

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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

John H. Lee Lee Pesticide Registration Consultant 9546 Elvis Lane Lanham, MD 20706

JUL 1 0 2008

Subject:

Spray Nine

EPA Registration No.6659-3

Amendment Dated: Feb 11, 2008 EPA Received Date: Feb 22, 2008

Dear Claudia E. Britton

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

Proposed Amendment

- Revise Label
- Submission of Efficacy Data

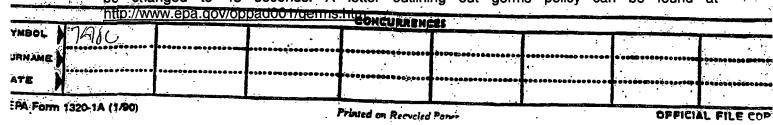
Data Summary

Data Requirement	Means of Support	Status
AOAC Use Dilution - Staphylococcus aureus	Submitted study, MRID 474113-01	Acceptable, 45 second contact time

Conditions

Revise the label as follows:

Revise the claim "kills 99.9% of germs in 10 seconds" to read "kills 99.9% of germs in 45 seconds". At a 10 second contact time the product is effective against bacteria. In order to have a germ claim a product must be effective against fungi viruses and bacteria. Your virus data and label require a 45 second contact time. Thus in order for your claim to be consistent with our policy the contact must be changed to 45 seconds. A letter outlining out germs policy can be found at



General Comments

A stamped copy of the accepted label with conditions is enclosed for your records. Submit (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

If the above conditions are not complied with the registration will be subject to cancellation in accordance with FIFRA section 6(c). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions

Should you have any questions or comments concerning this letter, please contact Velma Noble at (703) 308-6233.

Sincerely,

Velma Nobie

Product Manager (31)

Regulatory Management Branch I Antimicrobial Division (7510C)

Enclosure: Stamped Label

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

1/11/08

(FRONT PANEL)

Tough Task Cleaner
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

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 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 #
100.00%
‡ Includes detergents and other grease cutting agents.

ACCEPTED
with COMMENTS
in EPA Letter Doted:

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

NET

(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]

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 1 & 2] [Coxsackie B3 Virus] [Norwalk/Norovirus][Hepatitis B Virus][Hepatitis C Virus] 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 Enterococcus faecalis-VRE in just 1 minute.
- 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.

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

"PEEL OPEN FOR USE DIRECTIONS and complete disinfection information."

PA EST. 6659-NY-1. PA REG. NO. 6659-3 Made in USA [Stock number]

Page 2 of 6

PRESS TO RESEAL (small sizes only)

[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

Associated With:

Common Flu

Genital Disease

Norwalk Virus

AIDS

*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**

Hepatitis B Virus **

Hepatitis C Virus **

Food poisoning and gastroenteritis

Fever blisters, Mononucleosis

Hand-foot-mouth disease

Gastrointestinal illnesses

Salmonella enterica

Escherichia coli (E. coli)

Staphylococcus aureus

Staphylococcus aureus - MRSA Staphyloccus aureus-CA-MRSA

†BACTERIA (Contact time: 45 seconds)

Streptococcus pyogenes

Pseudomonas aeruginosa

Enterobacter aerogenes

Shigella dysenteriae

Hepatitis B infection related illnesses

Hepatitis C infection related illnesses

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

Upper respiratory tract illnesses including common cold

Respiratory illnesses – especially in children under 12.

Upper respiratory infections, Tonsillitis, Conjunctivitis

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

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.

(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.

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.

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

1/11/08

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. 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) (one minute for E. faecalis (VRE)) 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.

<u>TO CONTROL MOLD AND MILDEW</u> 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.

<u>FUNGICIDAL ACTIVITY:</u> Spray Nine kills Trichophyton mentagrophytes (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.

<u>FUNGISTATIC ACTIVITY</u>: 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 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 (1 minute to kill E. faecalis) 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.

<u>VETERINARY AND POULTRY USE</u>. 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.

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

1/11/08

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 surfaces 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

Made in USA

EPA REG. NO. 6659-3

[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 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.

8 8 8

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

1/11/08

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. Do not refill empty container with any other product.

(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

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