4338 FIRST AID KIT - 4338 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.

4338 First Aid Kit (1st aid Sp, EW, aypanal, aypanal, EX, miralac, amm. Inh, triple, burn spray WS, alcohol wipe, BZK wipes - Z019827)

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

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

Water Soluble 1st Aid Spray
Active ingredient

Benzethonium chloride 0.2% w/w - Benzocaine 10% w/w

Water Soluble 1st Aid Spray
Purpose

Topical antiseptic

Topical anesthetic

Water Soluble 1st Aid Spray
Uses

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

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

Water Soluble 1st Aid 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 temperature above 120 0 F

Do not use

- in the eyes or other mucous membranes
- in cases of serious burns
- in case of deep orpuncture wounds
- for a 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 occurs again within a few days
- redness, swelling, or irritation occurs

Keep out of reach of children

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

Water Soluble 1st Aid 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

Water Soluble 1st Aid pray
Other information

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

Water Soluble 1st Aid pray
Inactive ingredients

dipropylene glycol, isobutane, N-butane, propane

Burn Relief Water Soluble
Active ingredients

Benzethonium chloride 0.2% w/w

Benzocaine 10% w/w

Menthol 0.33% w/w

Burn Relief Water Soluble
Purpose

Topical antiseptic

Topical anesthetic

Topical anesthetic

Burn Relief Water Soluble
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 Relief Water Soluble
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 Relief Water Soluble
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 Relief Water Soluble
Other information

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

Burn Relief Water Soluble
Inactive ingredients

dipropylene glycol, isobutane, n-butane, propane

Triple
Active ingredients

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

Alcohol
Active ingredient

Isopropyl alcohol 70%

Alcohol
Purpose

First aid antiseptic

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

Alcohol
Warnings

For external use only

Flammable, keep away from fire or flame.

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 burns

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
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
Other information

store at room temperature 15 ^{0} to 25 ^{0} C (59 ^{0} to 77 ^{0} F)

Alcohol
Inactive ingredient

water

Miralac
Active ingredient (in each chewable tablet)

Miralac
Active ingredient (in each chewable tablet)

Calcium carbonate 420 mg

Miralac
Purpose

Antacid

Miralac
Uses

for the relief of
- acid indigestion
- heartburn
- sour stomach
- upset stomach associated with these symptoms

Warnings

Ask a doctor before use if you have
- kidney stones
- calcium-restricted diet

Ask a doctor before use if you are
- presently taking a prescription drug. Antacids may interfere with certain prescription drugs

When using this product
- do not take more than 12 tablets in a 24- hour period, or use the maximum dosage of this product for more than 2 weeks, except under the advice and supervision of a doctor.

Keep out of the reach of children.

In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.

Miralac
Directions
- chew 1 to 2 tablets every 4 hours as symptoms occur, or as directed by a doctor.

Miralac
Other information
- each tablet contains: calcium 170 mg
- sucrose free
- lactose free
- store at room temperature
- TAMPER EVIDENT PACKETS- DO NOT USE IF OPEN OR TORN

Miralac
Inactive ingredients

magnesium stearate, mint flavor, silicon dioxide, sorbitol, starch

Miralac
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 (5 ^{0} - 86 ^{0} F)
- do not reuse towelette

BZK
Inactiave ingredient

water

BzK
Questions

1-800-430-5490

Aypanal
Active ingredient (in each tablet)

Acetaminophen 500 mg

Aypanal
Purpose

Pain reliever/fever reducer

Aypanal
Uses

- temporarily relieves minor aches and pains due to the common cold and headache
- temporarily reduces fever

Aypanal
Warnings

Liver Warning: This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 4,000 mg in 24 hours, which is the maximum daily amount.
- with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks every day while using this product

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:
- skin reddening
- blisters
- rash

If skin reaction occurs, stop use and seek medical help right away

Do not use
- with any other drug containing acetaminophen (prescription or nonprescription).
- If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

Ask a doctor before use if you have
- liver disease

Ask a doctor or pharmacist before use if
- you are taking the blood thinning drug warfarin

Stop use and ask a doctor if
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present

If pregnant or breastfeeding
- ask a health professional before use.

Keep out of reach of children.

Keep out of reach of children.

