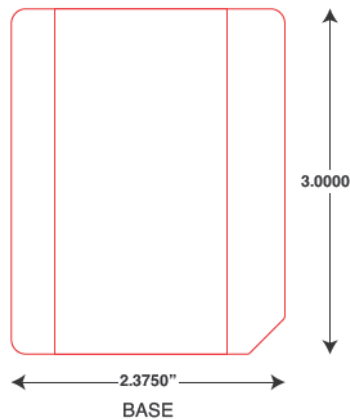
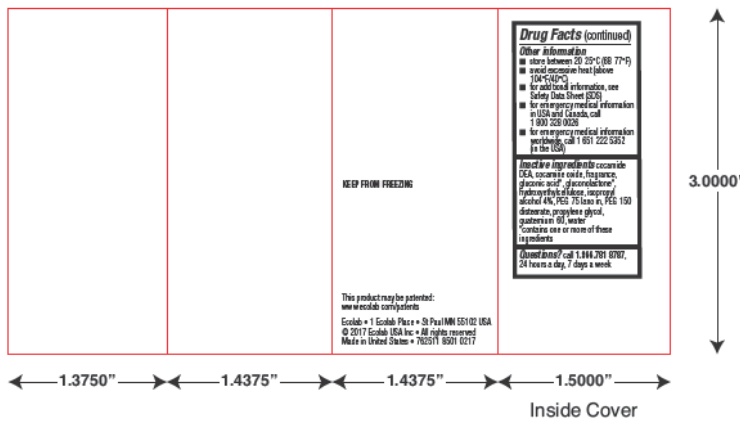
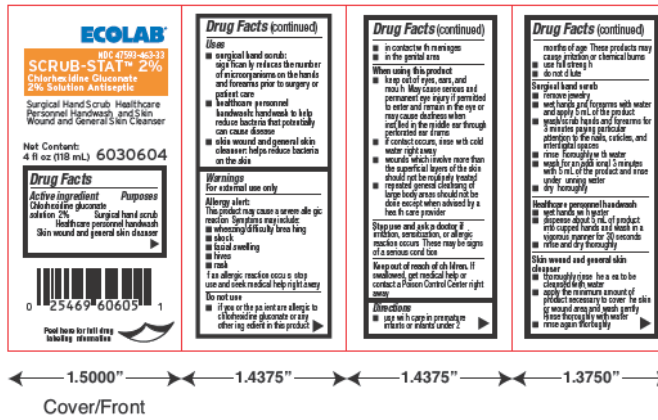
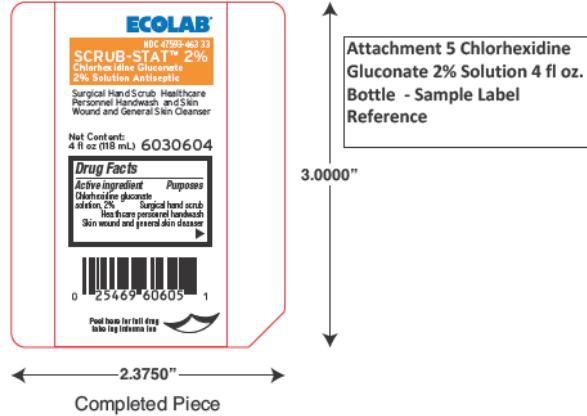


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NDA #: 019258

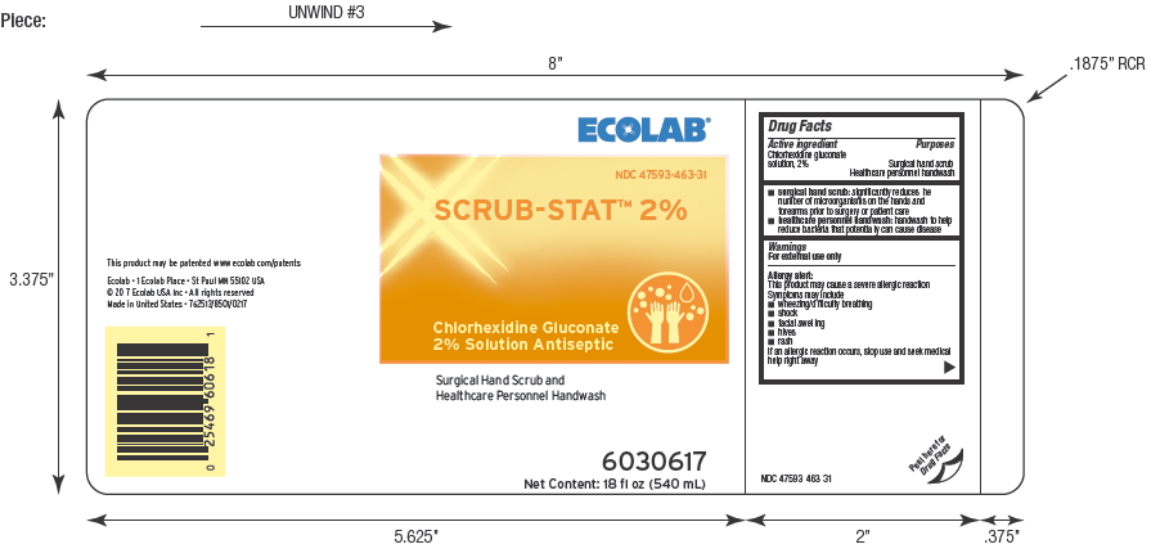


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Scrub-Stat

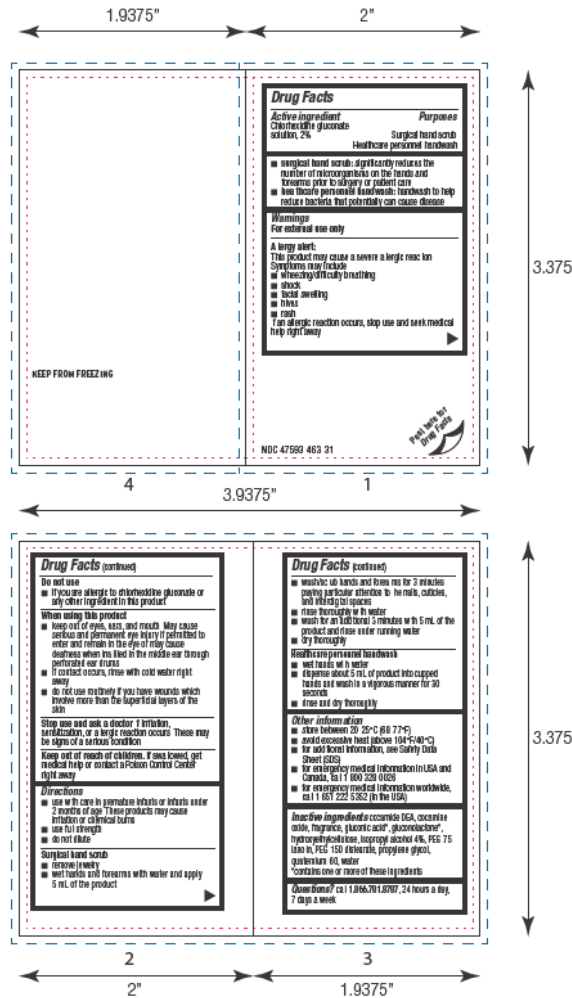
NDA #: 019258

Attachment 7 Chlorhexidine Gluconate 2% Solution 540 mL Bottle - Sample Label Reference

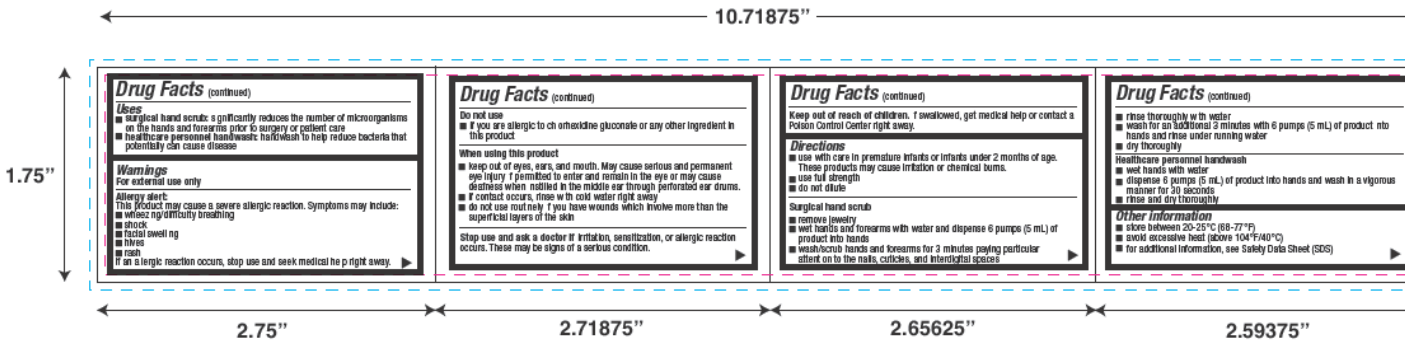
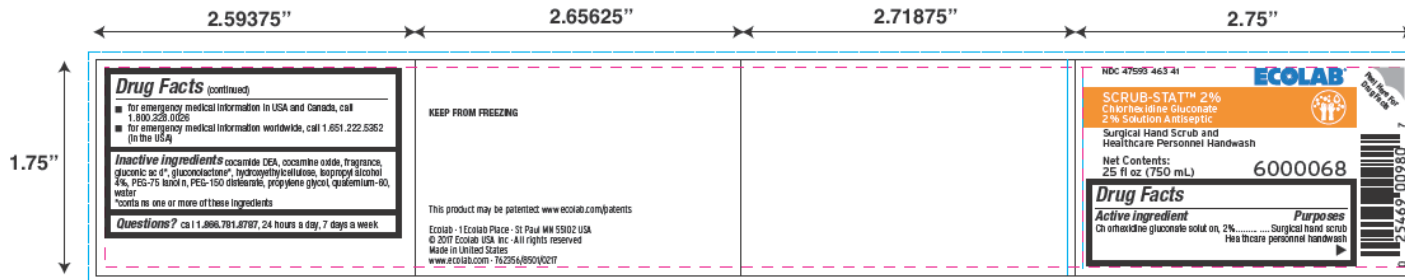
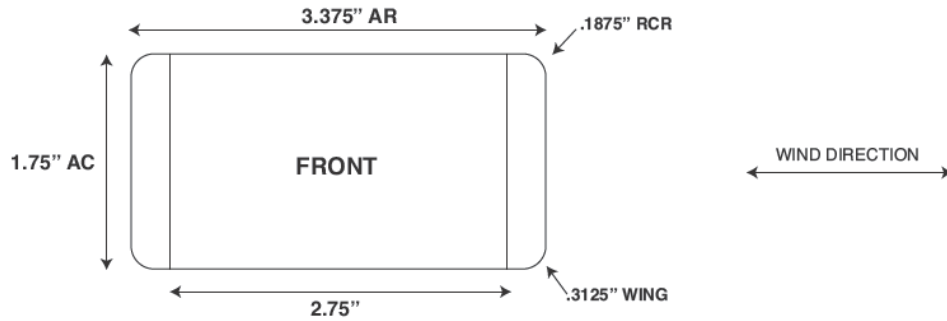
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Unfolded Piece:



