4186 FIRST AID KIT- 4186 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.

4186 First Aid Kit (FABC, PVP wipes, alcohol wipes, sting relief- 010176-4247)

First Aid Burn Cream *Active ingredient*

Benzalkonium chloride o.13%

Lidocaine HCl 0.5%

First Aid Burn Cream *Purpose*

First aid antiseptic

External analgesic

First Aid Burn Cream

Uses

- prevent skin infection
- for temporary relief of pain associated with minor burns

First Aid Burn Cream Warnings

For external use only

Do not use

- in or near the eyes
- if you are allergic to any of the ingredients
- in large areas of the body, particularly over raw surfaces or blistered areas
- for more than 10 days

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
- symptoms persist for more than 7 days or clear up and occurs again within a few days

First Aid Burn Cream

Directions

- adults and children 2 years of age and older:
- clean the affected area

- apply a small amount of this product (equal to the surface area of the tip of a finger) onto affected area 1 to 3 times daily
- may be covered with a sterile bandage
- children under 2 years of age: consult a doctor

First Aid Burn Cream

Other information

- tamper evident sealed packets
- do not use if packet is opened or torn

First Aid Burn Cream

Inactive ingredients

aloe barbadensis juice, cetyl alcohol, diazolidinyl urea, edetate disodium, glycerin, glyceryl stearate SE, methylparaben, mineral oil, PEG-100, propylene glycol, propylparaben, stearic acid, trolamine, water

First Aid Burn Cream Questions

1-800-430-5490

Sting Relief Active ingredient

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

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 wek 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 15 $^{\rm 0}$ to 25 $^{\rm 0}$ C (59 $^{\rm 0}$ to 77 $^{\rm 0}{\rm F})$

Alcohol Wipe Inactive ingredient

water

Alcohol Wipe Questions

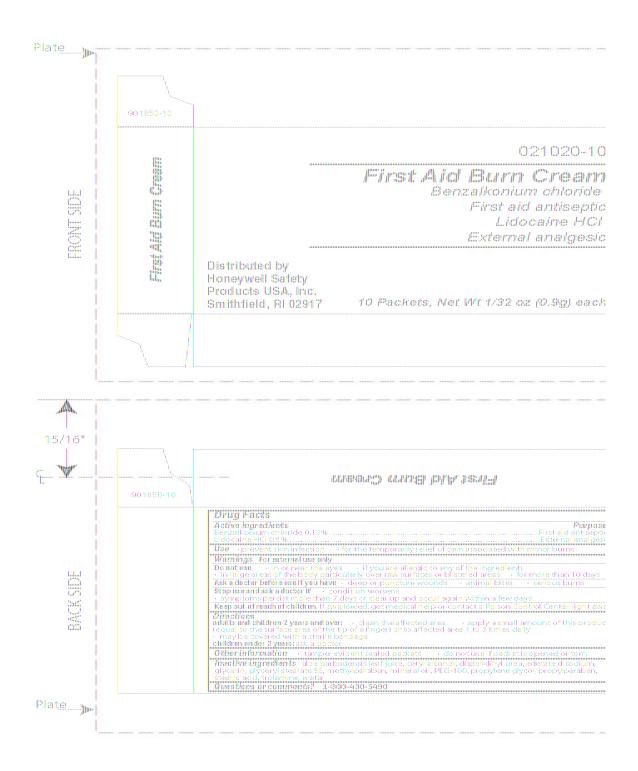
1-800-430-5490

4186 010176-4247 Kit Contents

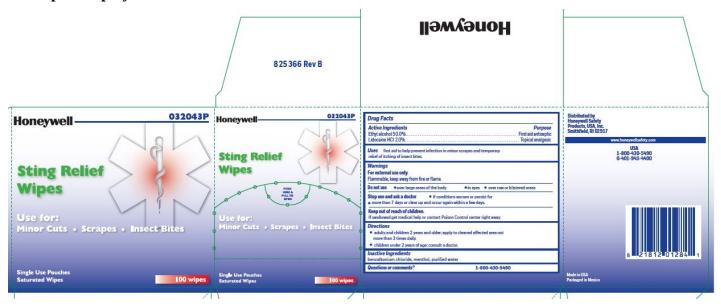
1 FIRST AID BURN CREAM 6 PER

- 1 TRIANGULAR BDG, NON-STERILE
- 2 GAUZE PADS, 3" X 3", 4 PER
- 1 ADH TAPE, .5" X 2.5 YD, 2 PER
- 1 GAUZE COMP, 1 SQ YARD, 1 PER
- 1 INSTANT COLD PACK 4" X 6"
- 1 BANDAGE COMP, 4" OFFSET, 1 PER
- 1 WATER JEL DRESSING,2" X 6"
- 1 PVP IODINE WIPES 10 PER
- 1 IVYX CLEANSER TOWEL 5 PER
- 1 BIOHAZARD BAG/SCRAPER BBP
- 1 BIOHAZARD BAG, WIPES/TOWELS BBP
- 1 BODY FLUID CLEAN-UP ABSORBENT
- 1 GERMICIDAL SURFACE CLEANER, BB
- 2 ADH BDG, CLOTH, 1"X3", 16 PER
- 1 MICROSHIELD W/VNL GLV/ALCL
- LBL STOCK 6-3/8"X4"
- LBL STOCK 4"X2-7/8"
- 1 LBL STOCK 3"x1-7/8"
- 2 1PR LRG NITRILE GLVES ZIP BAG
- 1 KIT STL 24 UN WHITE 01
- 1 LABL INSTR 24 & 36 UNIT KITS
- 1 STING Relief WIPES 10

