

**4192 FIRST AID KIT - 4192 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](#).*

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**4192 First Aid Kit (Ammonia Inh, Burn Jel, PVP wipes) 011077-4258**

***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, trolamine, water

**Burn Jel*****Questions***

1-800-430-5490

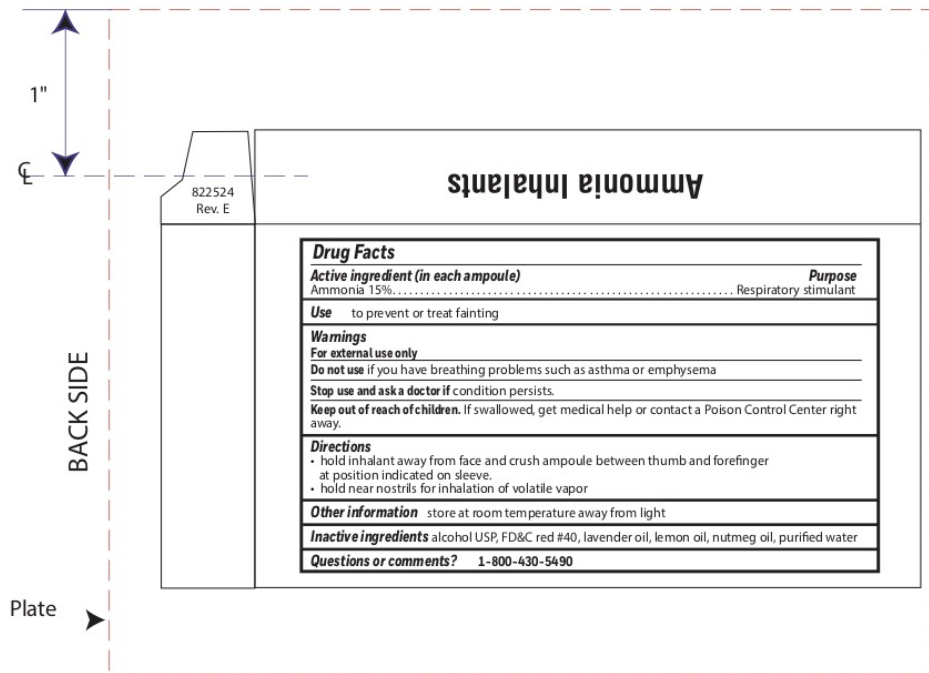
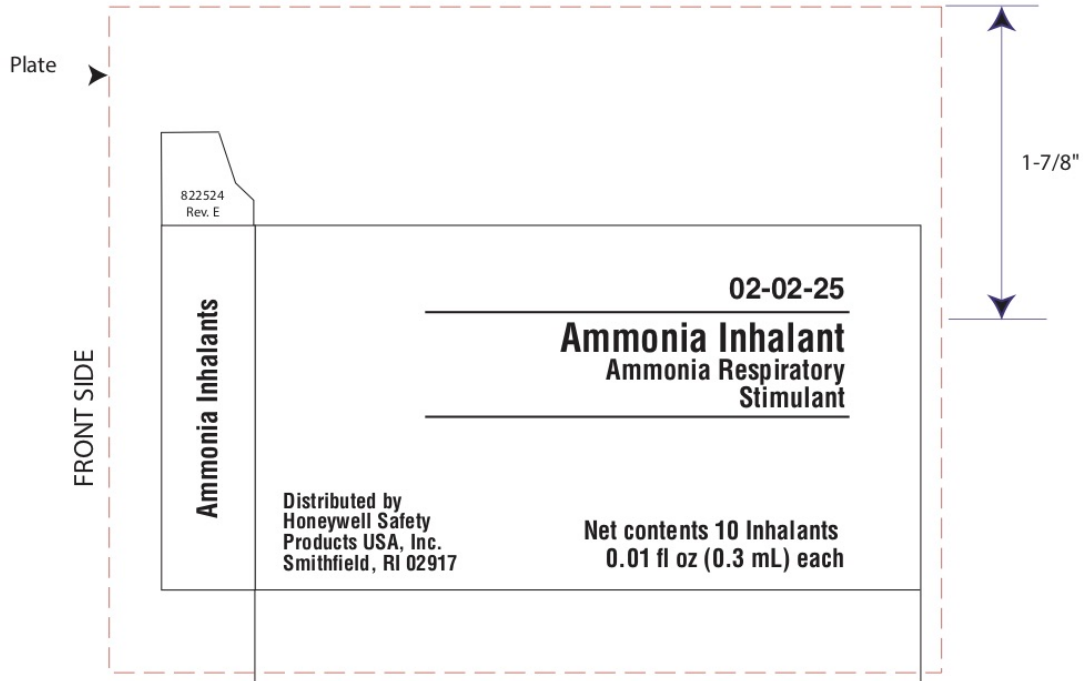
**4192**

**011077-4258 Kit Contents**

1 KNUCKLE BAND 8 PER  
2 AMMONIA INHALANTS 10 PER  
1 EYE DRESS PKT W/4 ADH STRIPS  
2 GAUZE BANDAGE, 4" X 6 YD  
2 TRIANGULAR BDG, NON-STERILE  
2 GAUZE PADS, 3" X 3", 4 PER  
1 ADH TAPE, .5" X 2.5 YD, 2 PER  
1 INSTANT COLD PACK 4" X 6"  
2 BANDAGE COMP, 2" OFFSET, 4 PER  
2 BANDAGE COMP, 4" OFFSET, 1 PER  
2 BURN JEL 1/8 OZ, 6 PER  
3 PVP IODINE WIPES 10 PER  
3 ADH BDG, CLOTH, 1"X3", 16 PER  
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  
1 LABL INSTR 24 & 36 UNIT KITS

**Principal Display Panel**

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



796006 Rev. E (page 3 of 3)

**Principal Display Panel**

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



**4192 Kit Label**  
**011077-4258**

Cover Dimensions: 9-1/2" X 9-1/2 (Two Color Job) First Pass Process blue Second pass Reflex blue Screen # 4258

24 UNIT FIRST AID KIT



# FIRST AID KIT

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

Telephone 800 430-4110 Facsimile 401 275-2616 Engineering Graphic Design	This drawing has been submitted for your approval .		
	<input type="checkbox"/> Needs changes (indicate changes and fax back to North Safety Products).		
<input type="checkbox"/> Approved (Sign below and fax to North Safety Products).			
Name _____	Signature _____	Date _____	

## 4192 FIRST AID KIT

4192 first aid kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0498-4192
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-4192-01	1 in 1 KIT	09/13/2018	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	20 AMPULE	6 mL
Part 2	12 PACKET	42 g
Part 3	30 POUCH	9 mL

### Part 1 of 3

## AMMONIA INHALENT

ammonia inhalent inhalant

### Product Information

<b>Item Code (Source)</b>	NDC:0498-3334
<b>Route of Administration</b>	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 2 of 3

### 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:98P200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	2 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
TEA TREE OIL (UNII: VIF565UC2G)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYLPARABEN (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)	
PROPYLPARABEN (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
OTC monograph not final	part348	09/19/2018	



## Part 3 of 3

### 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	

#### 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)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Honeywell Safety Products USA, Inc		079287321	pack(0498-4192)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Water-Jel Technologies		155522589	manufacture(0498-0203)

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

Revised: 3/2019

Honeywell Safety Products USA, Inc.