

EFFICACY AND SCIENCE SUPPORT BRANCH
ANTIMICROBIAL DIVISION
EFFICACY REVIEW - I

In: 9/11/98 Out: December 1, 1998

Reviewed by: Ian Blackwell Date: October 15, 1998

EPA Reg. No.: 5813-AT

DP Barcode: D249286

EPA Petition No.: none

Date Division Received: 8/21/98

Type Product: disinfectant for hard, non-porous surfaces

MRID No.: 446369-08 through 446369-34

Product Manager: Marshall Swindell, PM 33

PM Team Reviewer: Tony Kish

Product Name: Clorox 409-R

Company Name: The Clorox Company

Submission Purpose: Register product as a hard-surface disinfectant, sanitizer and hospital-use disinfectant. To demonstrate efficacy against additional organisms: Streptococcus pyogenes, Vancomycin resistant Enterococcus faecalis, Escherichia coli, Prtoeus mirabilis, Klebsiella pneumoniae, Listeria monocytogenes, Trichophyton mentagrophytes, Poliovirus type 1, Rotavirus, Herpes simplex virus type 2, Rhinovirus type 37, Influenza virus type A₂, Echovirus type 11, Hepatitis A virus, Human Immunodeficiency Virus Type 1, Adenovirus type 2, and Respiratory syncytial virus.

Type Formulation: Home and hospital type spray disinfectant and sanitizer.

Active Ingredients:

Octyl decyl dimethyl ammonium chloride	0.1890%
Diocetyl dimethyl ammonium chloride	0.0945%
Didecyl dimethyl ammonium chloride	0.0945%
Alkyl (50% C14, 40% C12, 10% C16) dimethyl benzyl ammonium chlorides	0.2520%
Ethanol	65.0000%

200.0 **Introduction:**

200.1 **Uses:** Hard surface disinfectant and/or sanitizer

200.2 **Background Information:** <none>

201.0 **Data Summary:**

201.1 **Abstract of Test Reports:**

None

201.2 **Brief Description of Test: (title)**

201.3 **Data Summaries**

None

201.4 **Other Summarized Results:**

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RISK ASSESSMENT AND SCIENCE SUPPORT BRANCH

ANTIMICROBIAL DIVISION

EFFICACY REVIEW - II

EPA Reg. No. or File Symbol: 5813-AT / Clorox 409-R

EPA Petition or EUP No.: none

Date Division Received: 8/21/98

Product Type: Hard surface disinfectant, sanitizer

MRID No(s): 446369-08 through 446369-34

Product Management Team: PM 33, Marshall Swindell

Product Name: Clorox 409-R

Company Name: The Clorox Company

202.0 Recommendations

202.1 Efficacy Supported By The Data:

1. The submitted data conducted by the AOAC Germicidal Spray Product Test Method are acceptable to support effectiveness of the product as a hospital disinfectant against Staphylococcus aureus ATCC 6538, Salmonella choleraesuis ATCC 10708, and Pseudomonas aeruginosa ATCC 15442 when used as an undiluted pressurized spray on pre-cleaned hard, non-porous surfaces for a contact time of 10 minutes at room temperature.
2. Also, the submitted data conducted by the AOAC Germicidal Spray Product Test Method are acceptable to support effectiveness of the product as a disinfectant against Escherichia coli 0157:H7 ATCC 35150, Staphylococcus aureus (MRSA) ATCC 33592, Streptococcus pyogenes ATCC 19615, Vancomycin-resistant Enterococcus faecalis ATCC 51299, Proteus mirabilis ATCC 9240, Klebsiella pneumoniae ATCC 4352 and Listeria monocytogenes ATCC 35152 when used as an undiluted pressurized spray on pre-cleaned hard, non-porous surfaces for a contact time of 10 minutes at room temperature.
3. Also, the submitted confirmatory efficacy data conducted by the AOAC Germicidal Spray Product Test Method on Formulas 046 and 047 are acceptable to support effectiveness of the product as a hospital disinfectant against Staphylococcus aureus ATCC 6538, Salmonella choleraesuis ATCC 10708 and Pseudomonas aeruginosa ATCC 15442 when used as an undiluted pressurized spray on pre-cleaned hard, non-porous surfaces for a contact time of 10 minutes at room temperature.
4. Also, the submitted data conducted by the AOAC Fungicidal Test Method are acceptable to support the effectiveness of the product as a fungicide against Trichophyton mentagrophytes ATCC 9533 when used as an undiluted pressurized spray on pre-cleaned, hard, non-porous surfaces for a contact time of 10 minutes at room temperature.
5. Also, the submitted virucidal data conducted by the AOAC Germicidal Spray Product Test Method are acceptable to support the effectiveness of the product as a virucide against Poliovirus Type 1, ATCC VR-1000, Strain Brunhilde, Rotavirus Strain WA, Herpes Simplex Virus Type 2, Rhinovirus Type 37, Influenza Virus Type A₂/Hong Kong, Echovirus Type II ATCC VR-41 Strain Gregory, Hepatitis A Virus, Human Immunodeficiency Virus Type 1, Adenovirus Type 2 and Respiratory Syncytial Virus.
6. Also, the submitted residual self-sanitizing test data appear to demonstrate residual self-sanitizing activity ($\geq 99.9\%$ reduction) of dried chemical residue on undisturbed, untouched, hard non-porous, inanimate surfaces in non-traffic areas over a period of 24 hours against Staphylococcus aureus ATCC 6538, Klebsiella pneumoniae ATCC 4352, Escherichia coli 0157:H7, and Salmonella choleraesuis ATCC10708 when used as an undiluted pressurized spray for a contact time of 10 minutes at room temperature.