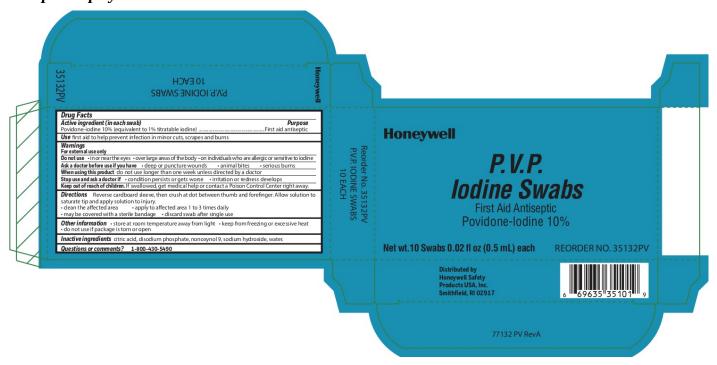
First Aid Burn Cream Principal Display Panel



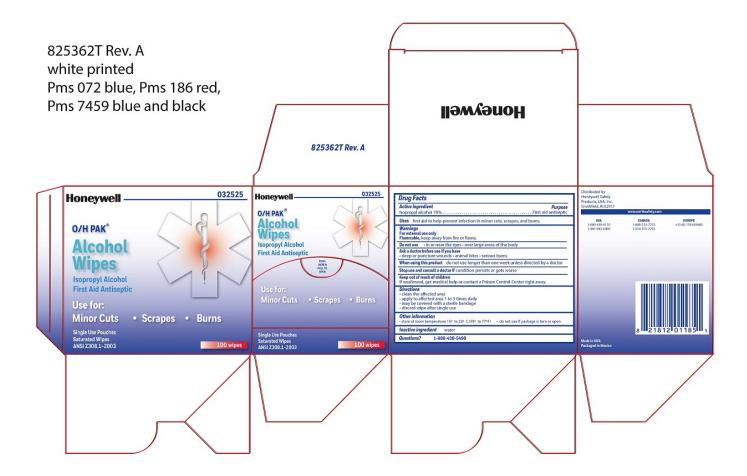
Principal Display Panel



Povidone Iodine Swab Principal Display Panel



Alcohol Wipe Principal Display Panel



4186 Kit Label 010176-4247

FIRST AID, CPR & SPILL CLEAN-UP KIT



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

4186 FIRST AID KIT

4186 first aid kit kit

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:0498-4186

Pack	

1 NDC 0409 4196 01 1 in 1 VII. Type 0. Not a Combination Product 10/19/2019	# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 INDC.0490-4100-01 I III 1 KI1, Type 0. Not a Combination Product 10/16/2016	1 NDC:0498-4186-01	1 in 1 KIT; Type 0: Not a Combination Product	10/18/2018	

Quan	tity of Parts	
Part #	Package Quantity	Total Product Quantity
Part 1	10 POUCH	4 mL
Part 2	6 PACKET	5.4 g
Part 3	1 PACKET	1.4 mL
Part 4	10 POUCH	3 mL

Part 1 of 4

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
LIDO CAINE HYDRO CHLO RIDE (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				
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7)					
MENTHOL (UNII: L7T10 EIP3A)					
WATER (UNII: 059QF0KO0R)					

ŀ	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.4 mL in 1 POUCH; Type 0: Not a Combination Product		

Marketing Inform	mation		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/23/2017	

Part 2 of 4

FIRST AID BURN

benzalkonium chloride, lidocaine hydrochloride cream

Product Information

Item Code (Source) NDC:0498-0903

Route of Administration TOPICAL

	Active Ingredient/Active Moiety		
l	Ingredient Name	Basis of Strength	Strength
	BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKO NIUM - UNII:7N6 JUD5X6 Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 g
	LIDO CAINE HYDRO CHLO RIDE (UNII: V13007Z41A) (LIDO CAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE	0.5 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6 DC9 Q16 7 V3)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
METHYLPARABEN (UNII: A218 C7H19 T)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)	
PEG-100 STEARATE (UNII: YD0 1N1999R)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)	
TROLAMINE (UNII: 903K93S3TK)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	

ı	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 NDC:0498-0903-34	10 in 1 BOTTLE, UNIT-DOSE		
	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 3 of 4

ANTISEPTIC TOWELETTE

benzalkonium chloride liquid

Product Information

Item Code (Source) NDC:0498-0501

Route of Administration TOPICAL

Active Ingredient/Active Moiety

retive ingredient retive in the control of the cont				
Ingredient Name	Basis of Strength	Strength		
	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL		

Inactive Ingredients

Ingredient Name	Strength
Ingredient rame	Strength

WATER (UNII: 059QF0KO0R)

Packaging

	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1	NDC:0498-0501-00	1.4 mL in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

9			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	12/22/2017	

Part 4 of 4

PVP IODINE WIPE

povidone-iodine 10% swab

Product Information

Item Code	(Source)	NDC:0498-0121

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Active ingredient/Active Molety				
Ingredient Name	Basis of Strength	Strength		
PO VIDO NE-IO DINE (UNII: 85H0 HZU99 M) (IO DINE - UNII:9679 TC07X4)	IODINE	10 mg in 1 mL		

Inactive Ingredients			
Ingredient Name	Strength		
NONOXYNOL-9 (UNII: 48Q180SH9T)			
WATER (UNII: 059QF0KO0R)			

ı	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	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	

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	
Honeywell Safety Products USA, INC		079287321	pack(0498-4186)	

Establishment							
Name	Address	ID/FEI	Business Operations				
Water-Jel Technologies		155522589	manufacture(0498-0903)				

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

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

Establishment					
Name	Address	ID/FEI	Business Operations		
Changzhou Maokang Medical		421317073	manufacture(0498-0501)		