

6659-3

12/4/2009

1088

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

DEC 4 2009

Mr. John Lee
Consultant for Spray Nine Corporation
9456 Elvis Lane
Lanham, MD 20706

Subject: Spray Nine
EPA Registration No.: 6659-3
Amendment Date: August 14, 2009
EPA Receipt Date: August 17, 2009

Dear Mr. Lee,

The following amendment submitted in connection with registration under FIFRA, as amended, is acceptable with the conditions listed below.

Proposed Amendment

Add Pandemic H1N1 Influenza A Virus Claims

Conditions

Revise your label as follows:

1) The Agency published guidance on the Internet pertaining to Testing and Labeling Claims against Pandemic 2009 H1N1 Influenza A Virus Claims. If your product bears a claim against human, avian, or swine influenza A virus and efficacy data was submitted and accepted, you may have the following claims (www.epa.gov/oppad001/h1n1-guide):

a) Respiratory illness attributable to Pandemic 2009 H1N1 are caused by Influenza A virus. This product (Spray Nine) is a broad spectrum hard surface disinfectant that has been shown to be effective against Influenza A2 Virus and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).

b) This product has demonstrated effectiveness against Influenza A2 and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 Influenza A Virus.

c) This product has demonstrated effectiveness against Influenza A2 Virus and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 Influenza

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

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A virus (formerly called swine flu).

d) Kills Pandemic 2009 H1N1 Influenza A virus (formerly called swine flu).

e) Kills Pandemic 2009 H1N1 Influenza A Virus

2) Delete references to "Swine Flu Virus" on page 1 and 3 and state "Pandemic 2009 H1N1 Influenza A Virus).

General Comments

A stamped label accepted with conditions is enclosed. Please submit one (1) copy of the final printed label before distributing or selling the product bearing the revised labeling.

Should you have any questions regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,



Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510P)

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

(FRONT PANEL)

Tough Task Cleaner
 Tough Task Cleaner & Disinfectant
 Deodorizes as it cleans
 Degreases and Disinfects
 Cuts Grease
 Reduces the risk of cross contamination
 Tough on Grease, Grime & Stains!
 Antibacterial Disinfectant/Sanitizer

Kills Germs Too!
 Removes Tough Stains
 Dissolves grease on contact
 Tackles Tough Soils

Spray Nine®
MULTI-PURPOSE CLEANER/DISINFECTANT

Kills **VIRUSES*** in 30 seconds!

Kills **Salmonella enterica, E. coli, and other germs in 45 seconds! †**

Kills **99.9% of Bacteria in 10 Seconds! ♦**

~~Kills Swine Flu Virus*!~~

~~Kills Swine Flu Virus in 30 seconds*!~~

~~Kills Swine Flu Virus Type H1N1*!~~

~~Kills Swine Flu Virus Type H1N1 in 30 seconds*!~~

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6659-3

KEEP OUT OF REACH OF CHILDREN
CAUTION

See Back Panel for Additional Precautionary Statements

Active Ingredients

n-Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈)	
dimethyl benzyl ammonium chloride	0.15%
n-Alkyl (68% C ₁₂ , 32% C ₁₄)	
dimethyl ethylbenzyl ammonium chloride	0.15%
Other Ingredients ‡	99.70%
	100.00%

‡ Includes detergents and other grease cutting agents.

NET _____

(BACK PANEL)**SPRAY NINE®**

Versatile

Tough Task Cleaner, Degreaser and Stain Remover

Multi-Purpose Cleaner/Degreaser.

Antibacterial Disinfectant/Sanitizer and Deodorizer

Disinfects and Deodorizes, too!

CLEANING – Spray Nine digs out tough soils like grease, oil, grime, food/drink stains, crayon, ink, fresh paint, fingerprints, soap scum, smoke, soot, fish blood, silt, tough automotive soils, tar, bug splatter, road grime, brake dust, grass stains, nicotine stains, suntan oil, adhesives, bird droppings, ground in dirt, wallpaper paste ---with spray on-wipe off ease. Powers off tough grease and grime. Spray Nine is great as a black streak remover. Removes burned on food and carbon deposits quickly and effectively. Spray Nine is great when used for prepping surfaces for paint, wall and decorative hangings.

