

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 3 - 2006

Ms. Claudia E. Britton
Spray Nine Corporation
251 North Comrie Ave.
Johnstown, NY 12095-0290

Subject: **Spray Nine**
EPA Registration Number 6659-3
Application Date May 8, 2006
EPA Received Date May 10, 2006

Dear Ms. Britton:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act,(FIFRA), as amended is acceptable with the following comment:

Proposed Amendments:

- Amendment to add germ kill claims

Efficacy Review Comments:

1. The proposed label claims are acceptable regarding the use of the product, Spray Nine (Ready-to-Use), as disinfectant against the following microorganisms on pre-cleaned, hard, non-porous surfaces for the contact times listed:

Feline calicivirus	30 seconds
Norwalk/Norovirus	30 seconds
Rotavirus	30 seconds
Coxsackie B3 virus	30 seconds
<i>Enterococcus faecalis</i> Resistant VRE	1 minute

Data provided support these claims. Please refer to the Conclusion section regarding Avian influenza claims.

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

2. The proposed label claims that the product, Spray Nine (Ready-to-Use), is an effective fungicide against *Aspergillus niger* on pre-cleaned, hard, non-porous surfaces for a contact time of 3 minutes. Data provided **do not support** this claim. Efficacy data provided demonstrate that the product is an effective fungistat, not fungicide. In order to include disinfectant/fungicide claims against *Aspergillus niger* on the proposed label, you must provide efficacy data that fully meet DIS/TSS-6 requirements for pathogenic fungi. Fungicidal label claims can be modified to fungistat label claims.

3. The proposed label claims that the product, Spray Nine, is effective in sanitizing non-food contact surfaces against *Salmonella choleraesuis* and *Klebsiella pneumoniae* for a contact time of 10 seconds. **Data provided support claims against *Staphylococcus aureus* and *Klebsiella pneumoniae*, but not *Salmonella choleraesuis* (now *Salmonella enterica*).** References to *Salmonella choleraesuis*, as they related to sanitizer claims, must be changed to *Staphylococcus aureus* on page 2 of the proposed label. Furthermore, the label language (on the front page) be expanded to clarify the specific microorganisms that are killed in 10 seconds ("Kills 99.9% of Germs in 10 Seconds").

4. The designation for *Salmonella choleraesuis* has been changed to *Salmonella enterica*. This change must be reflected on the current and future submissions.

5. In accordance with DIS/TSS-18 and -19, the "Veterinary and Poultry Use" section of the proposed label must be revised to include the following steps:

- Remove all litter, manure, and droppings from floors, walls, and surfaces of facilities occupied or traversed by animals and poultry.
- Empty all troughs, racks, and other feeding and watering appliances.
- Thoroughly clean all surfaces with soap or detergent and rinse with water.
- Saturate surfaces with the product for a period of 10 minutes.
- Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.
- Ventilate buildings, coops, vehicles, and other closed spaces. Do not house animals/poultry or employ equipment until treatment has been absorbed, set, or dried.
- Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, and water with soap or detergent, and rinse with potable water before reuse.

6. The proposed label indicates that the product may be used on carpets (see pages 2 and 6 of the proposed label). Carpets are porous materials, thus all references to carpet must be deleted.

7. The following changes must be made to the proposed label:

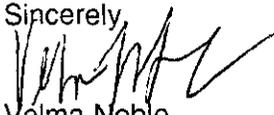
- On page 2 of the proposed label, change "BBQ Gills" to read "BBQ Grills"
- On page 2 of the proposed label, change "organism that causes Otomycosis" to read "organism that causes Otomycosis"
- On page 3 of the proposed label, change "Enterocuccus" to read "Enterococcus"
- On page 4 of the proposed label, change "nasal sinus infrections" to read "nasal sinus infections."

General Comments:

A stamped copy of the acceptable labeling is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Drusilla Copeland at (703) 308-6224.

Sincerely,



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

Enclosure: Efficacy Review Dated 8/18/06 and Label

4 8 9

(FRONT PANEL)

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

Kills Germs Too!
Removes Tough Stains
Kills Mold!

Spray Nine®
MULTI-PURPOSE CLEANER/DISINFECTANT

Kills **VIRUSES*** in **30 seconds!**
Kills **Salmonella choleraesuis, E. coli,** and
other germs in 45 seconds! †
Kills **99.9% of Germs in 10 Seconds!**

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 ‡	<u>99.70%</u>
	100.00%

‡ Includes detergents and other grease cutting agents.

