

**4188 FIRST AID KIT- 4188 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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**4188 First Aid Kit (Burn Jel, Ammonia Inh) 10704-4299**

***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

**4188**

**010704-4299 Kit Contents**

2 AMMONIA INHALANTS 10 PER

2 TOURNIQUET, 1 PER

15 TRIANGULAR BDG, NON-STERILE

4 BANDAGE COMP, 2" OFFSET, 4 PER

8 BANDAGE COMP, 4" OFFSET, 1 PER

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

1 BURN JEL 1/8 OZ, 6 PER

LBL STOCK 6-3/8"X4"

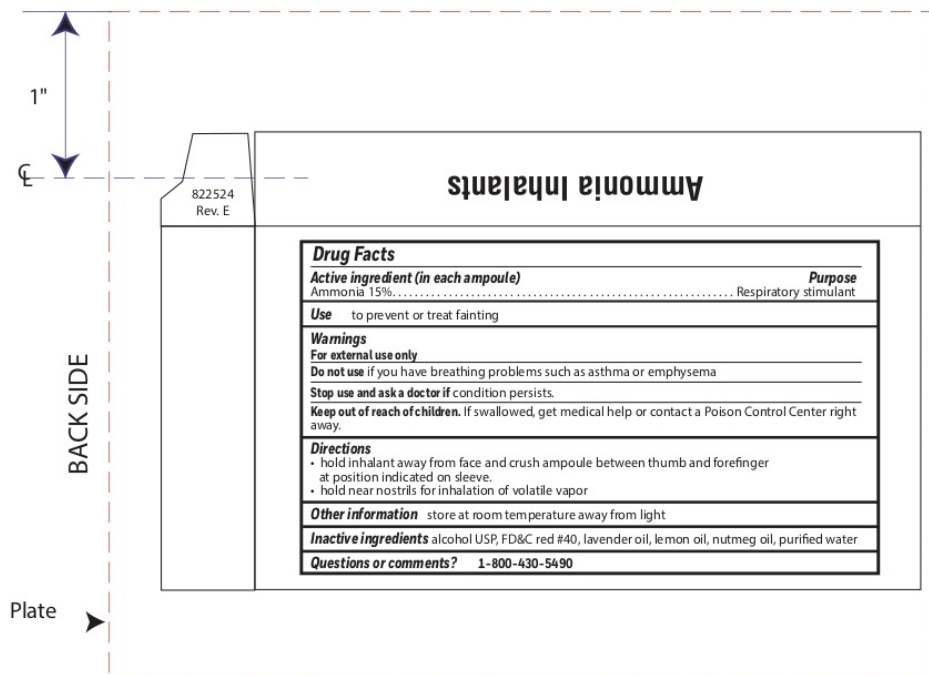
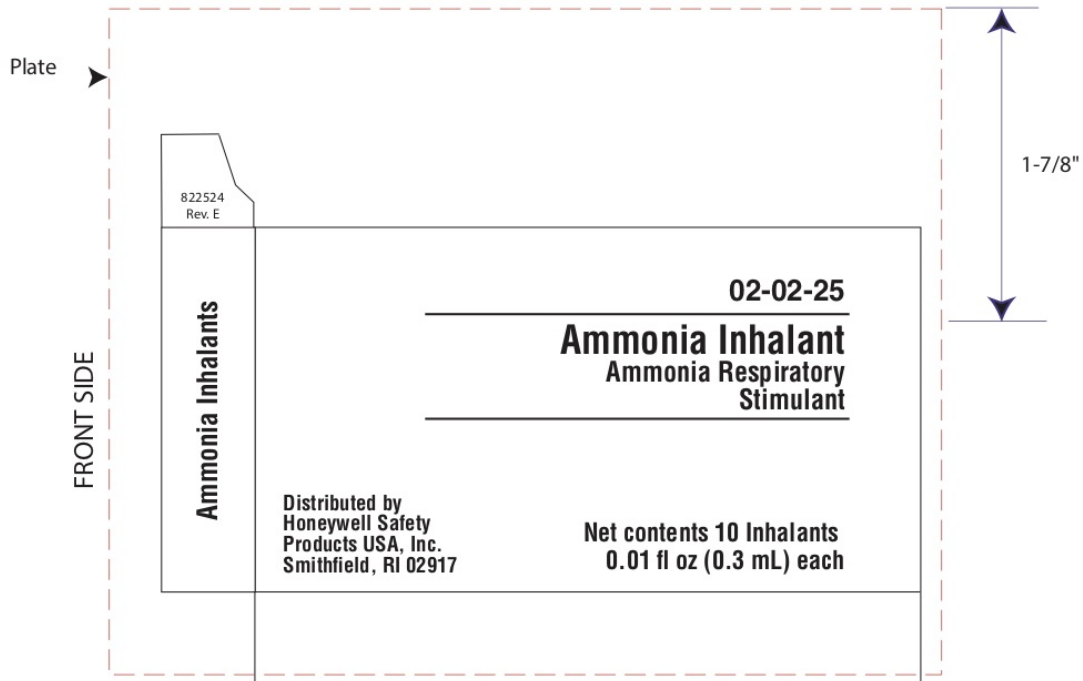
1 LBL STOCK 3"x1-7/8"

1 KIT STL 36 UN WHT 01 HOR SHELF

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



4188 Kit Label  
010704-4299

# FIRST A-I-D



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

## 4188 FIRST AID KIT

4188 first aid kit

### Product Information

|                     |                |                           |               |
|---------------------|----------------|---------------------------|---------------|
| <b>Product Type</b> | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:0498-4188 |
|---------------------|----------------|---------------------------|---------------|

### Packaging

| # | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:0498-4188-01 | 1 in 1 KIT          | 09/13/2018           |                    |

## Quantity of Parts

| Part # | Package Quantity | Total Product Quantity |
|--------|------------------|------------------------|
| Part 1 | 6 PACKET         | 21 g                   |
| Part 2 | 20 AMPULE        | 6 mL                   |

## Part 1 of 2

### 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<br>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 2 of 2

### 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           |                    |

#### 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(0498-4188)     |

## Establishment

| Name                   | Address | ID/FEI    | Business Operations    |
|------------------------|---------|-----------|------------------------|
| Water-Jel Technologies |         | 155522589 | manufacture(0498-0203) |

Revised: 3/2019

Honeywell Safety Products USA, Inc.