Peel Here To Open Label (small sizes only)

[kitchen pictograph]

Countertops · Stoves · Exterior surfaces of Refrigerators · Sinks

[bathroom pictograph]

Tubs · Showers · Tile · Sinks · Toilet Exteriors

[household pictograph]

Toys · Tools · Floors · Garbage Pails · Nursery

[outdoors pictograph]

Patio Furniture · Boats · BBQ Grills · Vinyl Siding · Jet Skis

[auto/rv pictograph]

Tires · Wheels · Vinyl · Mats

[institutional pictograph]

Rest Rooms · Cafeteria · Showers · Patient Rooms

Break Room – Workplace

DISINFECTING – When used as directed, Spray Nine will disinfect hard non-porous surfaces such as countertops, stainless steel, tables, walls and floors".

- Spray Nine kills [HIV-1 (associated with AIDS)] [Influenza A₂] [Rhinovirus Type 37] [Respiratory Syncytial Virus] [Herpes Simplex Virus Type 1 & 2] [Coxsackie B3 Virus] [Norwalk/Norovirus] [Hepatitis B Virus] [Hepatitis C Virus] [~~Swine Influenza Virus Type H1N1~~] and other viruses* in just 30 seconds.
- Spray Nine kills [Salmonella enterica] [E. coli] [Staphylococcus aureus] [Pseudomonas aeruginosa] [Staphylococcus aureus-MRSA] [Staphylococcus aureus-CA-MRSA] [Streptococcus pyogenes] [Enterobacter aerogenes] [Shigella dysenteriae] and other germs in just 45 seconds. †
- Spray Nine kills [Trichophyton mentagrophytes, the organism that causes Athlete's Foot fungus], [Candida albicans], helps control mold and mildew and destroys bacterial odors.

♦SANITIZING NON-FOOD CONTACT SURFACES -When used as directed, Spray Nine will sanitize hard non-porous surfaces such as tables, walls and floors.

- Spray Nine kills 99.9% Staphylococcus aureus in just 10 seconds.
- Spray Nine kills 99.9% Klebsiella pneumoniae in just 10 seconds.

INSTITUTIONAL USE – Spray Nine is ideal for hospitals, nursing homes, day-care centers, schools and other institutions where cleaning and disinfecting are of prime importance.

"PEEL OPEN FOR USE DIRECTIONS and complete disinfection information.

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Product: Spray Nine (EPA Reg. No. 6659-3) Registrant: Spray Nine Corp (EPA Est. 6659-NY-1) 8/6/09

[UPC Code] ["please recycle"]

Spray Nine Corporation

PO Box 290

Johnstown, NY 12095 · (518) 762-4591 · 1-800-477-7299

Spray Nine Corporation and ITW Performance Polymers

& Fluids; Illinois Tool Works Companies

Spray Nine is a trademark of Illinois Tool Works Inc. ©2009

Solon, OH 44139

Made in USA

www.spraynine.com

Item# 00000 0000000(component#)

(BACK PANEL CONTINUED)

When used as directed, Spray Nine provides effective Virucidal* / Bactericidal† / Fungicidal activity against the following organisms

***VIRUSES (Contact time: 30 seconds)**

Influenza A₂ Virus
 Rhinovirus Type 37
 Respiratory Syncytial Virus
 Adenovirus Type 2
 Herpes Simplex Virus Type I
 Herpes Simplex Virus Type II
 Coxsackie B3 Virus
 Norwalk/Norovirus
 Rotavirus
 HIV-1**
 Hepatitis B Virus **
 Hepatitis C Virus **
~~Swine Influenza Virus Type H1N1~~

Associated With:

Common Flu
 Upper respiratory tract illnesses including common cold
 Respiratory illnesses – especially in children under 12.
 Upper respiratory infections, Tonsillitis, Conjunctivitis
 Fever blisters, Mononucleosis
 Genital Disease
 Hand-foot-mouth disease
 Norwalk Virus
 Gastrointestinal illnesses
 AIDS
 Hepatitis B infection related illnesses
 Hepatitis C infection related illnesses
~~Swine Flu~~

†BACTERIA (Contact time: 45 seconds)

Salmonella enterica
 Escherichia coli (E. coli)
 Staphylococcus aureus
 Staphylococcus aureus – MRSA
 Staphylococcus aureus – CA-MRSA
 Streptococcus pyogenes
 Pseudomonas aeruginosa
 Enterobacter aerogenes
 Shigella dysenteriae

Food poisoning and gastroenteritis
 Food poisoning, urinary and wound infections
 Infections such as Meningitis and Carbuncles
 Methicillin-resistant Staphylococcus aureus
 Community acquired Methicillin-resistant Staphylococcus aureus
 Pharyngitis (strep throat), scarlet fever and impetigo
 Numerous hospital infections
 Coliform bacteria – causes food poisoning and spoilage
 Bacterial dysentery such as Montezuma's revenge