Overdose warning: In case ofl overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Aypanal
Directions
- **do not take more than directed (see overdose warning)**
- adults and children 12 years of age and over: Take 2 tablets with water every 6 hours while symptoms last.
- do not take any more than 8 tablets in 24 hours.
- children under 12: consult a doctor

Aypanal
Other information
- store at room temperature 15 ^{0} -30 ^{0} C (59 ^{0} -86 ^{0} F)
- TAMPER EVIDENT- DO NOT USE IF OPEN OR TORN

Aypanal
Inactive igredients

microcrystalline cellulose, povidone, sodium starch glycolate, starch, stearic acid

Aypanal
Questions or Comments

1-800-430-5490

4338
Z019827 KIT CONTENTS

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 EYE DRESS PKT W/4 ADH STRIPS

1 TWEEZER PLASTICS 4"

1 O/H TAPE ADHESIVE TRI-CUT

1 FIRST AID GUIDE ASHI

1 BLOODSTOPPER

1 NON-ADHERENT PADS 2"X3" 10'S

1 GZE PADS STERILE 3"X 3" 25'S

2 CTA 3" SINGLE TIP

1 ANTISEPTIC WIPES BZK CHL 20'S

1 FIRST AID SPRAY AEROSOL 3 OZ

1 ALCOHOL WIPES 50'S

1 AYPANAL NON-ASP IND 2/ENV 100

1 AYPANAL EX-STR 2/ENV 250

1 MIRALAC TABS IND PK 2/ENV 250

1 BURN SPRAY 3 OZ

1 TRIPLE BIOTIC .5 GRAM PKT 20

1 4OZ BFS EYEWASH TRILINGUAL BOTTLE

1 1 OZ, BUFF EYEWASH

1 SCISSOR BDGE 4" RED PLS HDL

1 400 EMPTY KIT BLANK

1 LBL STOCK 6-3/8"X4"

1 LBL STOCK 4"X2-7/8"

1 LBL CONTS 8"X8",CUSTOM ID B

1 LABEL COVER, GRAINGER Z019827

4 PR LRG NITRILE GLVES

1 SELF-ADH WRAP 2 X 5 YDS NORTH REV D

1 TRI BNDG NON WOVEN 40"X40"X56"

1 COLD PACK UNIT 4"X6" BULK

1 ZIP LOCK BAG 4 X 4" 2 MIL

Eyewash

Principal Display Panel

Honeywell

TAMPER-EVIDENT CAP.
TAPA CON SELLO DE SEGURIDAD.
BOUCHON INDICATEUR D'INFRACTION.

eyesaline®

LAVAOJOS EYESALINE	EYESALINE EYEWASH	LAVAGE OCULAIRE EYESALINE
Solución Isotónico Estéril	Sterile Isotonic Solution	La Solution Isotonique Stérile

16 fl. oz. (473 mL)

NPN: 80057528

3 64809 45033 7

Drug Facts (for USA only)

Active ingredient ***Purpose***
Sterile water 99% ..... Eyewash

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

Warnings
For external use only - Obtain immediate medical treatment for all open wounds in or near the 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 consult 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.

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

Inactive ingredients
sodium chloride, sodium phosphate dibasic, sodium phosphate monobasic

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

LABEL #32-004510 Rev. J REORDER / NUEVO PEDIDO / RÉAPPROVISIONNEMENT #32-000454-0000

space for lot code and supplier part number

PEEL / PELAR / PELER

Datos de medicamento (Para EE.UU. solamente)

Ingrediente Activo ***Propósito***
Agua estéril 99% ..... Lavaojos

Usos
para el lavado de ojo para quitar las particulas sueltas y extrañas, los contaminantes aeros, o agua de cloruro

Advertencias
Para el uso externo sólo - Obtenga tratamiento médico inmediato para todas las heridas abiertas en o cerca de los ojos. Para evitar la contaminación, no toque la punta del envase con ninguna superficie. No vuelva a usar. Vez abierto, descarte.

No se use • si la solución se enturbia o cambia de color
• si tiene heridas abiertas en o cerca del ojo, obtenga ayuda medica de inmediato

Deje de usar y consulte a un médico si:
• experimenta dolor de ojo • cambio de visión
• rojez continuo o irritación del ojo
• la condición empeora o persiste

Manténgase fuera del alcance de los niños.
En caso de ingestión accidental, obtenga atención médica o llame a un Centro de control de envenenamiento inmediatamente.

Instrucciones
• quitese los lentes de contacto antes de usar la solución
• tuerza la tapa para quitar
• enjuague el área afectada según se necesite
• controle el chorro haciendo presión el la botella
• si es necesario, sigue enjuagado con un lavaojos o ducha de emergencia

Ingredientes inactivos
cloruro de sodio, fosfato de sodio dibásico, fosfato de sodio monobásico

¿Preguntas? Llame al **1-800-430-5490**
Honeywell Safety Products USA, Inc. Smithfield, RI. 02917

Information

Usages
Pour le rinçage des yeux afin d'enlever un corps étranger, des polluants atmospheriques oú de l'eau chlorée.

Advertissements
Pour usage externe seulement - Obtenir immédiatement des soins médicaux pour toutes les plaies ouvertes dans ou près des yeux. Pour éviter toute contamination, ne pas toucher la pointe du récipient à n'importe quelle surface. Ne pas réutiliser. Une fois ouvert, jetez-les.