Attachment 1 Chlorhexidine Gluconate 2% Solution 750 mL Bottle - Sample Label Reference

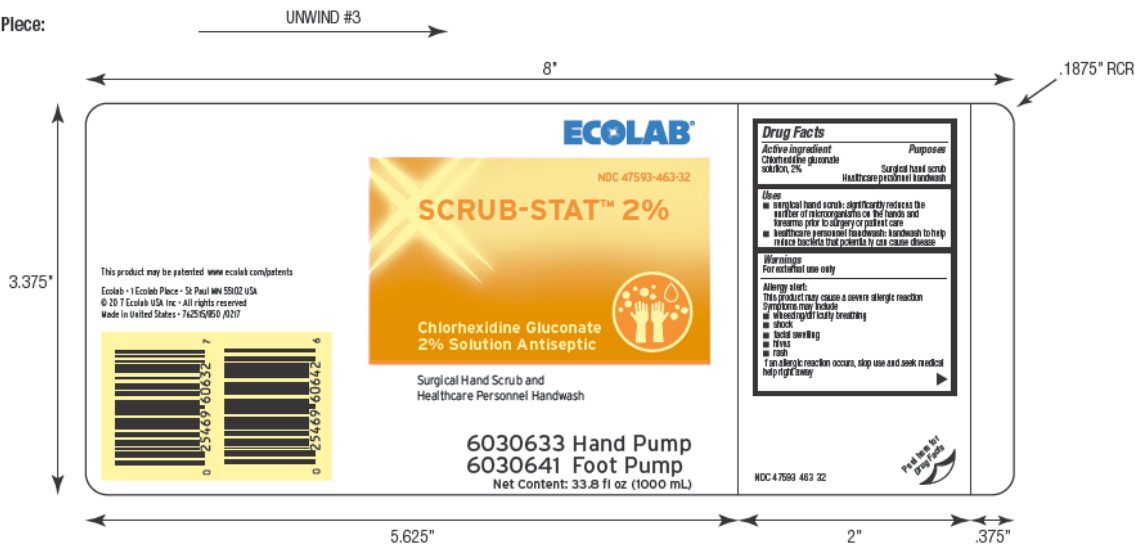


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Scrub-Stat

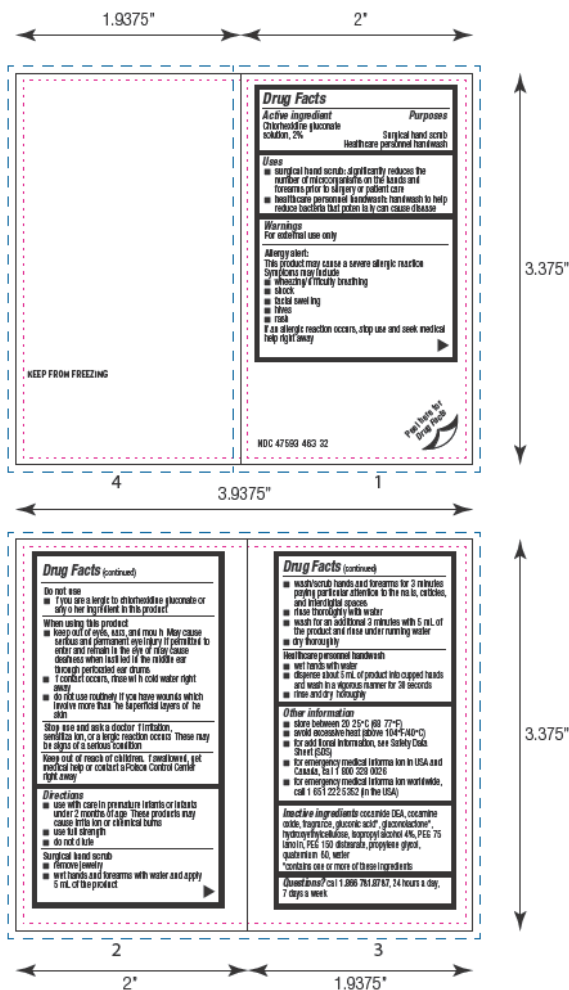
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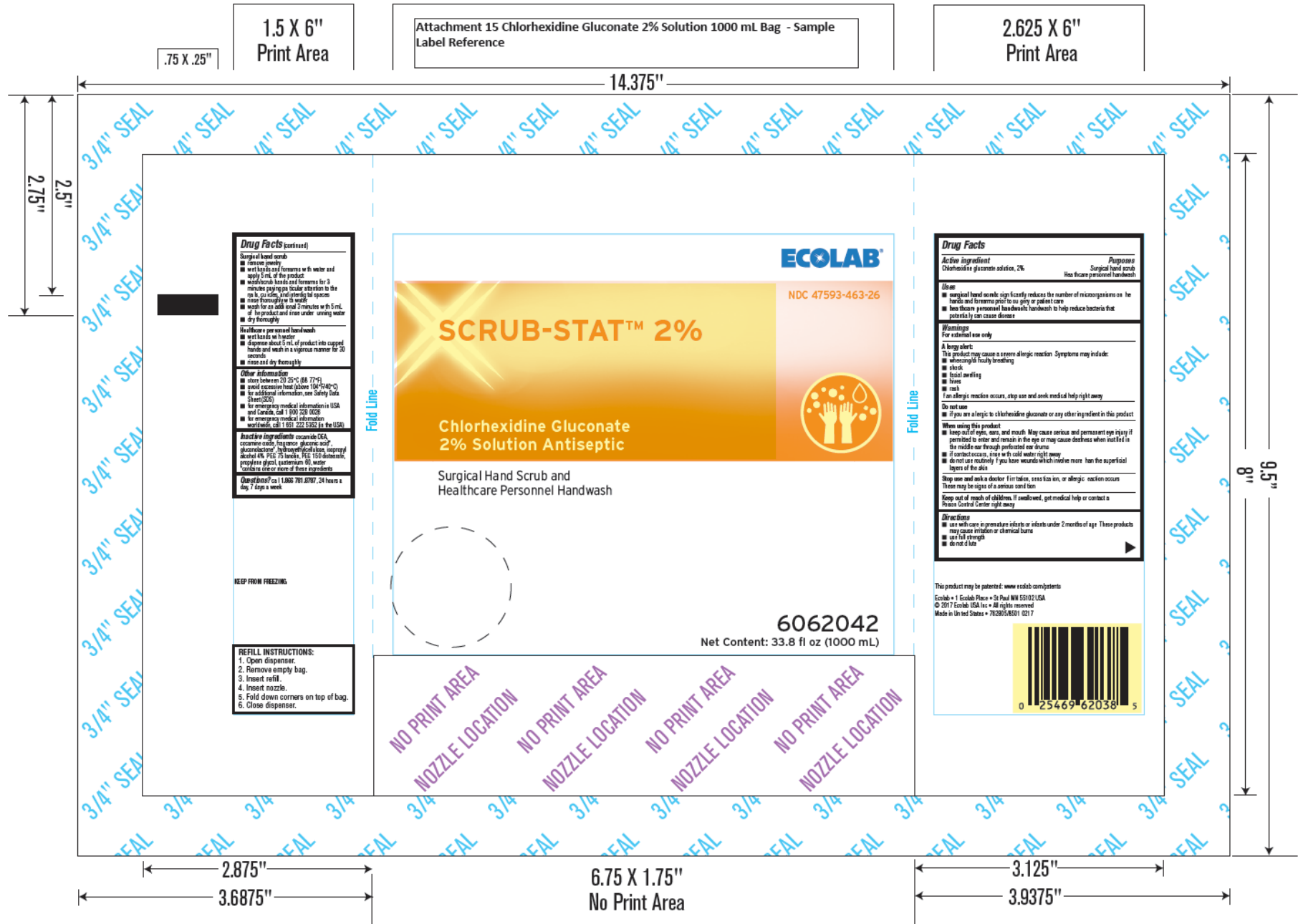
Attachment 9 Chlorhexidine Gluconate 2% Solution 1000 mL Bottle - Sample Label Reference

