



Two Nice-Pak Park  
Orangeburg, New York 10962  
pdihc.com

July 18, 2014

Re: Q89072 PDI Sani-Cloth® Plus Germicidal Disposable Cloth, EPA Reg. No. 9480-6  
Q85084 PDI Sani-Cloth® Plus Germicidal Disposable Cloth, EPA Reg. No. 9480-6  
Update on Labeling

Dear Distributor:

Professional Disposables International (PDI) is relabeling its Sani-Cloth® Plus Germicidal Disposable Cloth, EPA Reg. No. 9480-6 (Sani-Cloth® Plus) in order to remove the *Mycobacterium bovis* BCG (tuberculosis) claim.

PDI has taken this step voluntarily due to preliminary test results which indicate the product may not pass a test necessary to support a *Mycobacterium bovis* BCG (tuberculosis) claim. **Please note Sani-Cloth® Plus continues to be efficacious for use against the remaining 16 microorganisms referenced on the label (see attached updated technical data bulletin). The removal of the *Mycobacterium bovis* BCG (tuberculosis) claim only applies to PDI Sani-Cloth® Plus (Item numbers Q89072 and Q85084).**

**Please return all existing inventory of this product in your warehouse.** We are currently obtaining new labels and will begin shipping replacement product shortly. In the meantime, PDI offers several other products that have been proven efficacious for *Mycobacterium bovis* BCG (tuberculosis). These products are listed below for your convenience:

- Super Sani-Cloth® Germicidal Disposable Cloths (EPA Reg. No. 9480-4)
  - Item numbers: Q55172 and Q86984
- Sani-Cloth® AF3 Germicidal Disposable Cloths (EPA Reg. No. 9480-9)
  - Item numbers: P13872 and P63884
- Sani-Cloth® Bleach Germicidal Disposable Cloths (EPA Reg. No. 9480-8)
  - Item numbers: P54072 and P25784

Your customers can continue to use Sani-Cloth® Plus. **If any of your customers contact you with questions regarding the Sani-Cloth® Plus, please have them contact PDI directly at 1-800-999-6423 between 8:45am and 5:15 pm EST.**

#### **What is the reason for this notice?**

The EPA periodically collects and tests samples from a subset of registered public health products in the marketplace using efficacy test methods that provide a rigorous challenge to a product. EPA's Antimicrobial Testing Program recently completed testing on registered tuberculocidal products. The results raised questions about Sani-Cloth® Plus with respect to *Mycobacterium bovis* BCG (tuberculosis), although not with respect to other pathogens identified on the label. PDI has an independent laboratory conducting a test.



While testing is still ongoing, initial results raised a question about efficacy for *Mycobacterium bovis* BCG (tuberculosis). Pending further review and analysis, PDI is voluntarily removing that claim from the Sani-Cloth® Plus. We are working to resolve this issue as soon as possible. We are optimistic that the *Mycobacterium bovis* BCG (tuberculosis) claim will be back on the product label in the future.

**What should you do?**

Please return all existing inventory of the Sani-Cloth® Plus to us at the following address:

Nice Pak Products  
ATTN: RMA  
1 Nice Pak Road (formerly Haworth Road)  
Jonesboro, Arkansas 72404

Prior to returning the product, please call PDI at 1-800-999-6423 to obtain a RMA number. Your RMA number must be referenced on all paper work to ensure proper credit.

**What additional steps is PDI taking?**

PDI will be sending end users who have received this product in the last 24 months a separate notification that the *Mycobacterium bovis* BCG (tuberculosis) claim is being removed from the label until testing is completed. Your customers can continue to use the Sani-Cloth® Plus. The product continues to be efficacious for all other labeled claims.

PDI is committed to providing high quality, reliable products that help stop the spread of healthcare associated infections. PDI will continue to work closely with the EPA to ensure our products meet or exceed governmental requirements and protect the public safety.

If you have any questions, please contact PDI at 1-800-999-6423 between 8:45am and 5:15 pm EST.

Sincerely

A handwritten signature in black ink, appearing to read 'Patrick Treacy', is written over a white background.

Patrick Treacy  
EVP and President of PDI Healthcare

**SANI-CLOTH® PLUS**  
**GERMICIDAL DISPOSABLE CLOTH**

Technical Data Bulletin

PRODUCT DESCRIPTION

A quaternary/alcohol solution impregnated in a wiping cloth. A non-woven disposable cloth for use in hospitals and other critical care areas where the control of the hazards of cross-contamination between treated surfaces is required. Use on hard, non-porous surfaces and equipment made of stainless steel, plastic, Formica® and glass.

CHEMICAL COMPOSITION

Active Ingredients	
n-Alkyl (68% C <sub>12</sub> , 32% C <sub>14</sub> ) dimethyl ethylbenzyl ammonium chlorides .....	0.125%
n-Alkyl (60% C <sub>14</sub> , 30% C <sub>16</sub> , 5% C <sub>12</sub> , 5% C <sub>18</sub> ) dimethyl benzyl ammonium chlorides.....	0.125%
Other ingredients.....	99.750%
TOTAL (Does not include the weight of the cloth) .....	100.000%

Each cloth is nominally saturated with 2,500 ppm of active quaternary ammonium chlorides.