202.2 **Claims Not Related to Human Health:**

The claims against Aspegillus niger is not considered to be related to human health. Thus, supporting efficacy data are not required to be submitted. However, registrants are required to develop the data and keep on record. The Agency retains the right to call in such data at any time.

203.0 **Labeling:**

On page 2 , under the heading “To Sanitize [for 24 hours]”

1. Delete the statement, “*FOR INSTITUTIONAL PRODUCTS ONLY: Apply spray more often in high traffic areas-or-on frequently touched surfaces*” because these use conditions were not included in the residual self-sanitizing test or delete “[24 hours].”
2. Specify use areas, surfaces or objects intended for treatment.
3. Change “To Sanitize” to read “To Sanitize Non-Food Contact Surfaces.”
4. Change the heading “To Sanitize [for 24 hours]” to read “To Sanitize undisturbed, and untouched hard, nonporous non-food contact surfaces in non traffic areas [for 24 hours]:”

On page 2, under the heading, “To deodorize: spray on surfaces as needed” the statement, “Safe for [colored] surfaces -and/or-[colored] fabrics” suggests that 65% ethanol will not decolorize colored surfaces and colored fabrics. Please provide explanations.

On page 2:

1. The phrases, “Is safe for most hard, nonporous surfaces,” “Color safe,” “Safe for -or- on colors,” “Safe for [colored] hard, nonporous surfaces and fabrics” suggests that 65% ethanol will not decolorize colored surfaces and colored fabrics. Please provide explanations.
2. Submit documents to show that it is a patented formula or delete the phrase “Patented formula” wherever it appears on the label.
3. “For use throughout your house” is too broad and must be changed to “For use throughout your house on hard, non-porous surfaces.”
4. Delete the phrase “Nothing lasts longer than this product.”
5. Change “[Multi-purpose -or- multi-surface disinfectant spray]” to read “[Multi-purpose -or- multi-hard nonporous surface disinfectant spray].”

6. Under the heading "This [patented] formula disinfects against all of the following organisms..."
- a. Specify the type of Adenovirus, and strain of Influenza A2 virus.
 - b. Change "Kills contagious germs..." to read "Kills germs..."
 - c. Change "This product meets AOAC efficacy standards for hospital disinfectants" to read "This product meets AOAC Germicidal Spray Product Test efficacy standards for hospital disinfectants."
 - d. Revise the statement "Kills germs such as Staphylococcus aureus (staph)...on frequently touched hard, nonporous surfaces" to read "Kills germs such as Staphylococcus aureus (staph)...on hard, nonporous surfaces."
 - e. Revise the statement "Kills 99.9% of (household) germs...for 24 hours" to read "Kills 99.9% of (household) germs...for 24 hours on undisturbed, and untouched hard, nonporous surfaces in non traffic areas such as shower walls, public restroom walls near toilet."
 - f. Revise the statement "Kills germs such as Staphylococcus aureus...and continues to kill 99.9% of germs for 24 hours" to read "Kills germs such as Staphylococcus aureus...continues to kill 99.9% of germs for 24 hours on undisturbed, and untouched hard, nonporous surfaces in non traffic areas such as shower walls, public restroom walls near toilet."
 - g. Revise the statement "Kills germs such as Staphylococcus aureus...[and keeps killing them] for 24 hours" to read "Kills 99.9% of germs such as Staphylococcus aureus...[and keeps killing them] for 24 hours on undisturbed, and untouched hard, nonporous surfaces in non traffic areas such as shower walls, public restroom walls near toilet."
 - h. Revise the statement "Keeps killing germs...for 24 hours" to read "Keeps killing 99.9% of germs...for 24 hours on undisturbed, and untouched hard, nonporous surfaces in non traffic areas such as shower walls, public restroom walls near toilet."
 - i. Revise the statement "Sanitizes for 24 hours" to read "Sanitizes (99.9% kill) undisturbed, and untouched hard, nonporous non-food contact surfaces in non traffic areas such as shower walls, public restroom walls near toilet."
 - j. Revise the statement "Protects hard, nonporous surfaces from germs...for 24 hours" to read "Sanitizes (99.9% kill) undisturbed, and untouched hard, nonporous surfaces in non traffic areas such as shower walls, public restroom walls near toilet from germs...for 24 hours."