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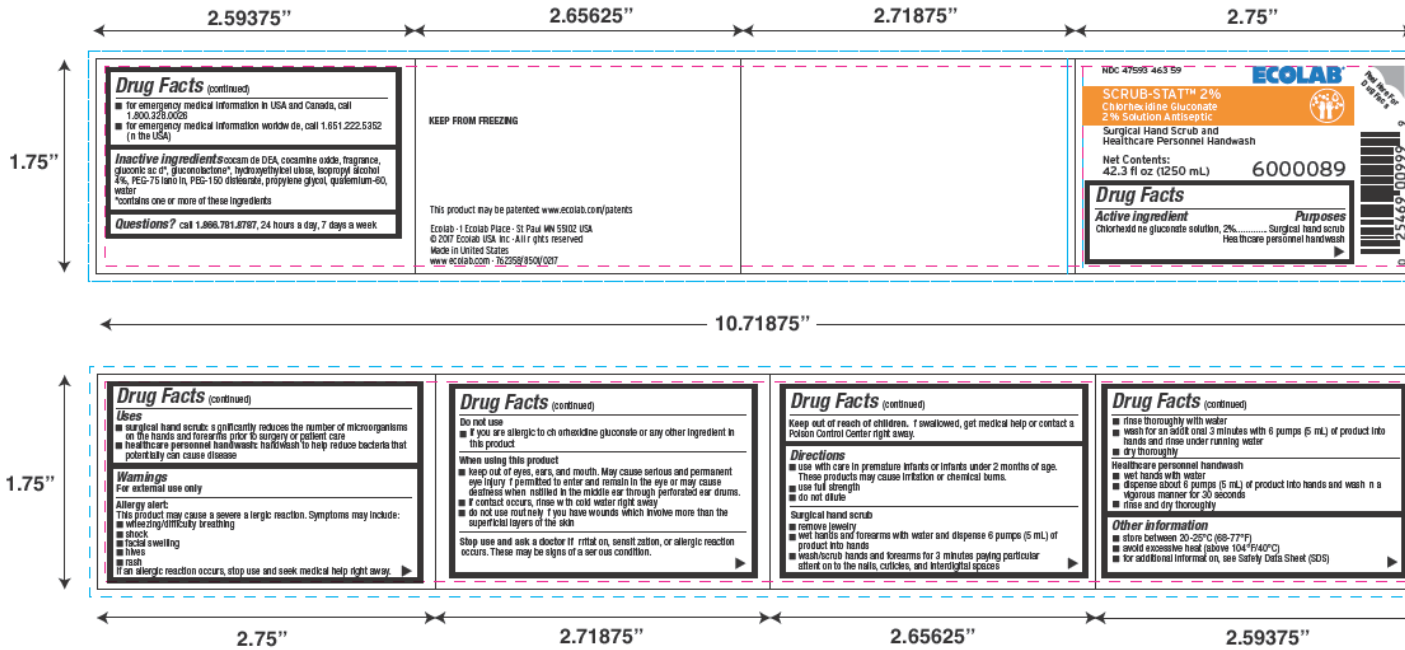
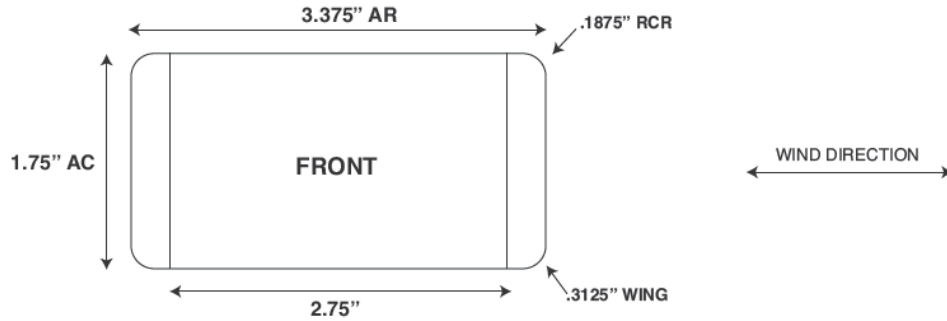


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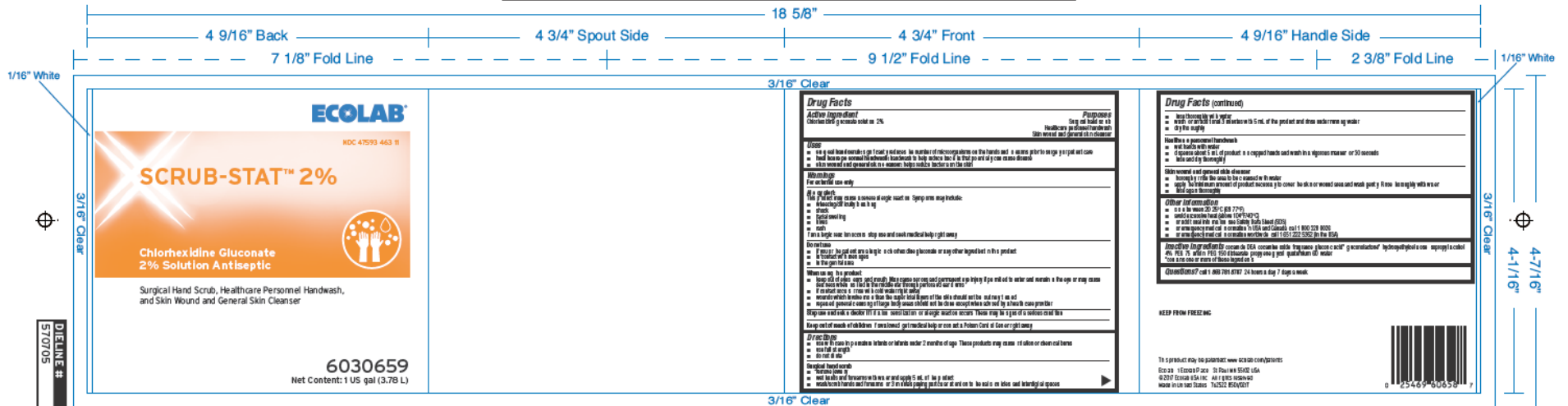
Attachment 3 Chlorhexidine Gluconate 2% Solution 1250 mL Bottle - Sample Label Reference

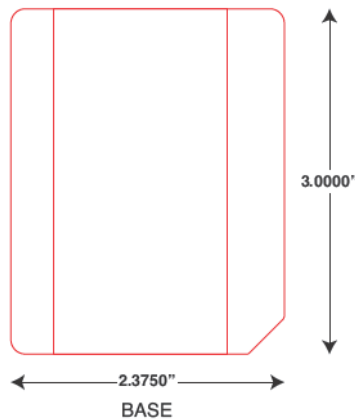
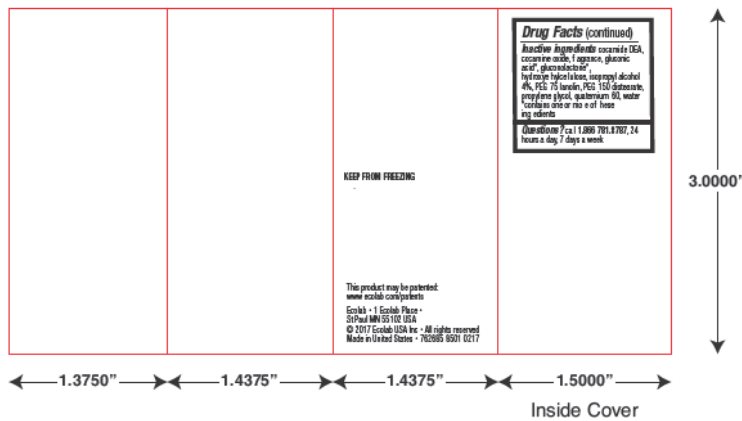
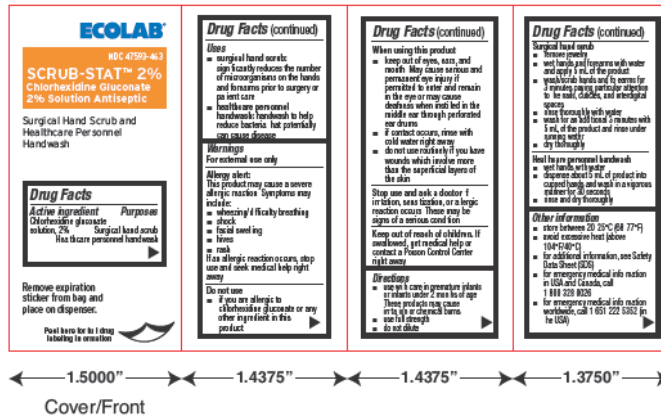
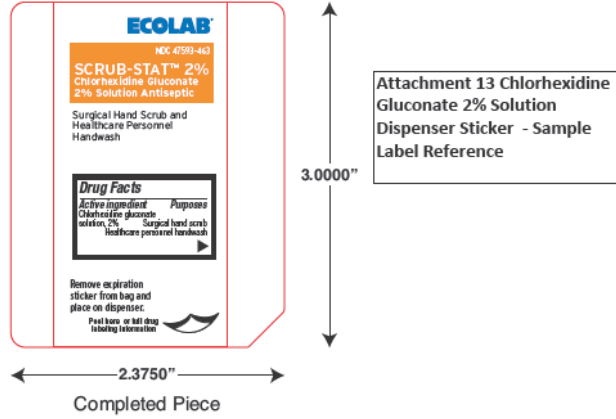


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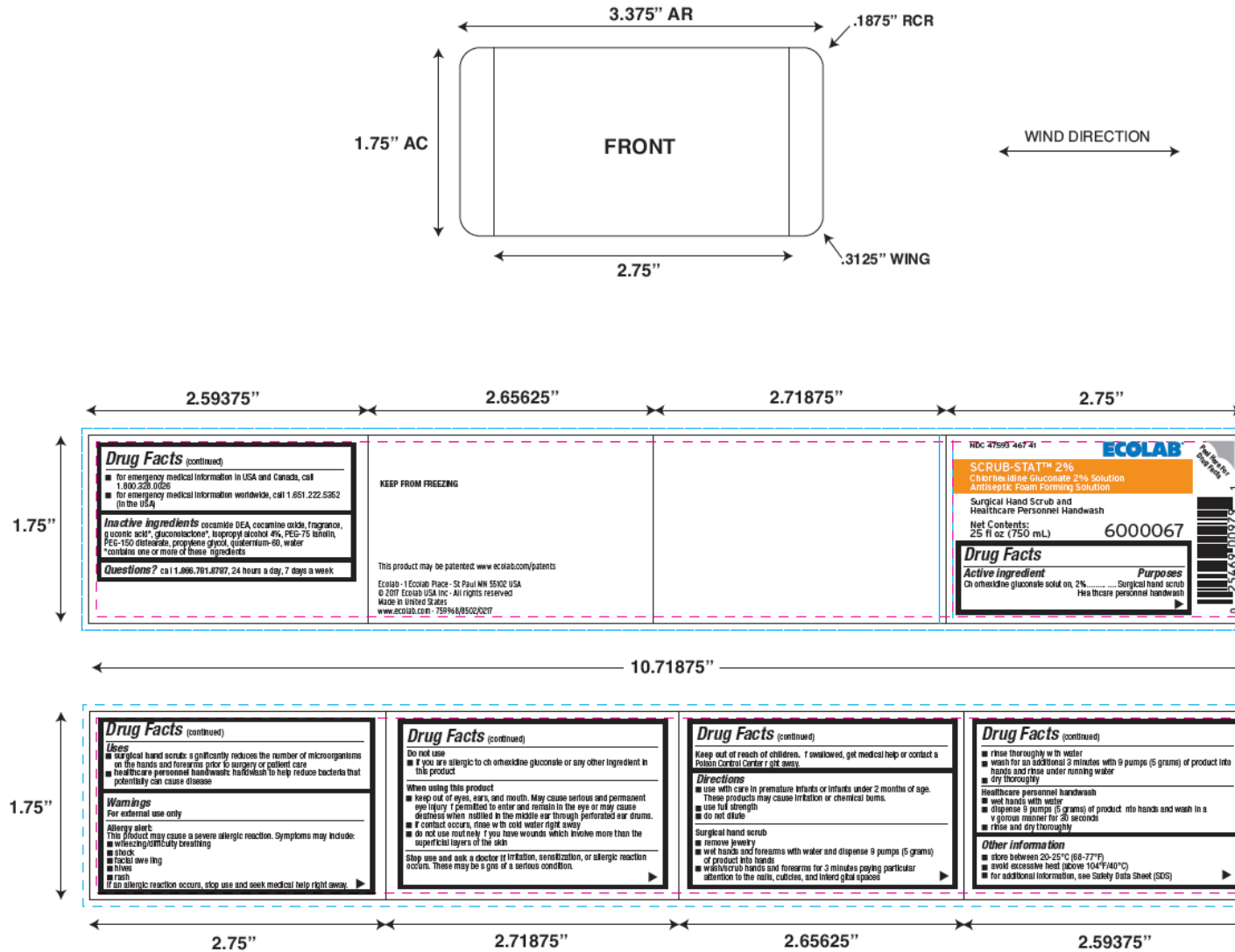
NDA #: 019258

