

1130-15

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

DEC 13 2007

Ms. Kim Davis
Agent for Burnshine Products
RegWest Company, LLC
30856 Rocky Road
Greeley, CO 80631-9375

Subject: Burnshine Germicidal Solution
EPA Registration No.: 1130-15
Amendment Date: July 6, 2007
EPA Receipt Date: July 10, 2007

Dear Ms. Davis,

The following amendment submitted in connection with registration under FIFRA section 3(c)(7)(A) is acceptable with the conditions listed below.

- Addition of microorganisms: E. coli, Rotavirus, and Avian Influenza A Virus
- Removing Isopropanol as an active ingredient

Conditions

Revise the label as follows:

1. On page 1 delete the phrase, "cause diseases such as boils, eye and skin infections, and food poisoning."
2. The nomenclature for Salmonella choleraesuis (ATCC 10708) has been changed to *Salmonella enterica*. You must make this correction to the label on pages 2 and 4.
3. On page 2, revise the statement, "This product may be used .. vinyl" to read "Use this product... vinyl" such that it is in compliance with PR Notice 2000-5, Mandatory Labeling.

4. On pages 2 and 3, revise the "Cleaning Hair Clippers and Electronic Shears" and "Cleaning Barber/Salon Shears and Other Implements" heading to indicate disinfection by stating "Disinfection of Hair Clippers and Electronic Shears" and "Disinfection Barber/Salon Shears and Other Implements".

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Other Implements.”

5. Since this product may be used in Veterinary and Animal Care Facilities, you must add the following directions:

Veterinary and Animal Care Facilities Disinfection: Remove all animals and feeds from premises, vehicles (trucks and cars), and enclosures (coops, crates, and kennels). Remove all litter, droppings, and manure from floors, walls, and surfaces of barns, pens, stalls, chutes, and other facilities and other fixtures occupied or traversed by animals. Empty all troughs, racks, and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Apply product to saturate surfaces such that they remain wet for 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. After application, ventilate buildings, coops, and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed or dried. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, and waterers and other equipment which may contact food or water with soap or detergent, and rinse with potable water before reuse.

6. Since this product may be used in Vehicles, you must add the following use directions:

Vehicle Disinfection: Clean all vehicles including mats, cabs, wheels with high-pressure water and this product. Apply solution to thoroughly wet all surfaces. Allow surfaces to remain wet for 10 minutes. Allow to surfaces to air dry.

7. Presently, your label cites five separate contact times for the use of this product as a disinfectant to mitigate a variety of organisms. This is confusing to the user who is not aware of the myriad of organisms that may be present on a particular surface. At your next label amendment, you must list one general contact time, 10 minutes, to alleviate this confusion.

8. Revise the “Storage and Disposal” statements for containers greater than 1 gallon in accordance with PR Notice 83-3 and Label Manual 3rd edition such that it reads as follows:

Storage and Disposal

Do not contaminate water, food, or feed by storage or disposal.

Storage: Store in original container in a cool well ventilated locked area inaccessible to children and persons unfamiliar with its use.

Pesticide Disposal: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

Container Disposal: Triple rinse (or equivalent) the plastic container then offer for recycling or reconditioning; or puncture and dispose of in a sanitary landfill; or incineration if allowed by state and local authorities. If burned, stay out of smoke.

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Acceptable Data

Data Requirement	Means of Support	Status
AOAC Germicidal Spray Test -E. coli	MRID No. 471837-01	Acceptable, RTU in 5% soil in 5 minutes.

General Comments

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

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). 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 Jacqueline McFarlane at (703) 308-6416.

Sincerely,



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

Enclosures: Stamped Label
 Efficacy Data Evaluation

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Burnishine Germicidal Solution

Cat. No. _____

Cleaner, Disinfectant & Deodorizer
Bactericidal, Tuberculocidal, Fungicidal and Virucidal
Cleaner, Deodorizer, Disinfectant, Sanitizer
For Disinfecting Contaminated Hard, Nonporous Surfaces/Articles
Ready-to-Use No Dilution Required

Active Ingredients:

n-Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈)	
dimethyl benzyl ammonium chloride	0.154%
n-Alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl ethylbenzyl	
ammonium chloride	0.154%
Other Ingredients	99.692%
Total	100.000%

Keep Out of Reach of Children
CAUTION
See side panel[s] for additional precautionary statements.

