

6659-3

5-13-2003

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAY 13 2003

Mr. John Lee  
Agent for Spray Nine Corporation  
Lee Pesticide Registration Consultants  
6546 Elvis Lane  
Lanham, MD 20706

Subject: Spray Nine  
EPA Registration No. 6659-3  
Amendment Date: February 6, 2003  
EPA Receive Date: February 12, 2003

Dear Ms. Jenkins,

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

- Additional label claims

**Conditions**

Revise the label as follows:

1. Page 1: Delete the claim, "For germ-free clean," because it implies indefinite protection which is considered heightened efficacy per PR Notice.
2. Pages 1 and 2: Delete the term, "harmful," in the phrase "other harmful germs."
3. Page 3: Delete the disease, "typhoid fever," because *Salmonella choleraesuis* is not the bacteria responsible for the disease.
4. Page 3: Revise the "BBQ Grill Directions" to state that the cooking grate must be rinse with potable water after cleaning.
5. Page 3: Revise the "Fungicidal Directions" to state "*Kills Trichophyton mentagrophytes (pathogenic fungi that causes Athletes Foot Fungus) and Candida albicans in areas such as shower and bath areas, locker rooms, and dressing rooms on precleaned hard nonporous surfaces: Spray thoroughly as to completely wet surface. Allow to stand 3 minutes before wiping surface.*"

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

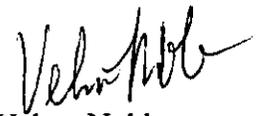
- 6. Page 4: Place the statement, "Hazard to humans and domestic animals," immediately under the heading, "Precautionary Statements."
- 7. Page 5: Place the statement, "Spray Nine has been tested ..... looks better and last longer," under the cleaning instructions with the heading, "For Prepping Paint Surfaces." You will need to repeat your cleaning instructions under the new heading.
- 8. Page 5: The "Environmental Hazards" statements are only necessary for container sizes 5 gallons or larger. You must delete the statement "Notice to large commercial and institutional users;" instead, you should place the phrase, "containers sizes 5 gallons or larger, in parentheses on the master label, so it will ensure that you place these statements on the appropriate container sizes.

**General Comments**

A stamped copy of the labeling accepted with conditions is enclosed. Submit three (3) copies of your 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 (7510C)

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Label Additions 2/6/03  
Product: Spray Nine(EPA Reg. No. 6659-3)  
Registrant: Spray Nine Corp.(EPA Est. 6659-NY-1)

**(FRONT PANEL)**

Tough Task Cleaner  
Deodorizes as it cleans  
Kills Germs Too!  
Removes Tough Stains  
Dissolves grease on contact  
Reduces the risk of cross contamination  
Tough on Grease, Grime & Stains!

Antibacterial Disinfectant  
For a germ-free clean  
Degreases and Disinfects  
Cuts Grease

**Spray Nine®  
MULTI-PURPOSE CLEANER/DISINFECTANT**

Kills **VIRUSES\*** in **30 seconds!**  
Kills **Salmonella choleraesuis, E. coli, and  
other harmful germs**  
in **45 seconds!** †

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

See Back Panel for Additional Precautionary Statements

**ACCEPTED  
with COMMENTS  
in EPA Letter Dated:**

**MAY 13 2003**

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. **6659-3**

**Active Ingredients**

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 chloride . . . . .	0.15%
n-Alkyl (68% C <sub>12</sub> , 32% C <sub>14</sub> )	
dimethyl ethylbenzyl ammonium chloride . . . . .	0.15%
<b>Inert Ingredients † . . . . .</b>	<b><u>99.70%</u></b>
	<b>100.00%</b>

† Includes detergents and other grease cutting agents.

NET \_\_\_\_\_

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Label Additions 2/6/03  
Product: Spray Nine(EPA Reg. No. 6659-3)  
Registrant: Spray Nine Corp.(EPA Est. 6659-NY-1)

**(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 surface for paint, wall and decorative hangings.

Peel Here To Open Label (small sizes only)

**[kitchen pictograph]**

Countertops · Stoves · 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

**[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 A<sub>2</sub>, Herpes Simplex 1 & 2 and other viruses\* in just 30 seconds.
- Spray Nine kills Salmonella choleraesuis, E. coli, Staphylococcus aureus, Pseudomonas aeruginosa and other harmful germs in just 45 seconds. †
- Spray Nine kills Trichophyton mentagrophytes, the organism that causes Athlete's Foot fungus, helps control mold and mildew and destroys bacterial odors.

**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.

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

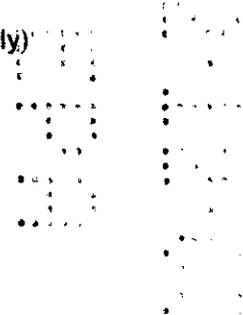
Made in USA  
[Stock number]

PRESS TO RESEAL (small sizes only)

Spray Nine Corporation  
PO Box 290

[UPC Code] ["please recycle"]

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



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(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 A<sub>2</sub> Virus  
Rhinovirus Type 37  
Respiratory Syncytial Virus  
Adenovirus Type 2  
Herpes Simplex I  
Herpes Simplex II  
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  
AIDS

†BACTERIA (Contact time: 45 seconds)

Salmonella choleraesuis  
Escherichia coli (E. coli)  
Staphylococcus aureus  
Pseudomonas aeruginosa  
Enterobacter aerogenes  
Shigella dysenteriae

Food poisoning, typhoid fever, gastroenteritis  
Food poisoning, urinary and wound infections  
Infections such as Meningitis and Carbuncles  
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 inconspicuous area to determine colorfastness and surface integrity before use. Do not use on wool, leather, glass, untreated wood or weathered surfaces.

TO CLEAN:

1. Spray on soiled surface.
2. Wipe immediately with a clean damp sponge or cloth.
3. For assistance with specific cleaning problems, call 1-800-477-7299.

**BBO 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.

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 off with a clean damp sponge or cloth.
5. When used on food contact surfaces such as counters, refrigerators, 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 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 the pathogenic fungi Trichophyton mentagrophytes (Athlete's Foot Fungus) and Candida albicans on pre-cleaned, hard, non-porous surfaces: Spray thoroughly, making sure to wet surface completely. Allow to stand 3 minutes minimum before rinsing.

Label Additions 2/6/03  
Product: Spray Nine(EPA Reg. No. 6659-)  
Registrant: Spray Nine Corp.(EPA Est. 6659-NY-1)

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**(BACK PANEL CONTINUED)**

**\*\*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.**

**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.

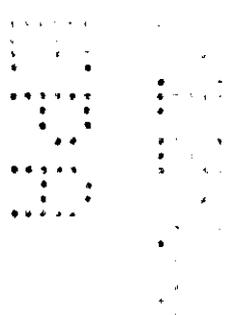
Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.

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



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

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

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, 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.

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.

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.

**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.

**Environmental Hazards. Notice to large commercial and institutional users: 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 permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems.**

**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  
Carpet & Mats · ~~Chairs~~

**INSTITUTIONS[pictograph]**

Rest Rooms · Cafeteria  
Showers · Patient Rooms  
Walls & Floors