Attachment 11 Chlorhexidine Gluconate 2% Solution 1 US Gallon - Sample Label Reference

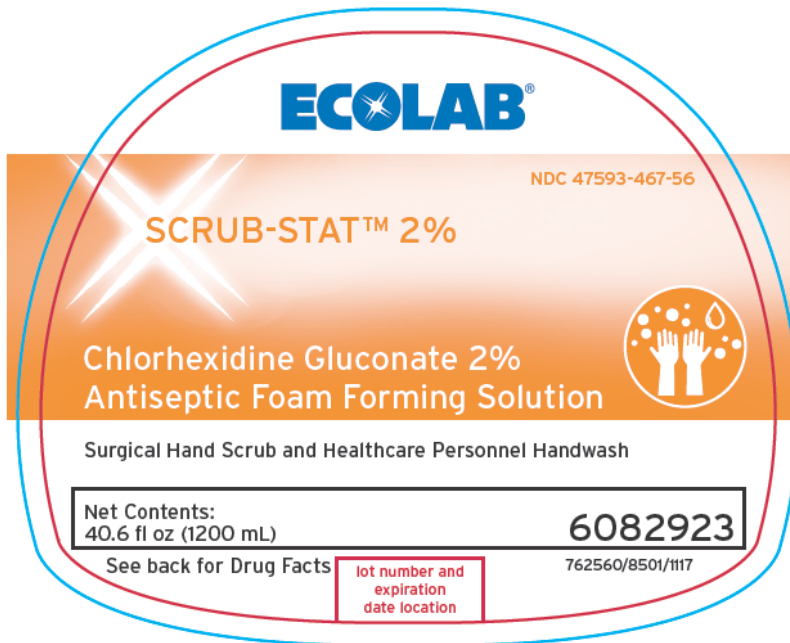




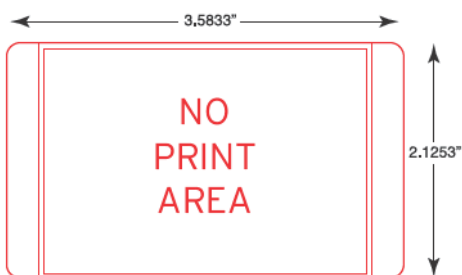
Attachment 17 Chlorhexidine Gluconate 2% Foam Forming Solution 750 mL Bottle - Sample Label Reference



Attachment 23 Chlorhexidine Gluconate 2% Foam
Forming Solution 1200 mL Bottle Front Label -
Sample Label Reference



Attachment 25 Chlorhexidine Gluconate 2% Foam Forming Solution 1200 mL Bottle
 Back Label - Sample Label Reference



FINISHED FRONT

Drug Facts		KEEP FROM FREEZING	
Active ingredient	Purposes		
Chlorhexidine gluconate solution, 2%	Surgical hand scrub Healthcare personnel handwash		
Uses			
<ul style="list-style-type: none"> surgical hand scrub: significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care healthcare personnel handwash: handwash to help reduce bacteria that potentially can cause disease 			
Warnings			
For external use only			

FRONT (TOP-PAGE 1)

Drug Facts (continued)
Allergy alert:
This product may cause a severe allergic reaction. Symptoms may include:
<ul style="list-style-type: none"> wheezing/difficult breathing shock facial swelling hives itch
If an allergic reaction occurs, stop use and seek medical help right away.
Do not use
<ul style="list-style-type: none"> if you are allergic to chlorhexidine gluconate or any other ingredient in this product
When using this product:
<ul style="list-style-type: none"> keep out of eyes, ears, and mouth. May cause serious and permanent eye injury if permitted to enter and remain in the eye or may cause distress when inhaled in the inside ear through perforated ear drums if contact occurs, rinse with cold water right away do not use routinely if you have wounds which involve more than superficial layers of the skin

BACK (PAGE 1)

Drug Facts (continued)
Stop use and seek a doctor if irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
Directions
<ul style="list-style-type: none"> Use with care to preclude infants or infants under 2 months of age. These products may cause irritation or chemical burns. Use full covering. Do not dilute.
Surgical hand scrub
<ul style="list-style-type: none"> remove jewelry wet hands and forearms with water and dispense 9 pumps (9 grams) of product into hands. wash hands and forearms for 3 minutes paying particular attention to the nails, cuticles, and interdigital spaces. rinse thoroughly with water.

FRONT (TOP-PAGE 1)

Drug Facts (continued)
<ul style="list-style-type: none"> wash for an additional 3 minutes with 9 pumps (9 grams) of product into hands and rinse under running water. dry thoroughly.
Healthcare personnel handwash
<ul style="list-style-type: none"> wet hands with water. dispense about 9 pumps (9 grams) of product into hands and wash in a vigorous manner for 30 seconds. rinse and dry thoroughly.
Other Information
<ul style="list-style-type: none"> store between 20-25°C (68-77°F) avoid excessive heat (above 104°F/40°C) for additional information, see Safety Data Sheet (SDS) for emergency medical information in USA and Canada, call 1 800 236 0026 for emergency medical information worldwide, call 1 651 222 5332 (in the USA)

BACK (PAGE 1)

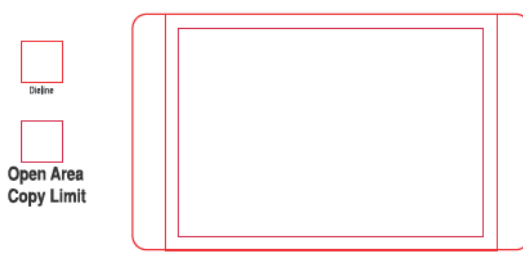
Drug Facts (continued)
Inactive ingredients: cocamide DEA, cocamine oxide, fragrance, gluconic acid, gluconolactone, isopropyl alcohol 4%, PEG-70 lanolin, PEG-120 distearate, propylene glycol, quaternium 15, water
Contains one or more of these ingredients.
Questions? call 1.866.781.8787, 24 hours a day, 7 days a week.
This product may be patented www.ecolab.com/patents
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FRONT (TOP-PAGE 1)

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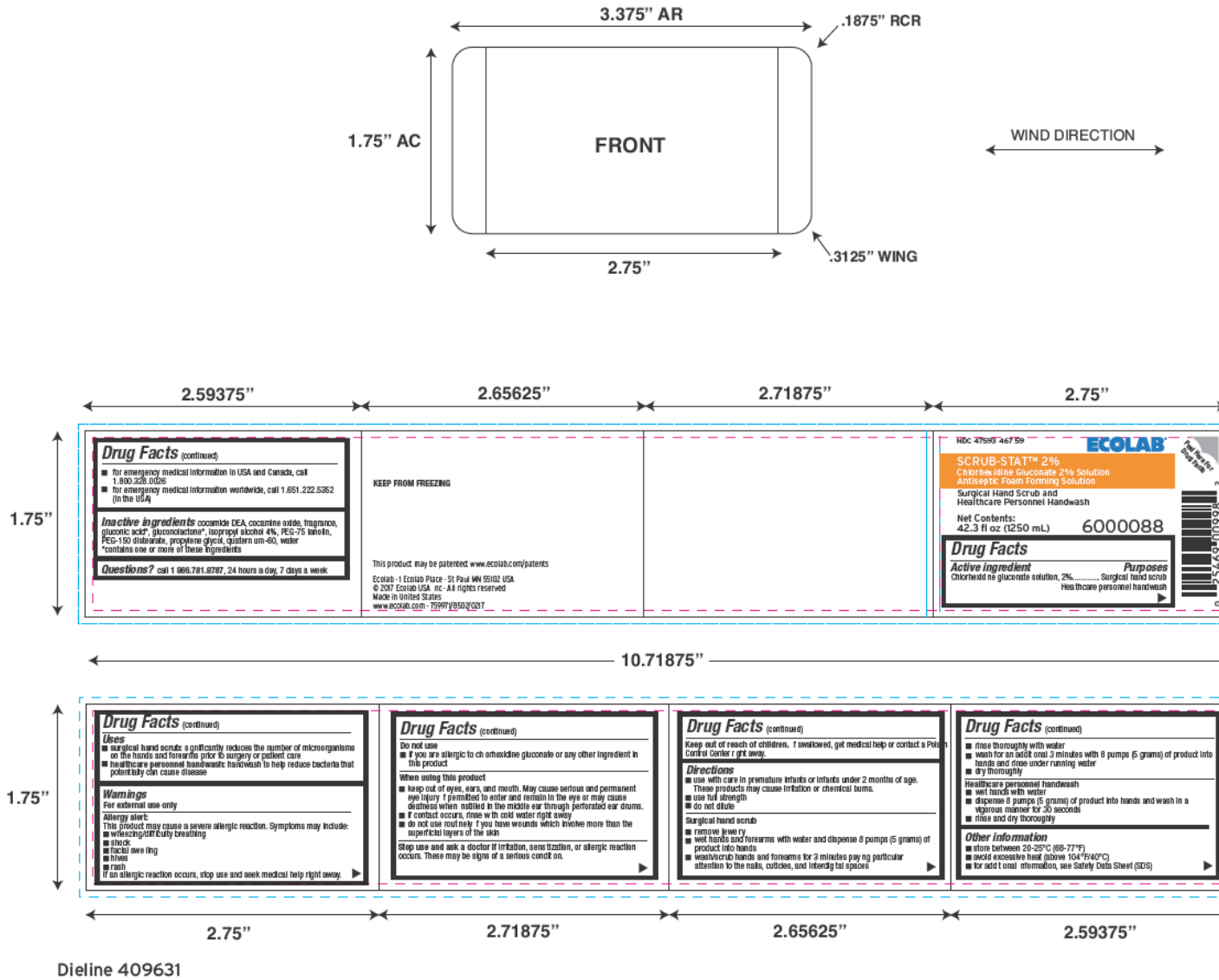
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BASE



