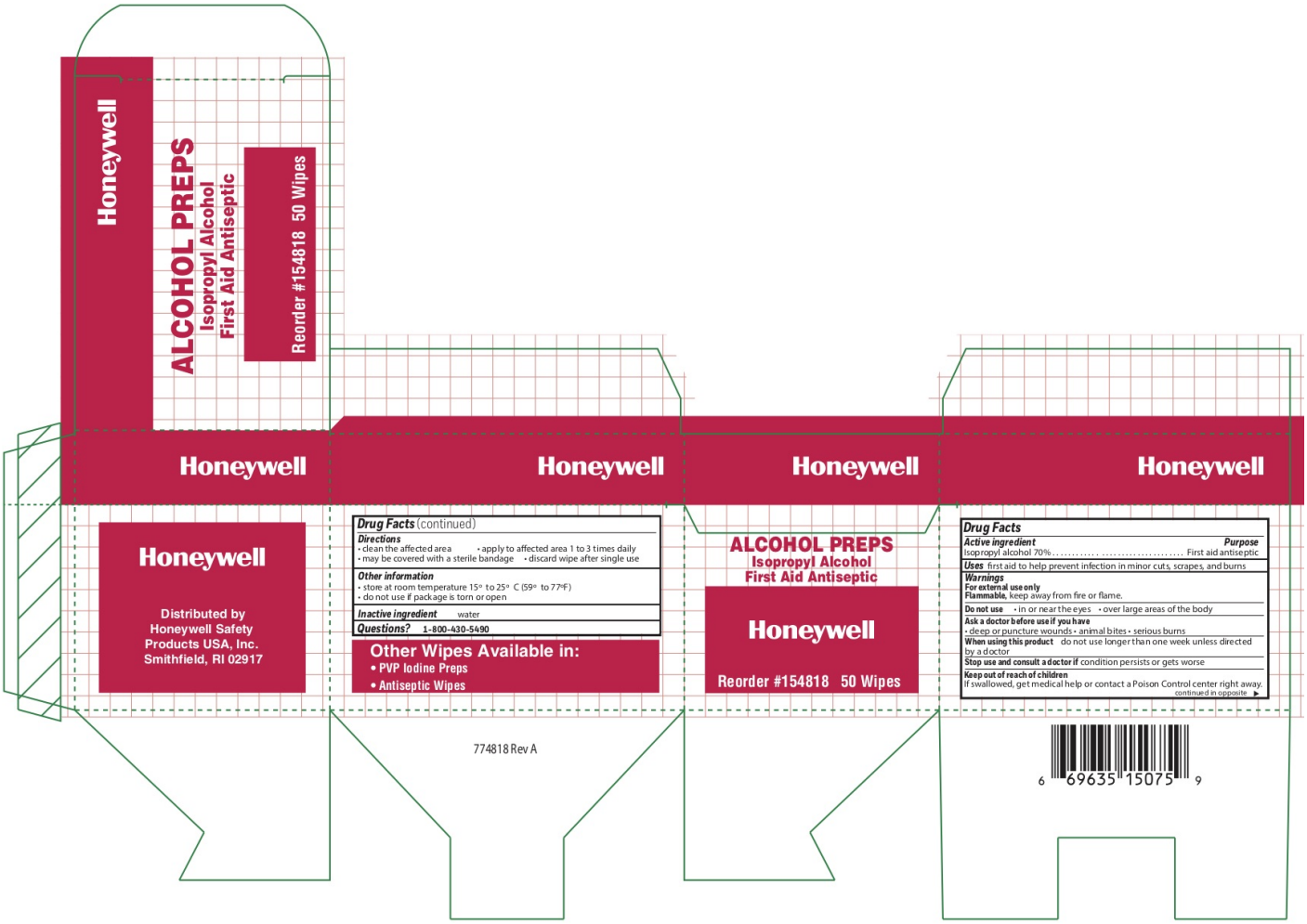
Ammonia
Principal Display Panel

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

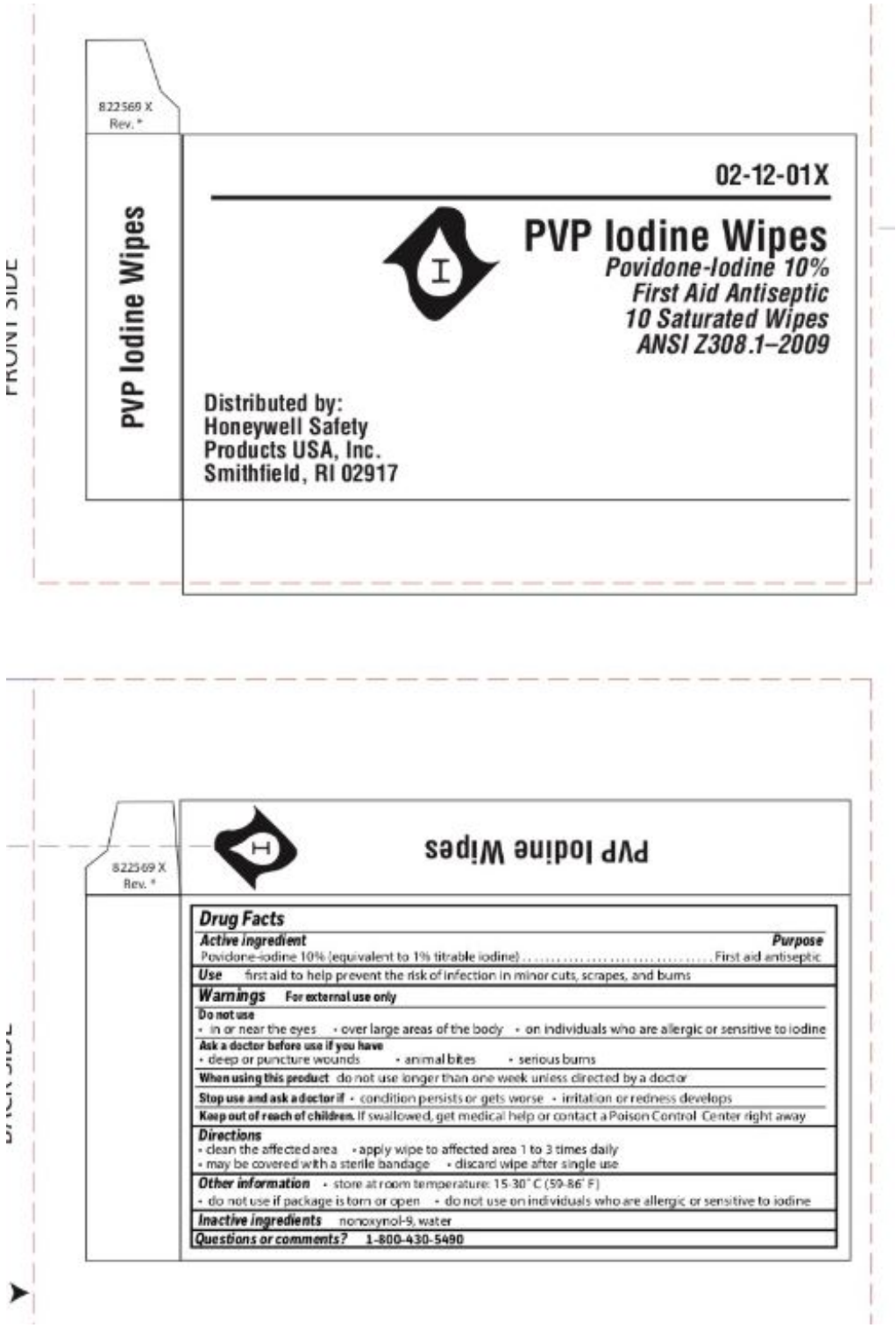


Alcohol

Principal Display Panel



PVP
Principal Display Panel



Sun X
Principal Display Panel

4293 Kit Label
SF-00004080

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

4362 FIRST AID KIT

4362 first aid kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0498-4362

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0498-4362-01	1 in 1 KIT	09/13/2018	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 PACKET	1.4 mL
Part 2	1 BOTTLE	30 mL
Part 3	10 PACKET	9 g
Part 4	10 POUCH	4 mL
Part 5	10 POUCH	4 mL
Part 6	10 PACKET	9 g
Part 7	10 AMPULE	3 mL
Part 8	10 POUCH	3 mL
Part 9	2 PACKET	88 mL

Part 1 of 9

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 2 of 9

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 3 of 9

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:0498-0750-35	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 4 of 9

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 5 of 9

STING RELIEF PAD

ethyl alcohol, lidocaine swab

Product Information	
Item Code (Source)	NDC:0498-0733
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	20 mg in 1 mL
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.5 mL in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
MENTHOL (UNII: L7T10EIP3A)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0733-00	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	part348	12/23/2017	

Part 6 of 9

HYDROCORTISONE

anti-itch cream

Product Information	
Item Code (Source)	NDC:0498-0801
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	HYDROCORTISONE ACETATE	1 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
TROLAMINE (UNII: 9O3K93S3TK)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0498-0801-35	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 not final	part348	10/15/2019	

Part 7 of 9