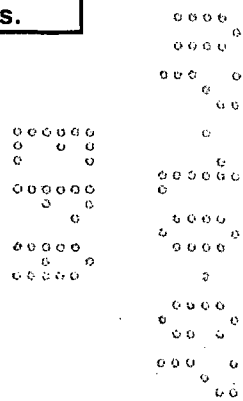
ACCEPTED
with COMMENTS
in EPA Letter Dated:
DEC 13 2007

Net Contents: _____ oz.

EPA Reg. No. 1130-15 EPA Est. 1130-IL-1

Burnishine Products
[755 Tri State Parkway]
Gurnee, Illinois 60031
800-837-8140
www.burnmedical.com

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. *1130-15*



{Side Panels}

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Burnishine Germicidal Solution [This product] is a general purpose cleaner, deodorizer and disinfectant to be used where control of cross-contamination hazards is of prime importance. Burnishine Germicidal Solution [This product] provides a novel way to effectively clean and disinfect hard, non-porous environmental surfaces. Burnishine Germicidal Solution [This product] aids in the reduction of cross-contamination hazards.

Burnishine Germicidal Solution [This product] kills, on hard, nonporous surfaces, a wide range of organisms that cause diseases (such as boils, eye and skin infections and food poisoning) including gram-negative and gram-positive bacteria, such as *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Klebsiella pneumoniae* and *Salmonella choleraesuis*. Burnishine Germicidal Solution [This product] kills pathogenic fungi (*Trichophyton mentagrophytes*) in 5 minutes.

A novel way to effectively clean, deodorize and sanitize against odor-causing organisms and disinfect hard, nonporous surfaces. Easy to use; no mixing or diluting [except for ultrasonic or manual cleaning]. Ready-to-use. For the reasonable person who wants to be sure.

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- [Effective in 30 seconds against:]** [Kills] Herpes Simplex II (causative agent of genital herpes), HIV-1 (AIDS Virus) and Influenza Strain A2/HK (representative of the common Flu virus) in the presence of a 5% organic soil load.
- [Effective in 3 minutes against:]** [Kills] Avian Influenza A Virus ATCC VR-2072, Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Polio I Virus ATCC VR-58, *Pseudomonas aeruginosa* ATCC 15442, Rhinovirus ATCC VR-286 (associated with common colds), Rotavirus Strain WA, *Salmonella choleraesuis* ATCC 10708 and *Staphylococcus aureus* ATCC 6538 in the presence of a 5% organic soil load; and *Staphylococcus aureus* (MRSA) ATCC 33591.
- [Effective in 5 minutes against:]** [Kills] *Acinetobacter baumannii* ATCC 17904, *Aspergillus niger* ATCC 10535, *Candida albicans* ATCC 10231, *Escherichia coli* ATCC 35150, Vancomycin-resistant *Enterococcus faecalis* (VRE) ATCC 51299, *Trichophyton mentagrophytes* ATCC 9533 and Canine Parvovirus in the presence of a 5% organic soil load.
- [Effective in 6 minutes against:]** [Kills] *Mycobacterium bovis* BCG ATCC 35743 (Tuberculosis) in the presence of a 5% organic soil load.
- [Effective in 10 minutes against:]** [Kills] Adenovirus Type 5, *Klebsiella pneumoniae* ATCC 4352, and Vaccinia virus ATCC VR-119 in the presence of a 5% organic soil load.

Burnishine Germicidal Solution [This product] is for use in:

- Barber Shops, Salons (such as beauty, manicure, skin care, tanning) and Spas
- Commercial Establishments (such as country clubs, dairies, factories, food/beverage processing/storage plants, kitchens, laundries, laundromats, office buildings, offices, restaurants and taverns)
- Emergency Vehicles (such as ambulances, fire trucks, helicopters, law enforcement)
- Funeral Homes and Morgues
- Health Clubs, Spas and Rehabilitation Facilities
- Medical Facilities (such as dental offices, hospitals, ophthalmic/optometric facilities, out-patient surgical centers)
- Prisoner Facilities (such as detention areas, jails, prisons, quarantine areas)
- Veterinary and Animal Care Facilities
- Residential and Lodging Structures (such as apartments, camping areas, homes; hotels, motels, RVs and watercraft)
- Other Facilities (such as day care, elder care, libraries, schools, universities)

Burnishine Germicidal Solution [This product] may be used on all hard, non-porous environmental surfaces/articles including: Chrome, Formica®, glass, painted surfaces, plastics (such as polycarbonate, polyvinylchloride, polypropylene and polystyrene), Plexiglas®, porcelain, stainless steel and vinyl.