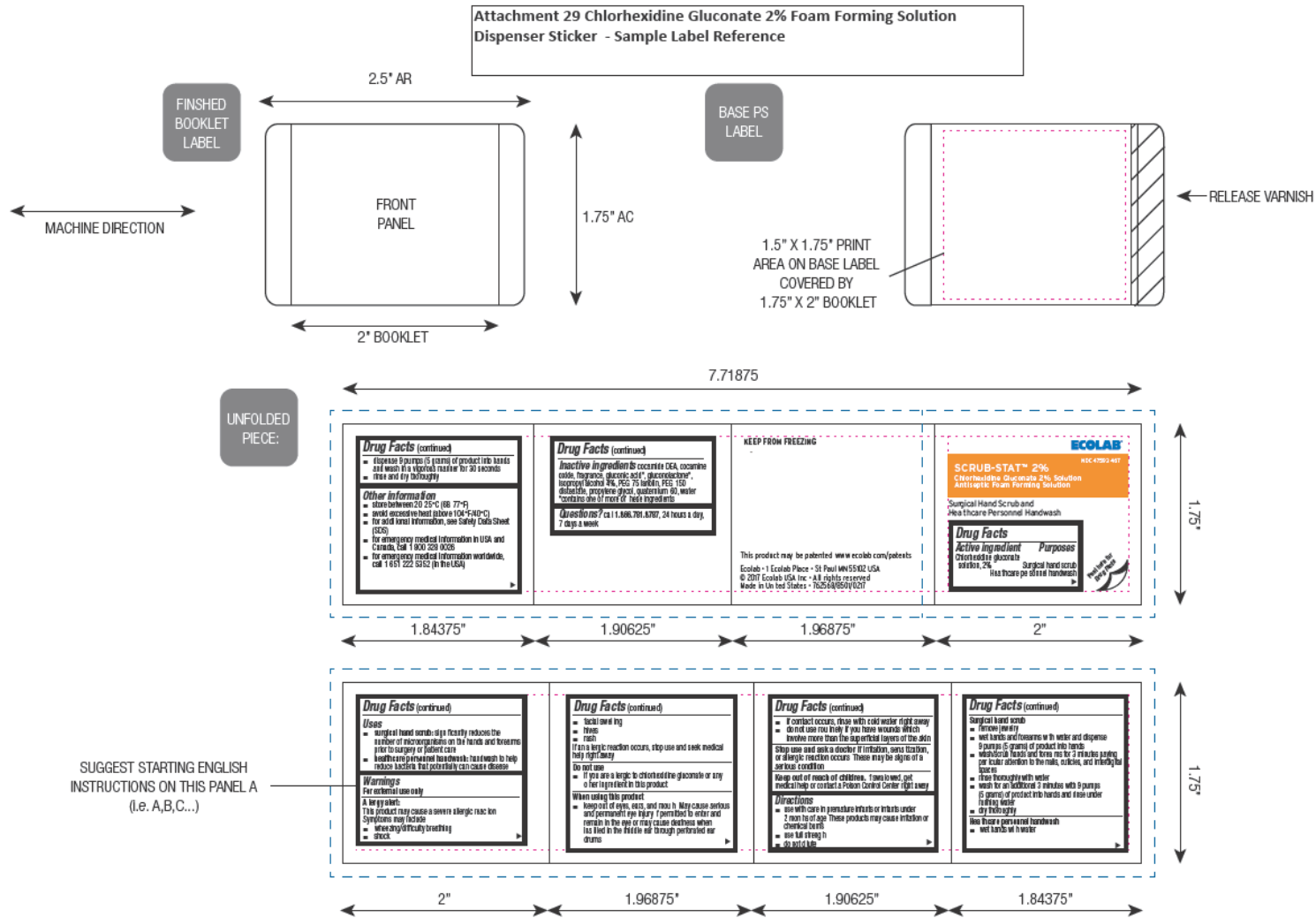
Printed Leave-Behind

Attachment 19 Chlorhexidine Gluconate 2% Foam Forming Solution 1250 mL Bottle - Sample Label Reference



Ecolab Inc.
 Scrub-Stat

NDA #: 019258



Ecolab Inc.
Scrub-Stat

NDA #: 019258

Attachment 27 Chlorhexidine Gluconate 2% Foam Forming Solution 55 U.S.
Gallons - Sample Label Reference



NDC 47593-467-21



Scrub-Stat™ 2%

Chlorhexidine Gluconate 2% Solution
Antiseptic Foam Forming Solution



Surgical Hand Scrub and Healthcare
Personnel Handwash

6018191
Net Content: 55 US gal (208 L)

Drug Facts

Active ingredient

Chlorhexidine gluconate solution, 2%

Purposes

Surgical hand scrub
Healthcare personnel handwash

Uses

- **surgical hand scrub:** significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care
- **healthcare personnel handwash:** handwash to help reduce bacteria that potentially can cause disease

Warnings

For external use only

Allergy alert:

This product may cause a severe allergic reaction. Symptoms may include:

- wheezing/difficulty breathing
- shock
- facial swelling
- hives
- rash

If an allergic reaction occurs, stop use and seek medical help right away.

Do not use

- if you are allergic to chlorhexidine gluconate or any other ingredient in this product

When using this product

- keep out of eyes, ears, and mouth. May cause serious and permanent eye injury if permitted to enter and remain in the eye or may cause deafness when instilled in the middle ear through perforated ear drums.
- if contact occurs, rinse with cold water right away
- do not use routinely if you have wounds which involve more than the superficial layers of the skin

Stop use and ask a doctor if irritation, sensitization, or allergic reaction occurs and lasts for 72 hours. These may be signs of a serious condition.

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

Directions

- use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.
- use full strength
- do not dilute

Surgical hand scrub

- remove jewelry
- wet hands and forearms with water and dispense 5 grams (70 mL of foam) of product into hands
- wash/scrub hands and forearms for 3 minutes paying particular attention to the nails, cuticles, and interdigital spaces
- rinse thoroughly with water
- wash for an additional 3 minutes with 5 grams (70 mL of foam) of product into hands and rinse under running water
- dry thoroughly

Healthcare personnel handwash

- wet hands with water
- dispense about 5 grams (70 mL of foam) of product into hands and wash in a vigorous manner for 30 seconds
- rinse and dry thoroughly

Other information

- store between 20-25°C (68-77°F)
- avoid excessive heat (above 104°F/40°C)
- for additional information, see Safety Data Sheet (SDS)
- for emergency medical information in USA and Canada, call 1.800.328.0026
- for emergency medical information worldwide, call 1.651.222.5352 (in the USA)

Inactive ingredients cocamide DEA, cocamine oxide, fragrance, gluconic acid*, gluconolactone*, isopropyl alcohol 4%, PEG-75 lanolin, PEG-150 distearate, propylene glycol, quaternium-60, water
*contains one or more of these ingredients