Ne pas utiliser
• si la solution a changé de couleur ou si elle est brouillée
• si vous avez des plaies ouvertes aux yeux ou à proximité, consultez immédiatement un médecin

Cesser d'utiliser la solution et consulter un médecin
• vous ressentez une douleur oculaire • si votre vision change
• rougeur ou irritation persistante des yeux
• condition empire ou persiste

Garder hors de la portée des enfants.
En cas d'ingestion, communiquer immédiatement avec un médecin ou avec un centre antipoison.

Mode d'emploi
• enlever les verres de contact avant l'utilisation • dévisser le bouchon pour l'enlever • rincer la zone touchée selon les besoins • ajuster le débit d'écoulement de la solution en augmentant ou en réduisant la pression exercée sur le contenant
• si nécessaire, continuer de rincer avec unesolution de rinçage oculaire d'urgence ou une douche

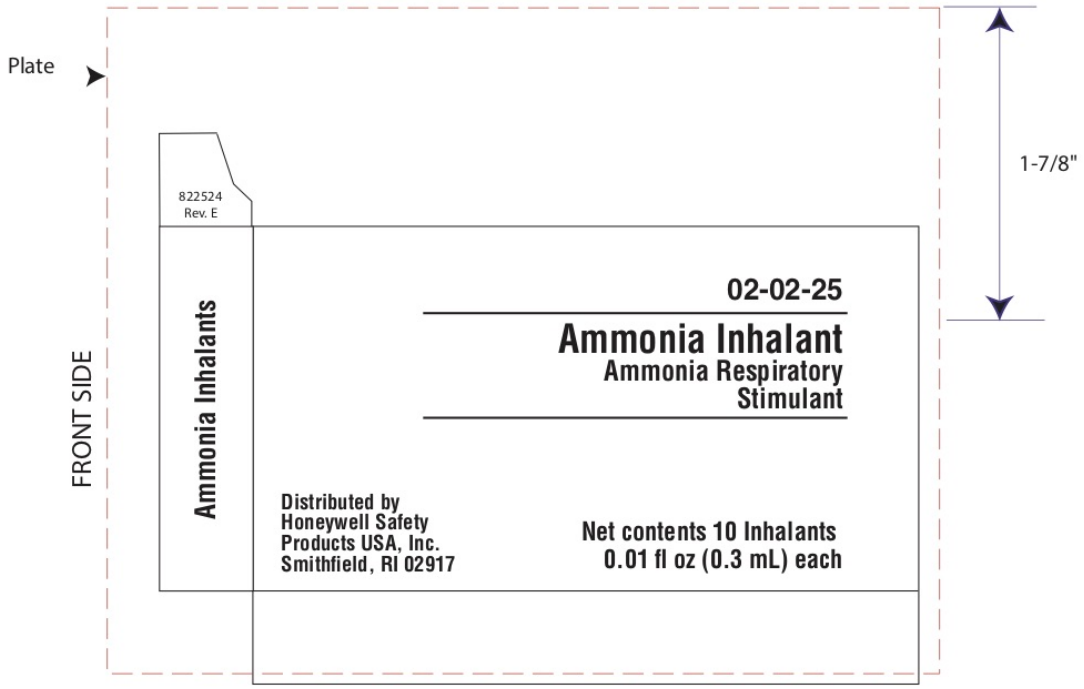
Ingrédients eau stérile, chlorure de sodium, phosphate dibasique de sodium, phosphate monobasique de sodium

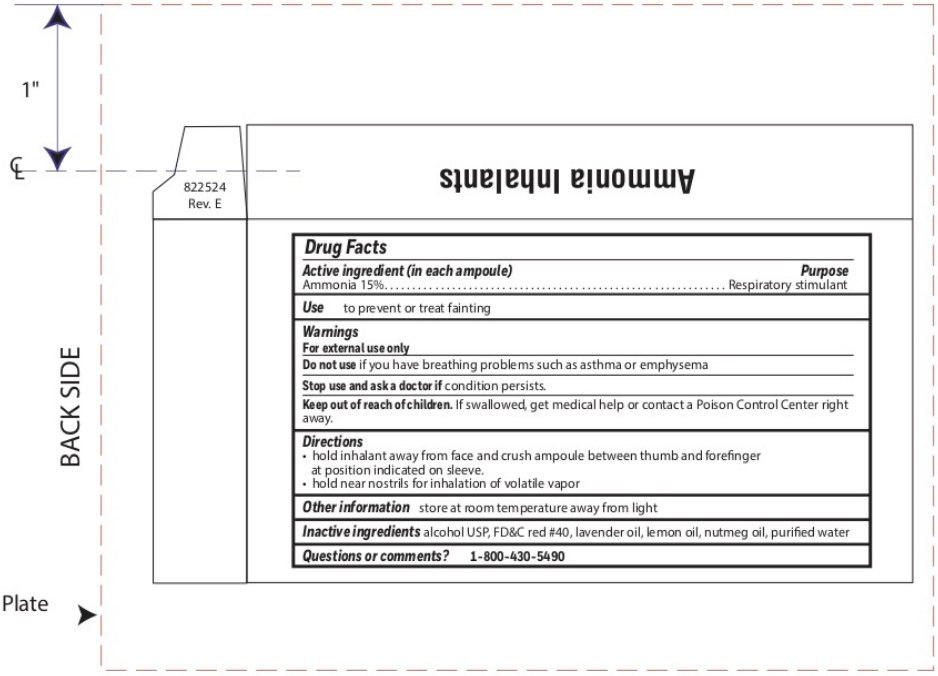
Des questions? Faites le **1-800-430-5490**
Honeywell Safety Products USA, Inc. Smithfield, RI. 02917