FUNGI (Contact time: 3 minutes)

Trichophyton mentagrophytes
 Candida albicans

Athletes Foot Fungus
 Diaper rash, thrush, vaginitis and dermatitis

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Some surfaces are inherently sensitive to alkaline cleaners. Always test on a small area of surface to be cleaned and air dry completely to determine colorfastness and surface integrity. Do not use on wool, leather, glass, untreated wood, treated fabrics or weathered surfaces. Do not use this product in combination with caustics, acids or bleach.

(Patio, BBQ and Marine – additional directions for use) Outdoor surfaces subjected to severe weather conditions, especially UV exposure, may be particularly sensitive to alkaline cleaners. Follow the outdoor surface manufacturer's recommended cleaning instructions. Do not use this product in combination with caustics, acids or bleach.

TO CLEAN:

1. Spray on soiled surface.
2. Wipe thoroughly with a clean damp sponge/cloth or rinse. (Do not allow to dry on surface)
3. For assistance with specific cleaning problems, call 1-800-477-7299.

Note: Heavy deposits, stubborn soils and stains may require scrubbing or additional applications.

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FOR PREPPING PAINT SURFACES: Spray Nine has been tested according to ASTM D 3395-95a and has proven to ensure maximum adhesion for paint, wallpaper border and decorative coverings for a professional job that looks better and lasts longer. To clean: 1. Spray on soiled surface. 2. Wipe thoroughly with a clean damp sponge/cloth or rinse. 3. For assistance with specific cleaning problems, call 1-800-477-7299.

BBQ GRILL DIRECTIONS: Do not spray on lava rocks, charcoal or heating elements. Always remove cooking grate prior to cleaning it. Turn off gas and allow surface to cool before applying. Use a brush to loosen and remove heavy deposits. Tough deposits may require additional applications and scrubbing. Cooking grate must be rinsed with potable water after cleaning it.

(BACK PANEL CONTINUED)

TO DISINFECT / DEODORIZE:

1. Clean surface as instructed above.
2. Repeat application making sure to wet all surfaces thoroughly.
3. Allow to stand for 45 seconds (30 seconds for viruses)
4. Wipe thoroughly with a clean damp sponge/cloth or rinse.
5. When used on food contact surfaces such as counters and tables, rinse thoroughly with potable water. Do not use on dishes, glasses, or silverware.
6. When used in Meat and Poultry Plants, food products and packaging materials must be removed from room or carefully protected. After use surfaces must be thoroughly rinsed with potable water.

TO SANITIZE HARD, NON-POROUS SURFACES:

1. Clean surface as instructed above.
2. Spray thoroughly, making sure to wet all surfaces completely.
3. Allow to stand for 10 seconds minimum.
4. Wipe thoroughly with a clean damp sponge/cloth or rinse.

TO CONTROL MOLD AND MILDEW on pre-cleaned, hard, non-porous surfaces: Spray thoroughly, making sure to wet surface completely. Allow to stand for 3 minutes. Wipe off with a clean damp sponge or cloth and rinse thoroughly. Reapply as necessary.

FUNGICIDAL ACTIVITY: Spray Nine kills Trichophyton mentagrophytes (pathogenic fungi that causes Athlete's Foot Fungus), and Candida albicans in areas such as shower and bath area, locker rooms, and dressing rooms on pre-cleaned, hard, non-porous surfaces: Spray thoroughly, making sure to wet surface completely. Allow to stand 3 minutes minimum before rinsing.

FUNGISTATIC ACTIVITY: When used as directed above, Spray Nine is an effective fungistat in controlling the growth of Aspergillus niger.

****KILLS HIV, HBV, and HCV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in health care settings (Hospitals, Nursing Homes) or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS), Hepatitis B virus, and Hepatitis C virus.

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV, HBV, and HCV OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS: **PERSONAL PROTECTION:** When handling items soiled with blood or body fluids, use disposable latex gloves, gowns, masks and eye coverings. **CLEANING PROCEDURES:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before disinfection. **CONTACT TIME:** Allow surface to remain wet for 30 seconds. Allow 45 seconds to kill bacteria and 3 minutes to kill fungi cited on the label.

DISPOSAL OF INFECTIOUS MATERIALS: Blood and other body fluids must be autoclaved and disposed of according to local regulations for infectious waste disposal.