Questions? call, 1.866.781.8787, 24 hours a day, 7 days a week

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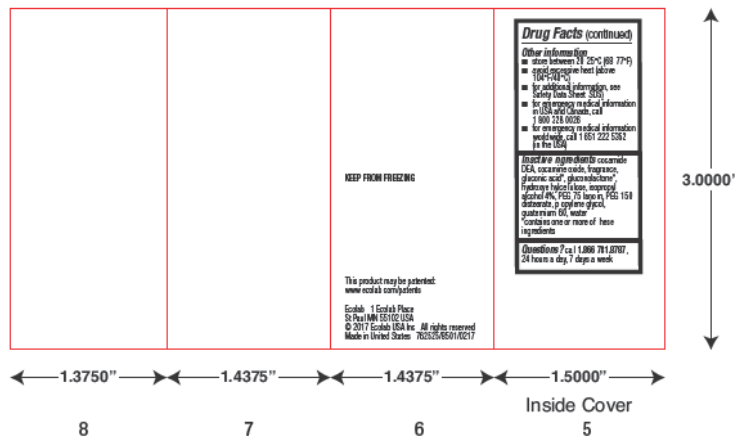
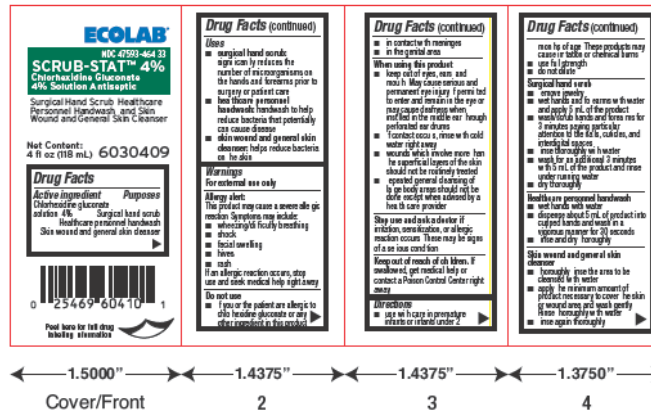
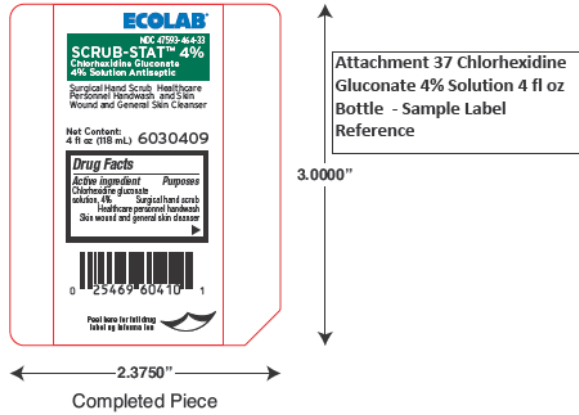
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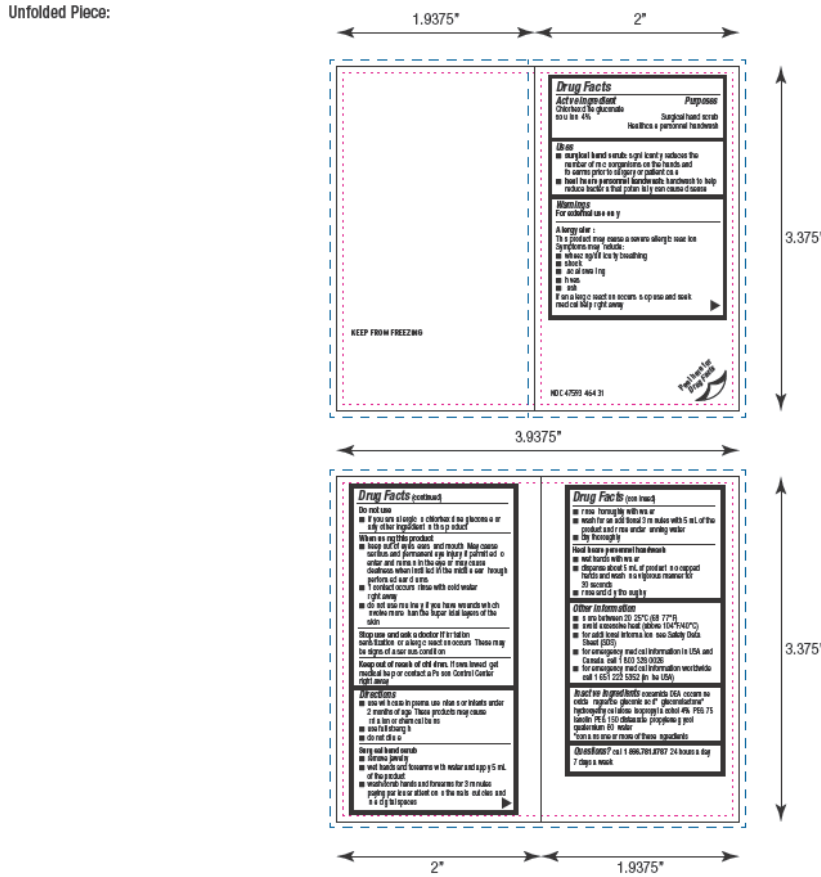
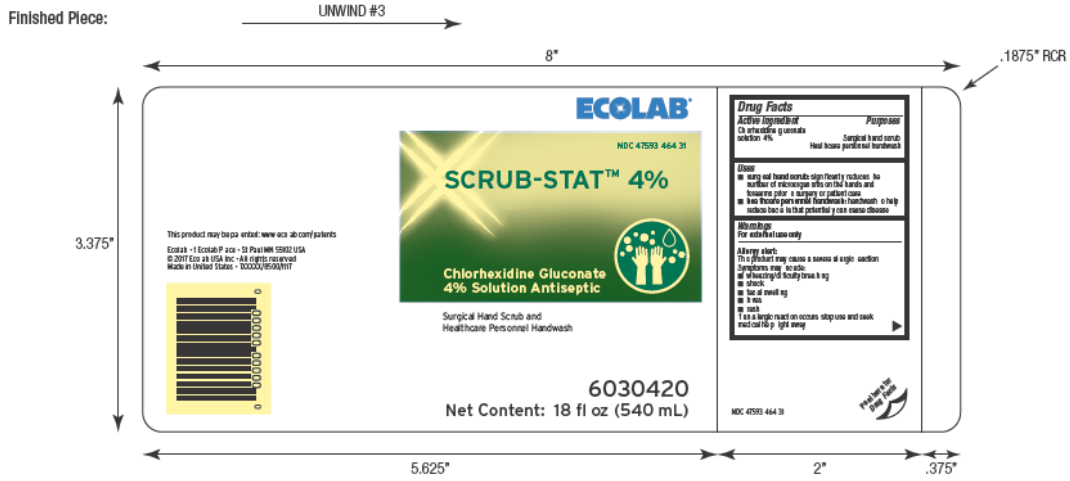
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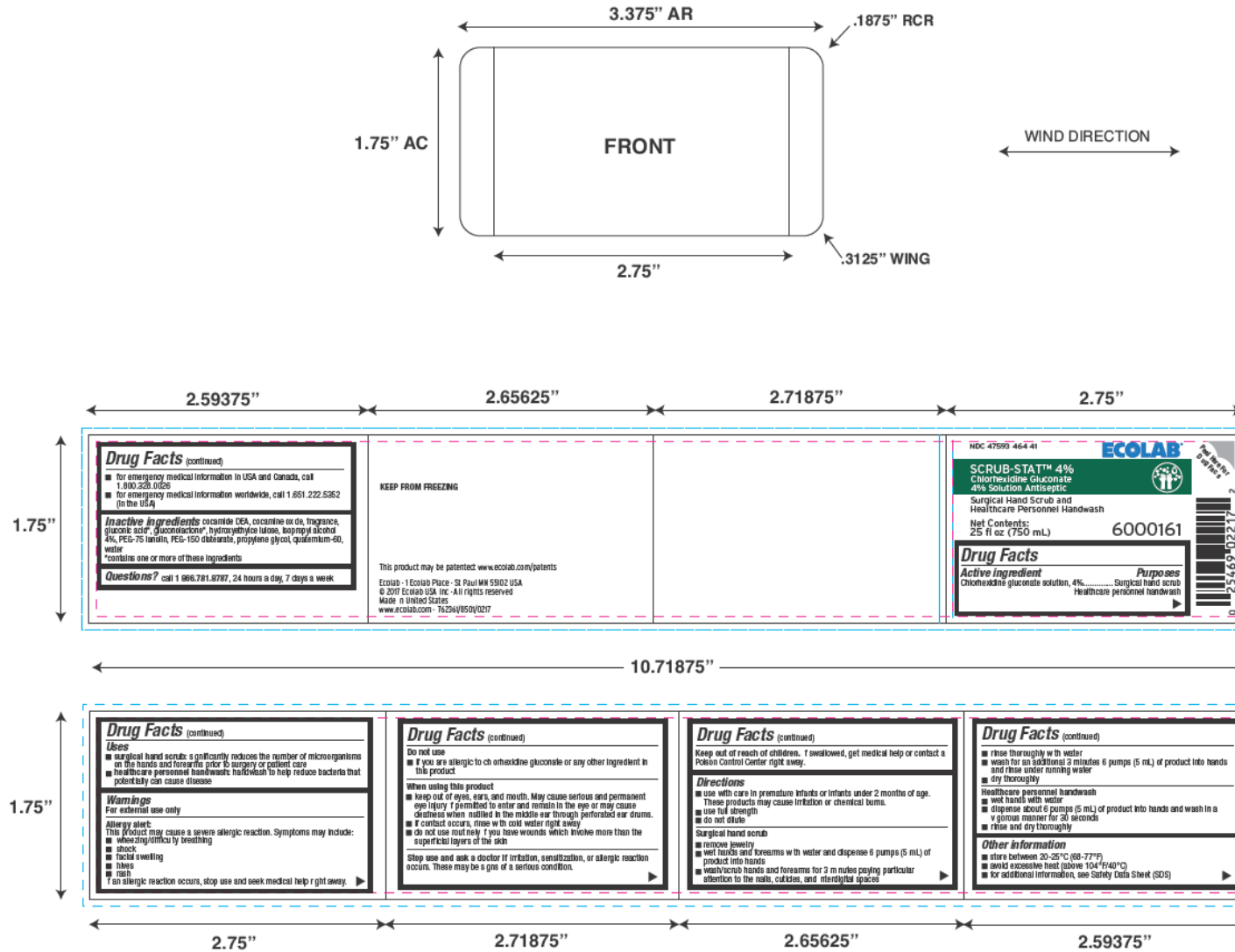
Ecolab Inc.
 Scrub-Stat

NDA #: 019258

Attachment 31 Chlorhexidine Gluconate 4% Solution 540 mL Bottle
 - Sample Label Reference



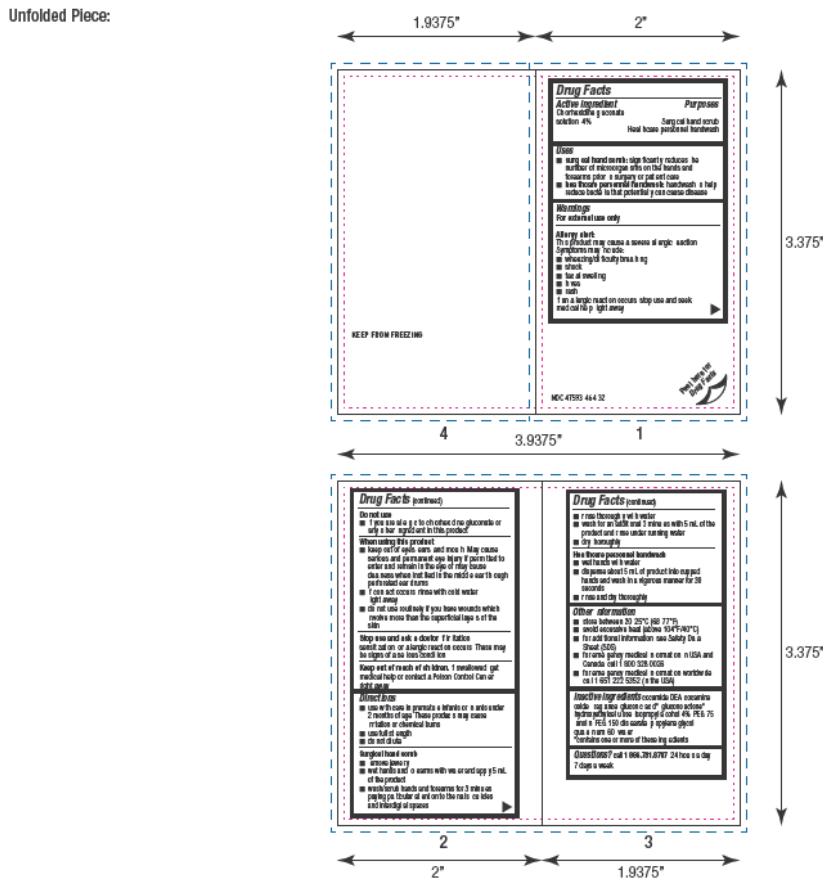
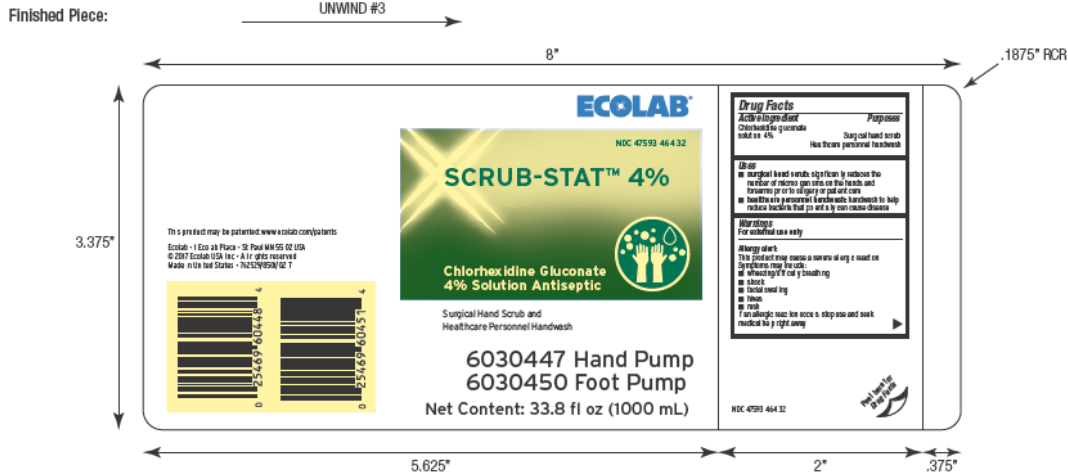
Attachment 33 Chlorhexidine Gluconate 4% Solution 750 mL Bottle - Sample Label Reference