Ammonia

Principal Display Panel

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





796006 Rev. E (page 3 of 3)

Water Soluble 1st Aid Spray

Principal Display Panel

SHAKE WELL BEFORE USING

Honeywell

FIRST AID ANTISEPTIC SPRAY

Water soluble
Benzethonium chloride
Topical antiseptic
Benzocaine
Topical anesthetic

Helps prevent infection and relieves pain.

CAUTION: FLAMMABLE
Contents under pressure
Read warning on back panel.

NET WT. 3 OZ (85gm.)

47.0303

Cat. No. 151019

DRUG FACTS

Active ingredients	Purpose
Benzethonium chloride 0.2% w/w	Topical antiseptic
Benzocaine 10% w/w	Topical anesthetic

Uses
• for the temporary relief of pain and itching and helps to protect against infection in
• minor cuts and scrapes • insect bites • minor skin irritations

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°F

Do not use • in or near eyes or other mucus membranes • in case of serious burns
• in case of deep or puncture wounds • for a prolonged period of time
• on large portion of the body

Stop use and ask a doctor if:
• conditions 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 reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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

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

Inactive ingredients dipropylene glycol, isobutane, n-butane, propane

Questions or comments? 1-800-430-5490

6 69635 15036 0

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Products USA, Inc.
Smithfield, RI 02917

Honeywell

Burn Relief Water Soluble
Principal Display Panel

SHAKE WELL BEFORE USING

Honeywell

BURN SPRAY

Water soluble
Benzethonium chloride
Topical antiseptic
Benzocaine
Topical anesthetic
Menthol
Topical anesthetic

Provides antiseptic treatment and helps relieve the pain of minor burns and sunburn.

CAUTION: FLAMMABLE
Contents under pressure
Read warning on back panel.

NET WT. 3 OZ (85gm.)

47.0306

Cat. No. 201005

DRUG FACTS

Active ingredients	Purpose
Benzethonium chloride 0.2% w/w	Topical antiseptic
Benzocaine 10% w/w	Topical anesthetic
Menthol .33%	Topical anesthetic

Uses • for the temporary relief of pain and itching and helps to protect against infection in
• minor cuts and scrapes • burns • sunburn • insect bites • minor skin irritations

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°F

Do not use • in or near eyes or other mucus membranes • in case of serious burns
• in case of deep or puncture wounds • for a prolonged period of time
• on large portion of the body

Stop use and ask a doctor if:
• conditions 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 reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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