Use Burnishine Germicidal Solution [this product] to clean, deodorize and disinfect such items as:

Ambulance equipment/surfaces, anesthesia machines, animal cages, baby cribs, barber instruments/implements, baskets, bathing units, bathroom fixtures, bathtubs, bed railings, bedpans, brushes, cabinets, carts, cervical collars, chairs, clipper blades, combs, counters/countertops, CPR training mannequins; curing lights, dental chairs/countertops/ instruments/implements/OR surfaces, diaper changing stations, door knobs, drained

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pedicure/whirlpool tanks, dryers, exercise equipment/benches/mats, external lenses vision correction (not for use on contact lenses), floors, folding tables, gurneys, hair clippers/cutting implements/dryers/rollers, hampers, handrails, hardhats, headphones, infant bassinets/cribs/warmers/incubators/care equipment, laboratory equipment/surfaces, light lens covers, manicure implements/tables, medical instruments/implements, nail care implements, neck braces, operating room lights/tables, optical instruments/implements, oxygen hoods, physical therapy equipment, razors, refrigerator units, respiratory therapy equipment, respirators/facepieces, salon surfaces, scissors, shampoo bowls, shears, shower stalls, sinks, slit lamps, spine backboards, stretchers, surgical instruments/implements, tables, tanning beds, telephones, toilets (exterior surfaces, seats and rim), unit stools, veterinary care surfaces/instruments/implements, walls, washable nail files, washers and workstations.

Use in bathrooms, breakrooms, cadaver processing areas, cafeterias, central supply areas, commercial laundries, critical care areas, dairies, emergency rooms, exercise/physical therapy areas, exam rooms, food establishments, food processing plants, hotels, intensive care units, isolation areas, kitchens, laboratories, locker rooms, neonatal units, nurseries, offices, operating rooms/theaters, orthopedics areas, patient care areas, public restrooms, radiology rooms, recovery rooms, respiratory therapy areas, restaurants, restrooms, shower areas, sickrooms, storage areas, surgical centers/suites, taverns and X-ray cat. laboratories.

General Cleaning and Precleaning

Prior to disinfection, preclean all surfaces with Burnishine Germicidal Solution, making sure to remove all gross filth and heavy soil. Apply solution to surface and allow surface to remain wet for 30 seconds prior to wiping with a paper towel or clean towel/sponge.

Ultrasonic Cleaning

Thoroughly pre-rinse instruments under running water to remove visible gross debris. Using 1 ounce of Burnishine Germicidal Solution [this product] per liter of water in ultrasonic unit, immerse instruments into solution and activate ultrasonic unit for 5 minutes (or longer if necessary). Remove and rinse instruments. Follow with appropriate cleaning and disinfection process. Change solution as needed when it becomes diluted or visibly soiled.

Manual Cleaning

Thoroughly pre-rinse instruments under running water to remove visible gross debris. Place pre-rinsed instruments into a solution of 1 ounce Burnishine Germicidal Solution [this product] per liter of water. Submerge instruments in solution and, using a stiff bristle brush, scrub instruments until visibly clean. Remove and rinse instruments. Follow with appropriate cleaning and disinfection process. Change solution as needed when it becomes diluted or visibly soiled.

Surgical Instrument Presoak

Fill appropriate sized container with sufficient amount of Burnishine Germicidal Solution in which to completely immerse instruments. Place precleaned instruments in undiluted solution to presoak surgical instruments for a minimum of 10 minutes then proceed with normal sterilization procedure.

Cleaning Hair Clippers and Electric Shears

While clipper/shear is running, hold in the downward position and spray Burnishine Germicidal Solution [this product] directly onto the blades two or three times to thoroughly wet the blades. Do not spray on the clipper case or drip into clipper housing. Allow to remain wet for a minimum of 10 minutes, turn off clipper/shear, then wipe dry with a clean, soft cloth. Lubricate as per clipper/shear manufacturer's instructions.