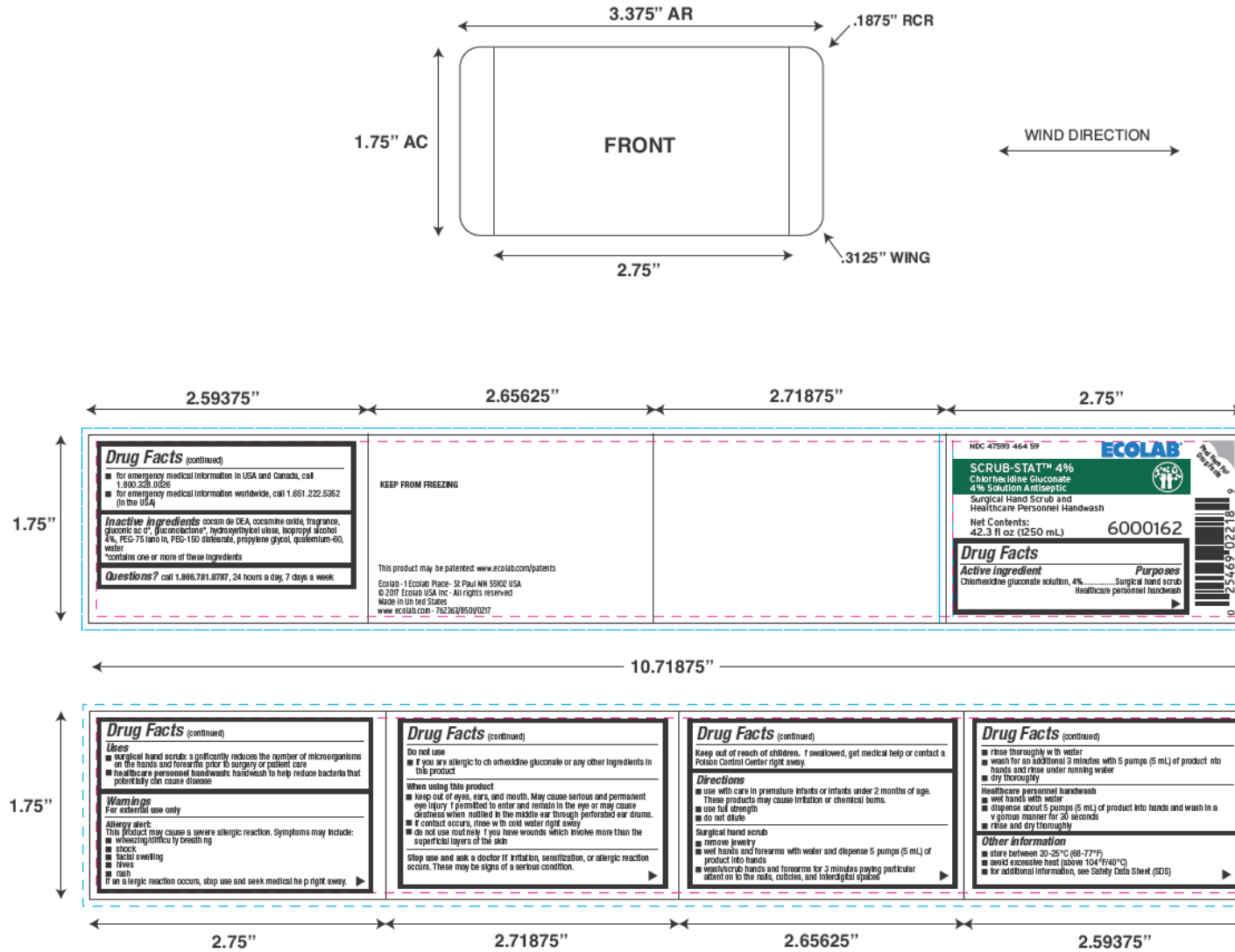
Ecolab Inc.
Scrub-Stat

NDA #: 019258

Attachment 39 Chlorhexidine Gluconate 4% Solution 1000 mL Bottle - Sample Label Reference



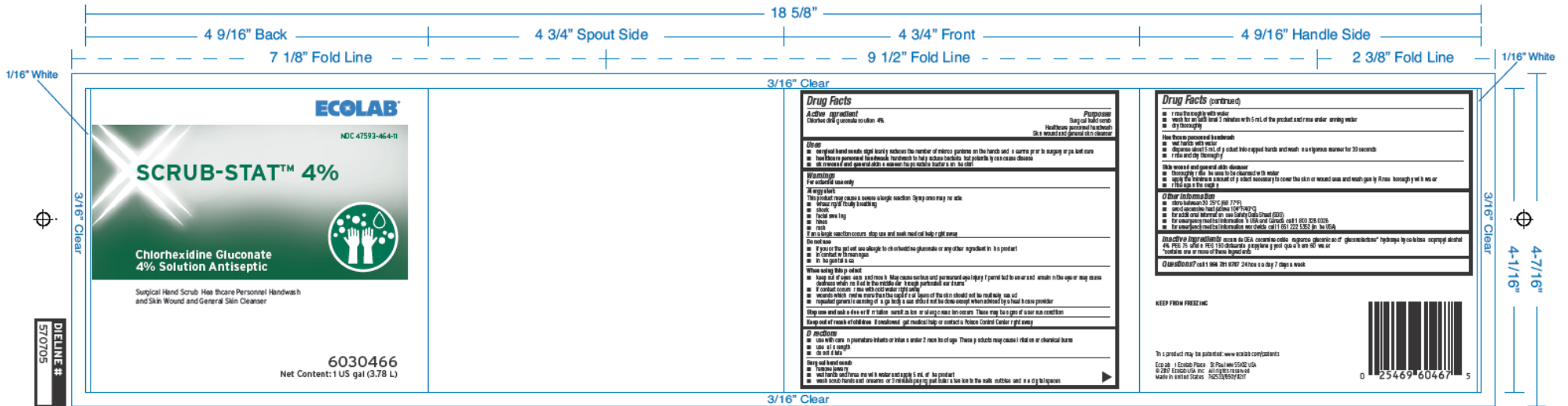
Attachment 35 Chlorhexidine Gluconate 4% Solution 1250 mL Bottle - Sample Label Reference



Ecolab Inc.
Scrub-Stat

NDA #: 019258

Attachment 41 Chlorhexidine Gluconate 4% Solution 1 US Gallon Bottle - Sample Label Reference



ECOLAB
NDC 47593-464-1

SCRUB-STAT™ 4%

**Chlorhexidine Gluconate
4% Solution Antiseptic**

Surgical Hand Scrub • Healthcare Personnel Handwash
and Skin Wound and General Skin Cleanser

6030466
Net Content: 1 US gal (3.78 L)

Drug Facts

Active ingredient: Chlorhexidine gluconate solution 4%

Purpose(s): Surgical hand scrub; Healthcare personnel handwash; Skin wound and general skin cleanser

Directions:
 • Surgical hand scrubs: Apply liberally to the palm of one hand and the back of the other hand. Rub hands together for 15 seconds. Rinse thoroughly with water.
 • Healthcare personnel handwash: Rub hands together for 15 seconds. Rinse thoroughly with water.
 • Skin wound and general skin cleanser: Apply to the skin to be cleaned. Rub hands together for 15 seconds. Rinse thoroughly with water.

Warnings:
 • Do not use if you are allergic to chlorhexidine gluconate or any other ingredient in this product.
 • Do not use if the product is expired.
 • Do not use if the product is discolored or contains particles.
 • Do not use if the product is past its expiration date.

Other information:
 • Store at room temperature (20° to 25°C (68° to 77°F)).
 • Do not use if the product is expired.
 • Do not use if the product is discolored or contains particles.
 • Do not use if the product is past its expiration date.

Drug Facts (continued)

• If you are allergic to chlorhexidine gluconate or any other ingredient in this product, you may have a severe allergic reaction. Stop use and seek medical help if you experience any of the following symptoms:
 • hives
 • difficulty breathing
 • swelling of the face, lips, tongue, or throat
 • severe dizziness
 • fainting or loss of consciousness

Other information:
 • Store at room temperature (20° to 25°C (68° to 77°F)).
 • Do not use if the product is expired.
 • Do not use if the product is discolored or contains particles.
 • Do not use if the product is past its expiration date.