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

Inactive ingredients dipropylene glycol, isobutane, n-butane, propane

Questions or comments? 1-800-430-5490

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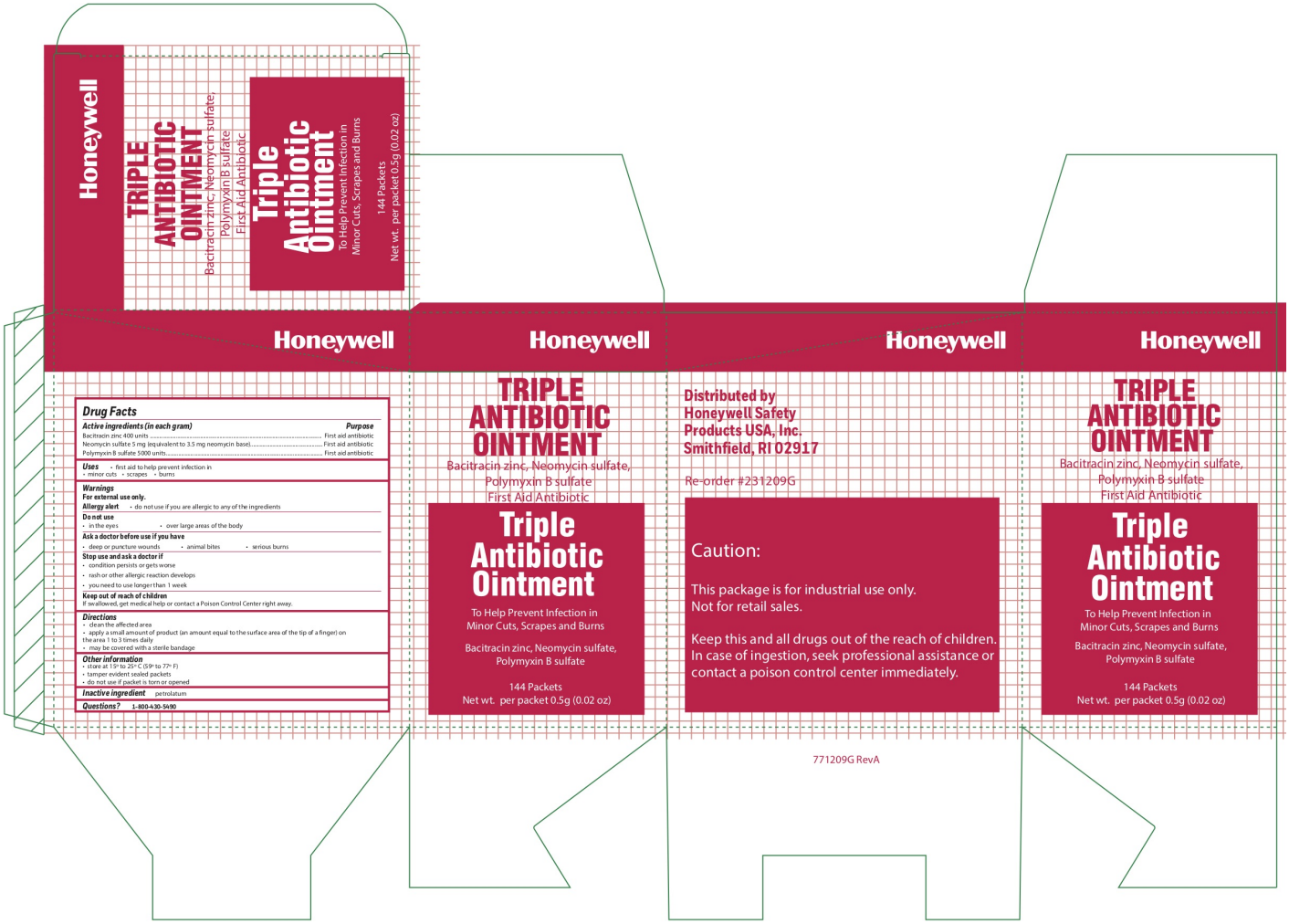
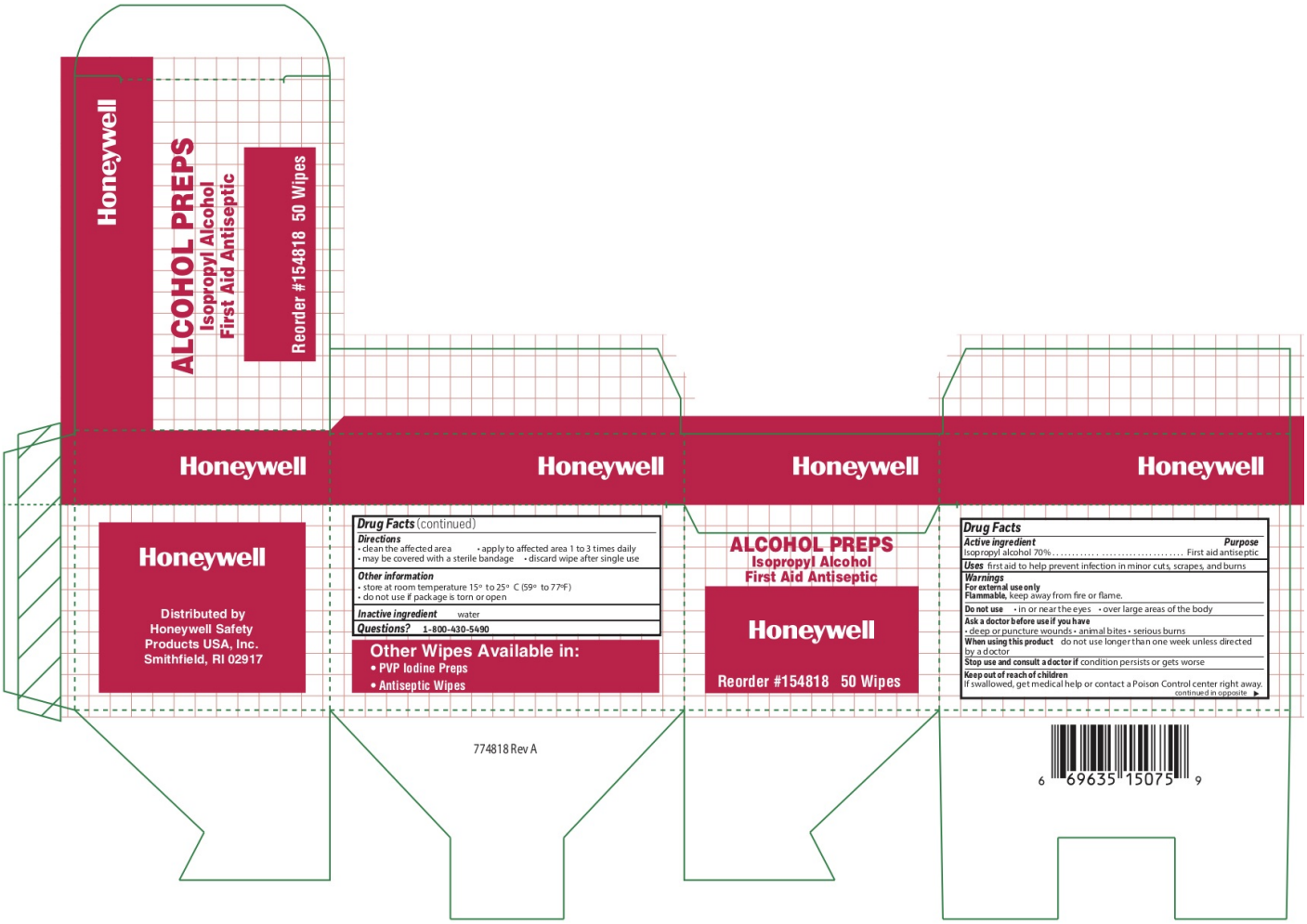
Smithfield, RI 02917