- k. Revise the statement "Kills germs such as Staphylococcus aureus (staph)...on frequently touched hard, nonporous surfaces for 24 hours" to read "Kills 99.9% of germs such as Staphylococcus aureus (staph)...on undisturbed, and untouched hard, nonporous surfaces in no traffic areas such as shower walls, public restroom walls near toilet for 24 hours."
- l. "Kills germs such as Staphylococcus aureus (staph)...on hard, nonporous surfaces for 24 hours, even after they've been touched" to read "Kills 99.9% of germs such as Staphylococcus aureus (staph)...on undisturbed, and untouched hard, nonporous surfaces in non traffic areas such as shower walls, public restroom walls near toilet for 24 hours."
- m. Revise the statement "With one spray, it keeps killing germs...on a hard, nonporous surface for 24 hours" to read "With one spray, it keeps killing 99.9% of germs...on undisturbed, and untouched hard, nonporous surfaces in non traffic areas such as shower walls, public restroom walls near toilet for 24 hours."
- n. Revise the statement "24 hour protection" to read "Provides 24 hour residual self-sanitizing activity (99.9% kill) on undisturbed, and untouched hard, nonporous surfaces in non traffic areas such as shower walls, public restroom walls."
- o. Revise the statement "Kills 99.9% of infectious germs such as Staphylococcus aureus...for 24 hours" to read "Kills 99.9% of infectious germs such as Staphylococcus aureus...for 24 hours on undisturbed, and untouched hard, nonporous surfaces in non traffic areas such as shower walls, public restroom walls near toilet."

On page 3:

- a. Delete the bullets "Breakthrough technology -or- formula" and "Long lasting formula".
- b. Change "This product meets [all] [established] AOAC efficiency standards for hospital aerosol disinfectants" to read "This product meets AOAC Germicidal Spray Product Test efficacy standards for hospital aerosol disinfectants."
- c. "Change "This product is considered a Hospital Grade [Level] Disinfectant" to read "This product is considered a Hospital Disinfectant."
- d. Change "Kills germs such as...on surfaces everyone gets their hands on - doorknobs..." to read "Kills germs such as...on hard nonporous surfaces, doorknobs..."
- e. Specify the strain of Influenza A2 virus.
- f. Delete the statement "This product is unlike any disinfecting spray available to date."

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- g. Revise the statement "This product eliminates odors and kills germs such as...for up to 24 hours even after -or-though the surface is touched" to read "This product eliminates odors and kills 99.9% of germs such as...for up to 24 hours on undisturbed, and untouched hard, nonporous surfaces in no traffic areas such as shower walls, public restroom walls near toilet."
- h. Revise the statement "This product is the first -or- only disinfecting spray that keeps killing [99.9%] of germs such as...for 24 hours" to read "This disinfecting spray product keeps killing [99.9%] of germs such as...for 24 hours on undisturbed, and untouched hard, nonporous surfaces in non traffic areas such as shower walls, public restroom walls near toilet."
- i. Revise the statement "This product continues to kill germs such as...long after you have sprayed" to read "This product continues to kill 99.9% of germs such as...24 hours long after you have sprayed on undisturbed, and untouched hard, nonporous surfaces in non traffic areas such as shower walls, public restroom walls near toilet."
- j. Revise the statement "From the makers of Clorox bleach -or- products comes a new, disinfecting spray that keeps killing 99.9% of germs such as...for 24 hours" to read "From the makers of Clorox bleach -or- products comes a new, disinfecting spray that keeps killing 99.9% of germs such as...for 24 hours on undisturbed, and untouched hard, nonporous surfaces in non traffic areas such as shower walls, public restroom walls near toilet."
- k. Revise the statement "Kills...for 24 hours" to read "Kills 99.9% of...for 24 hours on undisturbed, and untouched hard, nonporous surfaces in no traffic areas such as shower walls, public restroom walls near toilet."
- l. Revise the statement "This product kills household germs throughout the house [for 24 hours] plus prevents mold and mildew growth" to read "This product kills 99.9% of household germs throughout the house [for 24 hours] on undisturbed, and untouched hard, nonporous surfaces in non traffic areas such as shower walls, public restroom walls near toilet, plus controls mold and mildew growth."
- m. Include the disclaimer statement "This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection".
- n. Under the heading "Disinfects:-or-Effective disinfectant and deodorize for:-or-Excellent for controlling mold and mildew on:-or-Excellent for:-or Excellent [for] use on:-or-Effective on: change "Sick Rooms" to read "non-critical surfaces/items in Sick Rooms" and "Patient Care Items" to read "Non-Critical Patient Care Items".

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Also, specify these items.

- o. Under the heading **“For use on hard, non-porous surfaces in:-or Great for use in:-or-For use in:-or-Effective disinfectant and deodorizer in:-or Excellent for controlling mold and mildew in:-or-Excellent in:”** remove “Hospitals”, “Patient Rooms”, “Emergency Rooms”, “Nursing Homes”, “Operating Rooms”, “Recovery Rooms”, “Blood Banks”, “Medical/Dental/Physician Offices”, “[Medical] Clinics”, and “Examination Tables” and list them under a separate heading, **“For use on non-critical, hard, non-porous surfaces in:-or Great for use on non-critical surfaces in:-or-For use on non-critical surfaces in:-or-Effective disinfectant and deodorizer on non-critical surfaces in:-or-Excellent for controlling mold and mildew in:-or-Excellent on non-critical surfaces in:”**