MEDICAL USE 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 normal 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.**

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Product: Spray Nine (EPA Reg. No. 6659-3) Registrant: Spray Nine Corp (EPA Est. 6659-NY-1) 8/6/09

VETERINARY AND POULTRY USE- Spray Nine may be used as directed to treat high touch hard nonporous surfaces (e.g. cages, equipment tables, lab benches, faucet handles, or door knobs) in residential, commercial, institutional, and industrial settings.

Spray Nine is effective against the following Veterinary/Poultry related organisms:

VIRUSES-(30 second contact time)

- Feline Calicivirus –Associated with upper respiratory infections and pneumonia in cats
- Avian Influenza A Virus (H3N2)- Kills avian influenza A virus on pre-cleaned environmental surfaces-this product is for use on hard nonporous not conducive to treatment by immersion or excess liquid against Avian Influenza A.

PRECAUTIONARY STATEMENTS

Hazards to humans and domestic animals.

Caution. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. For prolonged use, protective gloves are recommended. Wash thoroughly with soap and water after handling.

FIRST AID

If in eyes: Hold eyelid open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes. Then continue rinsing eye. Call a poison control center or doctor for treatment advice.

If on skin or on clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.

EPA EST. 6659-NY-1
EPA REG. NO. 6659-3

Made in USA
[Stock number]

EPA EST. 6659-OH-1
EPA REG. NO. 6659-3

SPRAY NINE CORPORATION

PO Box 290, Johnstown, NY 12095 · (518) 762-4591 · 1-800-477-7299

Spray Nine Corporation and ITW Performance Polymers
& Fluids; Illinois Tool Works Companies
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Solon, OH 44139
Made in USA
www.spraynine.com
Item# 00000 0000000(component#)

(BACK PANEL VARIATIONS AND ADDITIONAL INFORMATION FOR INDUSTRIAL AND INSTITUTIONAL SIZES ONLY)

Spray Nine
Effective, Versatile, Multi-Purpose
Cleaner · Degreaser · Disinfectant · Virucide* · Fungicide · Deodorizer · Sanitizer

Spray Nine® digs out tough grease, grime and other stubborn soils with "Spray on – Wipe off" ease from stainless steel, plastic, glazed tile, rubber, vinyl, fiberglass bathtubs and sinks, glazed porcelain, formica and other hard surfaces. Spray Nine is ideal for hospitals, nursing homes, day-care centers, schools and other institutions where cleaning and disinfecting are of prime importance. Spray Nine is authorized by USDA for use in federally inspected meat and poultry plants.

MEDICAL USE 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 normal 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.**

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STORAGE AND DISPOSAL

(for containers 1 gallon or less):

Storage and Disposal: Keep from freezing or temperature greater than 120°F. Store in original container in area inaccessible to children and persons unfamiliar with proper product use. Container may be refilled with Spray Nine. Do not reuse empty bottle with any other product. Rinse empty container thoroughly and discard in trash or recycle where available.

(for containers greater than 1 gallon):

Storage and Disposal: Do not contaminate water, food or feed by storage or disposal.

Storage: Keep from freezing or temperature greater than 120°F. Store in original container in area inaccessible to children and persons unfamiliar with proper product use.

PESTICIDES DISPOSAL: Wastes resulting from the use of this product may be disposed of on-site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Nonrefillable Container. Do not refill or reuse container. Triple rinse as follows: Fill container ¼ full with water and recap. Shake for 10 seconds. Follow pesticide disposal instructions for rinsate disposal. Drain for 10 seconds after the flow begins to drip. Repeat procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill.

(all container sizes)

ENVIRONMENTAL HAZARDS: This product is toxic to fish, aquatic invertebrates, shrimp, and oysters.

(containers sizes 5 gallons or larger)

ENVIRONMENTAL HAZARDS:

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the pertaining authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water or Regional Office of the EPA. This product is toxic to fish, aquatic invertebrates, shrimp, and oysters.

HOME [pictograph]

Kitchen · Bathroom · Work
Shop · Vinyl Siding & Wall
Covering · Tools · Toys

OUTDOORS [pictograph]

Boats · RV's · Sporting &
Camping Equipment ·
Outdoor Furniture

AUTO/RV [pictograph]

Tires · Wheels · Vinyl
Bumpers · Seats
Mats · Chrome

INSTITUTIONS [pictograph]

Rest Rooms · Cafeteria
Showers · Patient Rooms
Walls & Floors