Honeywell

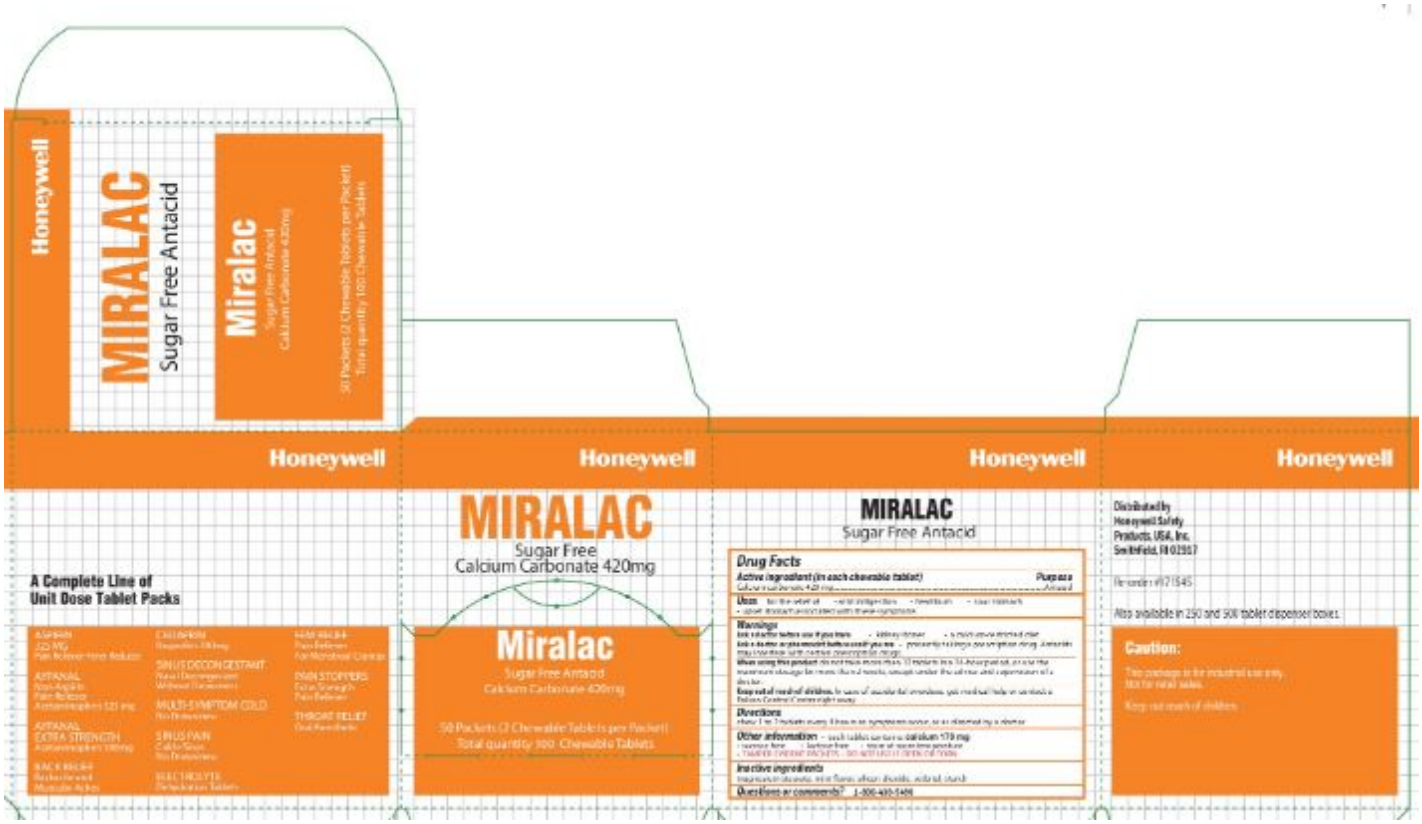
Triple
Principal Display Panel



Alcohol
Principal Display Panel



Miralac
Principal Display Panel



BZK
Principal Display Panel

47001083
Rev B

Antiseptic Towelettes

Honeywell

02-16-35MD

Antiseptic Towelettes

Benzalkonium chloride
First aid antiseptic

Six–Saturated Towelettes

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

47001083
Rev B

Antiseptic Towelettes

Honeywell

Drug Facts

Active Ingredient ***Purpose***
Benzalkonium chloride 0.133% w/v ..... First aid antiseptic