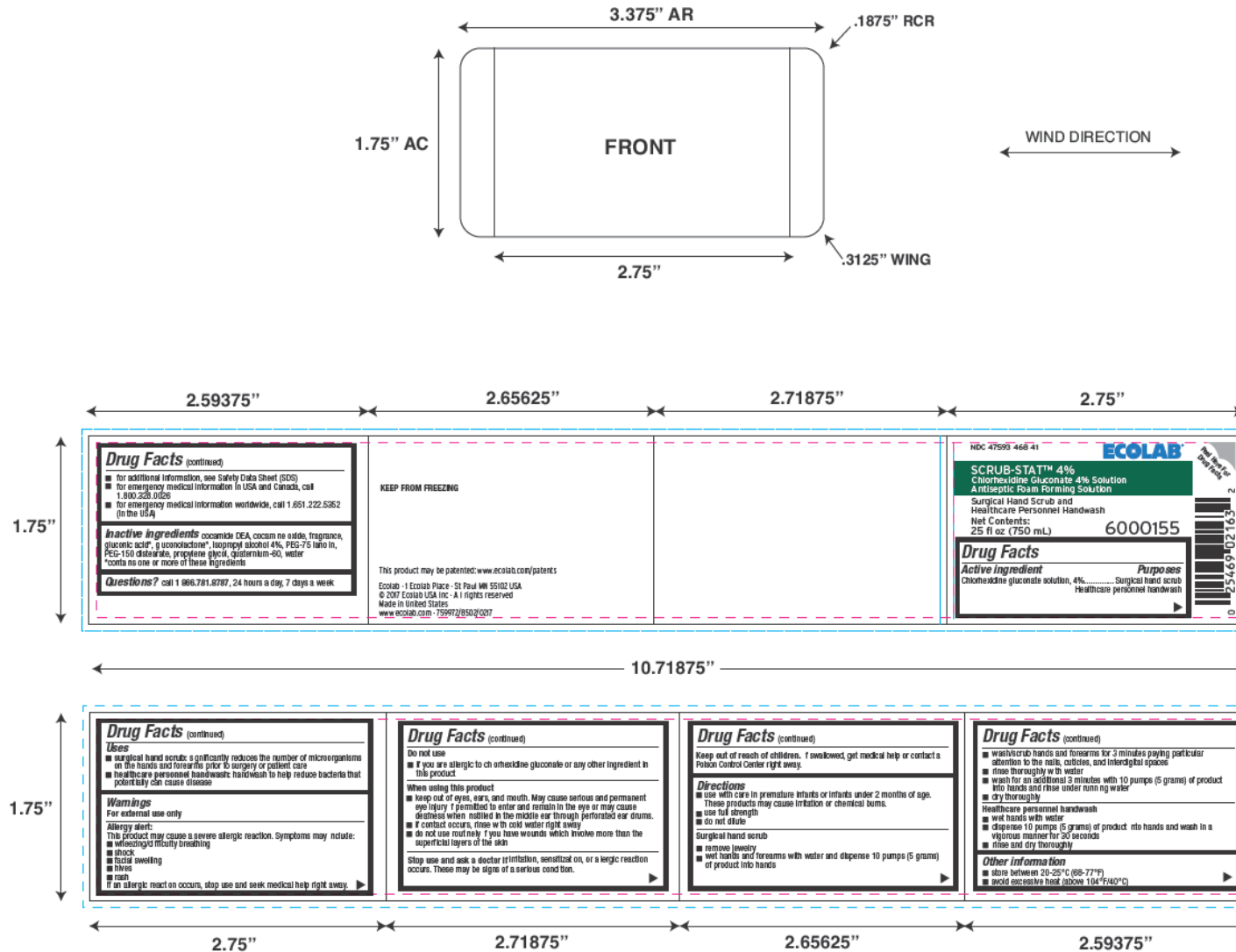
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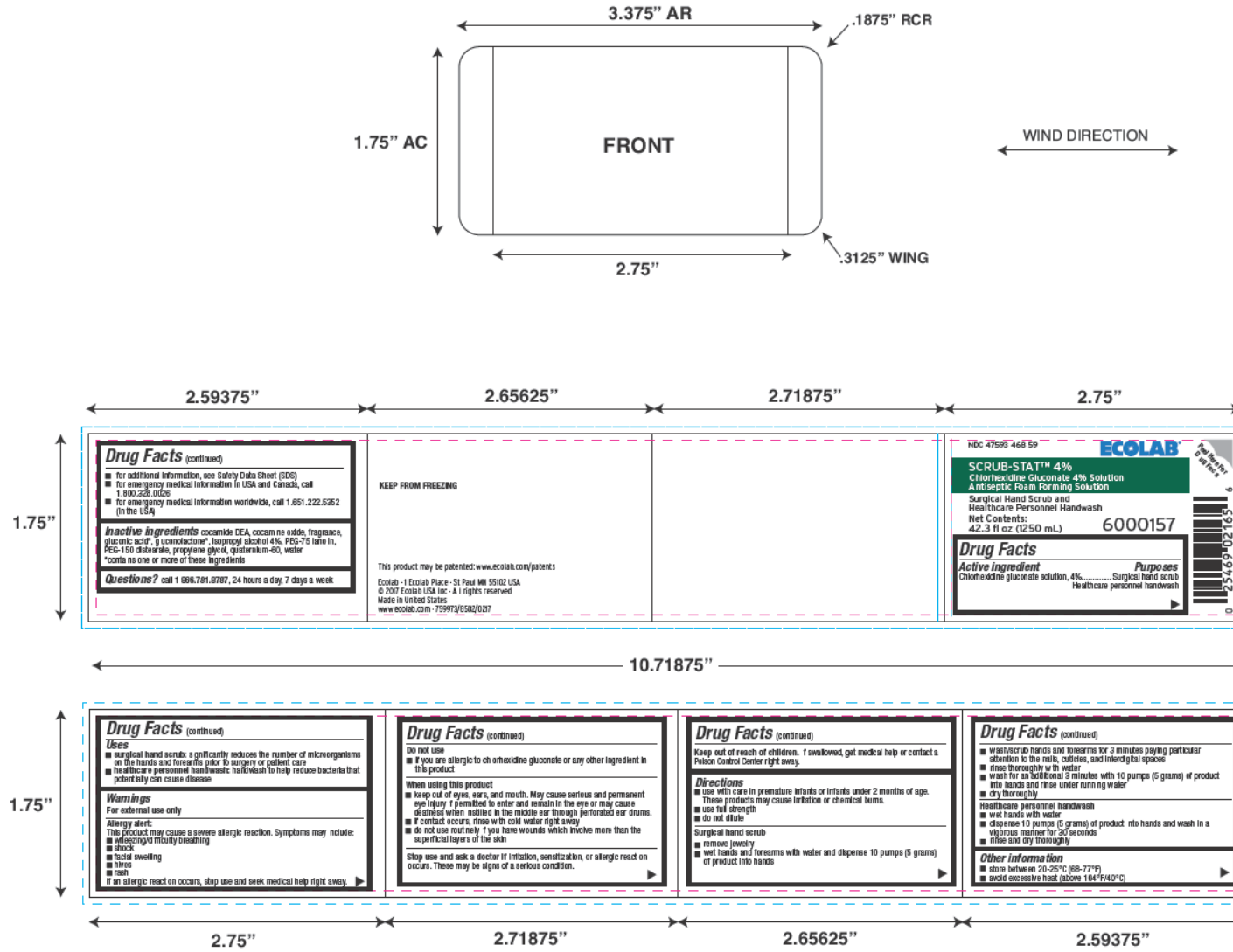
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Attachment 45 Chlorhexidine Gluconate 4% Foam Forming Solution 750 mL Bottle - Sample Label Reference



Attachment 47 Chlorhexidine Gluconate 4% Foam Forming Solution 1250 mL Bottle - Sample Label Reference



Ecolab Inc.
Scrub-Stat

NDA #: 019258

Attachment 49 Chlorhexidine Gluconate 4% Foam Forming Solution
55 U.S. Gallons - Sample Label Reference

ECOLAB[®]

NDC 47593-468-21



Scrub-Stat™ 4%

**Chlorhexidine Gluconate 4% Solution
Antiseptic Foam Forming Solution**



**Surgical Hand Scrub and Healthcare
Personnel Handwash**

6018241
Net Content: 55 US gal (208 L)

Drug Facts

Active ingredient

Chlorhexidine gluconate solution, 4%Surgical hand scrub
Healthcare personnel handwash

Purposes

Uses

- **surgical hand scrub:** significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care
- **healthcare personnel handwash:** handwash to help reduce bacteria that potentially can cause disease

Warnings

For external use only

Allergy alert:

This product may cause a severe allergic reaction. Symptoms may include:

- wheezing/difficulty breathing
- shock
- facial swelling
- hives
- rash

If an allergic reaction occurs, stop use and seek medical help right away.

Do not use

- if you are allergic to chlorhexidine gluconate or any other ingredient in this product

When using this product

- keep out of eyes, ears, and mouth. May cause serious and permanent eye injury if permitted to enter and remain in the eye or may cause deafness when instilled in the middle ear through perforated ear drums.
- if contact occurs, rinse with cold water right away
- do not use routinely if you have wounds which involve more than the superficial layers of the skin

Stop use and ask a doctor if irritation, sensitization, or allergic reaction occurs and lasts for 72 hours. These may be signs of a serious condition.

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

Directions

- use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.
- use full strength
- do not dilute

Surgical hand scrub

- remove jewelry
- wet hands and forearms with water and dispense 5 grams (70 mL of foam) of product into hands
- wash/scrub hands and forearms for 3 minutes paying particular attention to the nails, cuticles, and interdigital spaces
- rinse thoroughly with water
- wash for an additional 3 minutes with 5 grams (70 mL of foam) of product into hands and rinse under running water
- dry thoroughly

Healthcare personnel handwash

- wet hands with water
- dispense about 5 grams (70 mL of foam) of product into hands and wash in a vigorous manner for 30 seconds
- rinse and dry thoroughly

Other information

- store between 20-25°C (68-77°F)
- avoid excessive heat (above 104°F/40°C)
- for additional information, see Safety Data Sheet (SDS)
- for emergency medical information in USA and Canada, call 1.800.328.0026
- for emergency medical information worldwide, call 1.651.222.5352 (in the USA)

Inactive ingredients cocamide DEA, cocamine oxide, fragrance, gluconic acid*, gluconolactone*, isopropyl alcohol 4%, PEG-75 lanolin, PEG-150 distearate, propylene glycol, quaternium-60, water
*contains one or more of these ingredients

Questions? call 1.866.781.8787, 24 hours a day, 7 days a week.

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/s/

THERESA M MICHELE
01/10/2018