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 8 of 9

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**
WATER (UNII: 059QF0KO0R)	
NONOXYNOL-9 (UNII: 48Q180SH9T)	

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 9 of 9

CORETEX SUN X SPF 30

avobenzone, homosalate, octinoxate, octisalate, oxybenzone lotion

Product Information

Item Code (Source)	NDC:65753-100
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	5 g in 100 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	6 g in 100 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
CARBOMER HOMOPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: F68VH75CJC)	

NASTURTIUM OFFICINALE (UNII: YH89GMV676)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
C12-20 ALKYL BENZOATE (UNII: Y15I6XI14C)	
CHAMOMILE (UNII: FGL3685T2X)	
PEG-100 STEARATE (UNII: YD01N1999R)	
COMFREY LEAF (UNII: DG4F8T839X)	
EDETATE SODIUM (UNII: MP1J8420LU)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
WATER (UNII: 059QF0KO0R)	
ETHYLPARABEN (UNII: 14255EXE39)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TROLAMINE (UNII: 9O3K93S3TK)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
DIMETHYL CAPRAMIDE (UNII: O29Y6X2JEZ)	

Product Characteristics

Color	white (Thick White Lotion)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65753-100-37	44 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	part352	01/25/2013	

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
CoreTex Products Inc		061944620	manufacture(65753-100)

Establishment

Name	Address	ID/FEI	Business Operations
Honeywell Safety Products USA, Inc		079287321	pack(0498-4362)

Establishment

Name	Address	ID/FEI	Business Operations
Water-Jel Technologies		155522589	manufacture(0498-0750, 0498-0801)

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)

Establishment

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

Establishment

Name	Address	ID/FEI	Business Operations
Safetec of America Inc		874965262	manufacture(0498-0733)