Uses • antiseptic cleaning of face, hands and body without soap and water. • air dries in seconds

Warnings
For external use only

When using this product • do not use in the eyes or apply over large areas of the body

Ask a doctor before use • in case of deep or puncture wounds, animal bites, or serious burns

Stop use and consult a doctor if
• irritation, redness or other symptoms develop • condition persists or gets worse

Do not use • longer than 1 week unless directed by doctor

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

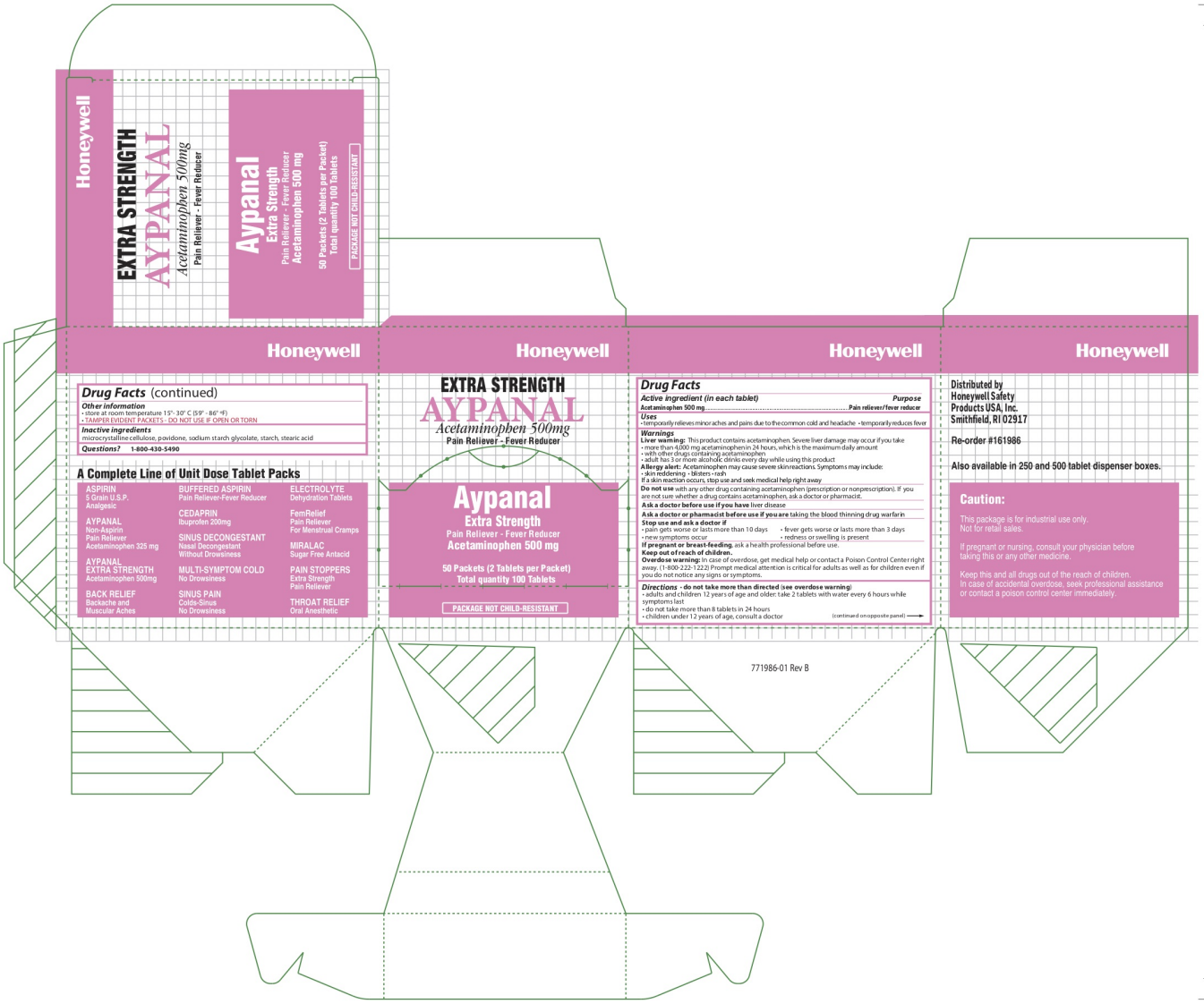
Directions • tear open packet, unfold and use as washcloth