NET _____

ACCEPTED
with COMMENTS
in EPA Form 7000-1
OCT 3 2006
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 6659-3

5 7 9

(BACK PANEL)

SPRAY NINE®

Versatile
Multi-Purpose Cleaner/Degreaser.
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, brakedust, 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]

Tools · Floors · Garbage Pails · Nursery

[outdoors pictograph]

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

[auto/rv pictograph]

Tires · Wheels · Vinyl · Carpets · 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 1 & 2] [Coxsackie B3 Virus] [Norwalk/Norovirus] and other viruses* in just 30 seconds.
- Spray Nine kills [Salmonella choleraesuis] [E. coli] [Staphylococcus aureus] [Pseudomonas aeruginosa] [Staphylococcus aureus-MRSA] [Streptococcus pyogenes] [Enterobacter aerogenes] [Shigella dysenteriae] and other germs in just 45 seconds. †
- Spray Nine kills Enterococcus faecalis-VRE in just 1 minute.
- Spray Nine kills [Trichophyton mentagrophytes, the organism that causes Athlete's Foot fungus] [the organism that causes Otomycosis and nasal sinus infections] [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% Salmonella choleraesuis 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.

6 8 9

Product: Spray Nine (EPA Reg. No. 6659-3) Registrant: Spray Nine Corp (EPA Est. 6659-NY-1) 4/20/06

[UPC Code] ["please recycle"]

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

(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 I
Herpes Simplex II
Coxsackie B3 Virus
Norwalk/Norovirus
Rotavirus
HIV-1**

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

†BACTERIA (Contact time: 45 seconds)

Salmonella choleraesuis
Escherichia coli (E. coli)
Staphylococcus aureus
Staphylococcus aureus – 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
Pharyngitis (strep throat), scarlet fever and impetigo
Numerous hospital infections
Coliform bacteria – causes food poisoning and spoilage
Bacterial dysentery such as Montezuma's revenge

BACTERIA (Contact time: 1 minute)

Enterococcus faecalis-Resistant-VRE

Vancomycin –resistant Enterococcus faecalis

FUNGI (Contact time: 3 minutes)

Trichophyton mentagrophytes
Candida albicans
~~Aspergillus niger~~

Athletes Foot Fungus
Diaper rash, thrush, vaginitis and dermatitis
~~Otomycosis (fungal condition of the ear) and onychomycosis~~

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.

(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.

- 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.

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.

TO DISINFECT / DEODORIZE:

7 8 9

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) minimum.
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), Aspergillus niger (pathogenic fungi that causes Otomycosis and nasal sinus infections) 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.

****KILLS HIV 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).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 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 or 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 should 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.**

VETERINARY AND POULTRY USE- When used as directed, Spray Nine will deodorize and disinfect hard non-porous surfaces such as walls and floors of housing quarters, and feeding and care equipment such as troughs, racks and watering appliances. Prior to disinfection, all animals, poultry and their feeds must be removed from the premises. Spray Nine is effective against the following Veterinary/Poultry related organisms:

VIRUSES-(30 second contact time)
Feline Calicivirus
Avian Influenza A Virus (H3N2)

ASSOCIATED WITH:
Upper respiratory infections and pneumonia in cats
Avian (Bird) Flu

8 8 9

Product: Spray Nine (EPA Reg. No. 6659-3) Registrant: Spray Nine Corp (EPA Est. 6659-NY-1) 4/20/06
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) minimum.
4. Wipe thoroughly with a clean damp sponge/cloth or rinse.
5. When used on surfaces which will contact food or drinking water, rinse thoroughly with potable water before reusing.

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]

SPRAY NINE CORPORATION

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

(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.**

STORAGE AND DISPOSAL

(for containers 1 gallon or less):

Storage and Disposal: Keep from freezing. Store in original container and place in locked storage areas. Container may be refilled with Spray Nine. Do not reuse empty bottle with any other product. Discard empty container by wrapping in newspaper and discarding in trash.

(for containers greater than 1 gallon):

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

Storage: Keep from freezing. Store in original container and place in locked storage areas.

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

9 8 9

Product: Spray Nine (EPA Reg. No. 6659-3) Registrant: Spray Nine Corp (EPA Est. 6659-NY-1) 4/20/06

CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

(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.

HOME [pictograph]

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

AUTO/RV [pictograph]

Tires · Wheels · Vinyl
Bumpers · Seats
Carpet & Mats · Chrome

OUTDOORS[pictograph]

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

INSTITUTIONS[pictograph]

Rest Rooms · Cafeteria
Showers · Patient Rooms
Walls & Floors