EFFICACY

BACTERIAL ORGANISM EFFICACY

**ORGANISMS:** Methicillin Resistant *Staphylococcus aureus* (MRSA) (ATCC 33592)  
*Staphylococcus aureus* (ATCC 6538)  
*Salmonella enterica* (ATCC 10708)  
*Pseudomonas aeruginosa* (ATCC 15442)  
*Escherichia coli* (E.coli) O157:H7 (ATCC 35150) (PATHOGENIC STRAIN)  
*Escherichia coli* (E.coli) (ATCC 11229)  
*Campylobacter jejuni* (ATCC 29428)

Test Method Used: AOAC Germicidal Spray Slide Test-5% Horse Serum as organic soil  
Exposure Time: 3 minutes at 69°-76° F  
Incubation: 48 hours at 98.6°F  
Results: No growth observed

**ORGANISM:** Vancomycin Resistant *Enterococcus Faecalis* (VRE) (ATCC 51299)

Test Method Used: AOAC Germicidal Spray Slide Test-5% Horse Serum as organic soil  
Exposure Time: 3 minutes at 68°F  
Incubation: 48 hours at 98.6°F  
Results: No growth observed

**VIRAL ORGANISM EFFICACY**

<b>ORGANISMS:</b>	Hepatitis B Virus (HBV), DHBV 16 strain Hepatitis C Virus (HCV), Bovine viral diarrhea virus
Test Method Used:	This test was conducted according to U.S. Environmental Protection Agency guidelines in effect at the time of test for determining virucidal efficacy of disinfectants intended for use on dry nonporous inanimate surfaces.
Organic Soil Load:	Hepatitis B Virus (HBV) 100% duck serum Hepatitis C Virus (HCV) 5% horse serum
Exposure Time:	2 minutes at room temperature (68°–77°F)
Results:	Virucidal against Hepatitis B and Hepatitis C virus according to the criteria established by the U.S. Environmental Protection Agency.
<b>ORGANISM:</b>	Respiratory Syncytial Virus (RSV)
Test Method Used:	This test was conducted according to U.S. Environmental Protection Agency guidelines in effect at the time of test for determining virucidal efficacy of disinfectants intended for use on dry nonporous inanimate surfaces.
Organic Soil Load:	5% fetal bovine serum
Exposure Time:	1 minute at room temperature (68°–77°F)
Results:	Virucidal against Respiratory Syncytial Virus (RSV) according to the criteria established by the U.S. Environmental Protection Agency.
<b>ORGANISM:</b>	Influenza A (H1N1) Virus (ATCC VR-98) (Strain A/Malaya/302/54)
Test Method Used:	This test was conducted according to U.S. Environmental Protection Agency guidelines in effect at the time of test for determining virucidal efficacy of disinfectants intended for use on dry nonporous inanimate surfaces.
Organic Soil Load:	5% fetal bovine serum
Exposure Time:	3 minutes at room temperature (68°–77°F)
Results:	Virucidal against Hepatitis B and Hepatitis C virus according to the criteria established by the U.S. Environmental Protection Agency.
<b>ORGANISMS:</b>	Influenza A2/Hong Kong Herpes Simplex Type 2
Test Method Used:	This test was conducted according to U.S. Environmental Protection Agency guidelines in effect at the time of test for determining virucidal efficacy of disinfectants intended for use on dry nonporous inanimate surfaces.
Organic Soil Load:	5% fetal bovine serum
Exposure Time:	1 minute
Results:	Virucidal according to the criteria established by the U.S. Environmental Protection Agency.
<b>ORGANISM:</b>	HIV-1 (AIDS Virus)
Test Method Used:	This test was conducted according to U.S. Environmental Protection Agency guidelines in effect at the time of test for determining virucidal efficacy of disinfectants intended for use on dry nonporous inanimate surfaces.
Organic Soil Load:	5% fetal bovine serum
Exposure Time:	1 minute at room temperature (68°–77°F)
Results:	Virucidal against HIV-1 according to the criteria established by the U.S. Environmental Protection Agency.

## TOXICITY

### ACUTE ORAL TOXICITY STUDY OF SANI-CLOTH® PLUS

**Conclusion:** A single-dose of Sani-Cloth® Plus solution was administered and observed for 14 days. No signs of toxicity were observed during the 14-day observation period of this study. Based on the results of this study, the acute oral toxicity LD50 of Sani-Cloth® Plus is greater than 5g/kg of body weight.

### PRIMARY EYE IRRITATION OF SANI-CLOTH® PLUS

**Conclusion:** One eye of each subject was instilled with the undiluted solution, while the contralateral eye remained untreated and served as a control. Under the conditions of the test, Sani-Cloth® Plus produced eye irritation clearing in 7 days or less.

### ACUTE DERMAL TOXICITY OF SANI-CLOTH® PLUS

**Conclusion:** Following the single dermal administration, the subjects were observed for 14 days. Under the conditions of this test, the acute dermal LD50 of Sani-Cloth® Plus was found to be greater than 2g/kg of body weight.

### PRIMARY DERMAL IRRITATION SANI-CLOTH® PLUS

This test was conducted according to U.S. Environmental Protection Agency guidelines in effect at the time of testing. The subjects were exposed to the moist towelette for a total of 4 hours. Under the conditions of this test, Sani-Cloth® Plus produced only very slight erythema at 72 hours.

### DERMAL SENSITIZATION TEST: SANI-CLOTH® PLUS

This test was conducted according to U.S. Environmental Protection Agency guidelines in effect at the time of testing to determine the potential for Sani-Cloth® Plus to produce sensitization after repeated topical applications. Based on the results of this test, Sani-Cloth® Plus would not be considered a dermal sensitizing agent.