Other Information
• store at room temperature 15° -30° C (59° -86° F) • do not reuse towelette

Inactive ingredient water

Questions or comments **1-800-430-5490**

Aypanal EX
Principal Display Panel



4338 Kit Label
Z019827

4338 FIRST AID KIT

4338 first aid kit kit

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0498-4338

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-4338-01	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	148 mL
Part 2	10 AMPULE	3 mL
Part 3	1 CAN	85 g
Part 4	1 CAN	85 g
Part 5	20 PACKET	10 g
Part 6	50 POUCH	20 mL

Part 7	125 PACKET	250
Part 8	20 PACKET	28 mL
Part 9	125 PACKET	250
Part 10	20 PACKET	18 g
Part 11	50 PACKET	100

Part 1 of 11

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:0498-0100-02	118 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	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 11

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 11

FIRST AID ANTISEPTIC WATER SOLUBLE

benzethonium chloride, benzocaine spray

Product Information	
Item Code (Source)	NDC:0498-0031
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZETHONIUM CHLORIDE (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP)	BENZETHONIUM CHLORIDE	0.2 g in 100 g
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	10 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ISOBUTANE (UNII: BXR49TP611)	
BUTANE (UNII: 6LV4FOR43R)	
PROPANE (UNII: T75W9911L6)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0031-40	85 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	part333E	09/19/2018	

Part 4 of 11

BURN WATER SOLUBLE

benzocaine, benzethonium chloride, menthol spray

Product Information

Item Code (Source)	NDC:0498-0021
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZETHONIUM CHLORIDE (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP)	BENZETHONIUM CHLORIDE	0.2 g in 100 g
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	10 g in 100 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.33 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ISOBUTANE (UNII: BXR49TP611)	
BUTANE (UNII: 6LV4FOR43R)	
PROPANE (UNII: T75W9911L6)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0021-40	85 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	11/12/2018	

Part 5 of 11

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 11

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 7 of 11

MIRALAC

calcium carbonate tablet

Product Information

Item Code (Source)	NDC:0498-0303
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB, CARBONATE ION - UNII:7UJQ5OPE7D)	CALCIUM CARBONATE	420 mg

Inactive Ingredients	
Ingredient Name	**Strength**
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SORBITOL (UNII: 506T60A25R)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics			
Color	white	**Score**	2 pieces
Shape	ROUND	**Size**	11mm
Flavor	MINT	**Imprint Code**	FR8
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		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 final	part331	02/22/2012	

Part 8 of 11

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	12/22/2017	

Part 9 of 11

AYPANAL EX

acetaminophen tablet

Product Information

Item Code (Source)	NDC:0498-2110
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

Inactive Ingredients

Ingredient Name	Strength
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	white	**Score**	no score

Shape	ROUND	**Size**	12mm
Flavor		**Imprint Code**	FR1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-2110-01	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	01/02/2017	

Part 10 of 11

FIRST AID BURN

benzalkonium chloride, lidocaine hydrochloride cream

Product Information

Item Code (Source)	NDC:0498-0903
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 g
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE	0.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
TROLAMINE (UNII: 9O3K93S3TK)	
GLYCERIN (UNII: PDC6A3C0OX)	

PROPYLPARABEN (UNII: Z8IX2SC1OH)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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	part333A	12/20/2017	

Part 11 of 11

AYPANAL NON-ASPIRIN

acetaminophen tablet

Product Information

Item Code (Source)	NDC:0498-2001
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	

Product Characteristics

Color	white	**Score**	2 pieces
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	circle;U
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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	04/10/2012	

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(0498-4338)

Establishment

Name	Address	ID/FEI	Business Operations
Dixon Investments		115315822	manufacture(0498-2110, 0498-0303, 0498-2001)

Establishment

Name	Address	ID/FEI	Business Operations
Honeywell Safety Products USA, Inc.		167518617	manufacture(0498-0031, 0498-0021)

Establishment

Name	Address	ID/FEI	Business Operations
Changzhou Maokang Medical		421317073	manufacture(0498-0750)

Establishment

Name	Address	ID/FEI	Business Operations
Water-Jel Technologies		155522589	manufacture(0498-0100)

Establishment

Name	Address	ID/FEI	Business Operations
Ultra Seal Corporation		085752004	manufacture(0498-0143, 0498-0501)