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Cleaning Barber/Salon Shears and Other Implements

Spray shear/implement until thoroughly wet. Wipe away visible debris using a soft bristle brush or cloth. Immerse precleaned shear/implement into a container of undiluted Burnishine Germicidal Solution [product] for a minimum of 10 minutes. Remove shear/implement and wipe dry; no rinsing necessary. Use fresh solution when immersion tank [bowl] [sink] solution becomes diluted or visibly soiled.

To Disinfect Hard, Nonporous, Surfaces/Articles

Using Burnishine Germicidal Solution [this product] as is (do not dilute), apply solution to thoroughly wet precleaned surfaces. Allow to remain wet for the times specified below prior to wiping or allow surfaces to air dry. For disinfection of Avian Influenza A, use this product only for surfaces that are not conducive to treatment by immersion or excess liquid. **Note:** Disinfected food contact surfaces must be rinsed with potable water after cleaning and/or disinfection and before reuse. After disinfection, critical and semi-critical devices must undergo appropriate terminal sterilization/high-level disinfection.

Organisms	Minimum Contact Time
Herpes Simplex II, HIV-1 (AIDS Virus) and Influenza Strain A2/HK	30 seconds
Avian Influenza A Virus, Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Polio I Virus, <i>Pseudomonas aeruginosa</i> , Rhinovirus, Rotavirus Strain WA, <i>Salmonella choleraesuis</i> , <i>Staphylococcus aureus</i> and <i>Staphylococcus aureus</i> (MRSA)	3 minutes
<i>Acinetobacter baumannii</i> , <i>Aspergillus niger</i> , <i>Candida albicans</i> , <i>Escherichia coli</i> , Vancomycin-resistant <i>Enterococcus faecalis</i> (VRE), <i>Trichophyton mentagrophytes</i> and Canine Parvovirus	5 minutes
<i>Mycobacterium bovis</i> BCG (Tuberculosis)	6 minutes
Adenovirus Type 5, <i>Klebsiella pneumoniae</i> and Vaccinia virus	10 minutes

Special Instructions for Cleaning and Decontamination Against HBV, HCV and HIV-1 (AIDS Virus) for Surfaces or Objects Soiled with Blood or Body Fluids

Kills HBV, HCV and HIV-1 (AIDS Virus) on pre-cleaned environmental surfaces or objects previously soiled with blood or body fluids in 30 seconds at room temperature (20-25°C) in health care settings 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 HBV, HCV and the human immunodeficiency virus Type 1 (HIV-1) associated with AIDS.

Personal Protection: When using the germicidal solution, wear disposable latex gloves, protective gown, face mask or eye covering as appropriate when handling HBV, HCV and HIV-1 infected blood or body fluids.

Cleaning Procedure: All blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of the germicidal solution.

Contact Time: Thoroughly wet surface. Allow to remain wet 30 seconds, let air dry. Use a 10-minute contact time for disinfection against all of the organisms claimed.

Disposal of Infectious Materials: Dispose of used solution in accordance with local regulations for infectious waste disposal.

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.

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{For non-household/domestic use products:}

Storage and Disposal

Do not contaminate water, food or feed by storage or disposal.

Storage: Store in a cool, well-ventilated area. **Disposal:** Wastes resulting from the use of this product may be disposed of on site, or at an approved waste disposal facility. Unused product may be discarded by pouring down drain and flushing with a large quantity of water. Triple rinse (or equivalent) the plastic container then offer for recycling or reconditioning; or puncture and dispose of in a sanitary landfill; or incineration; or if allowed by state and local authorities, by burning (if burned, stay out of smoke).

{For household/domestic use products:}

Storage: Store in the original container in a cool, well ventilated, locked storage area. **Disposal:** Do not reuse empty container; wrap and put in trash.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION: Harmful if inhaled or absorbed through skin. Causes moderate eye irritation. Avoid breathing vapors and contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

First Aid

If Inhaled	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.
If on Skin or Clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes.
If in Eyes	<ul style="list-style-type: none"> • Hold eye 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.
<p>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. [You may also contact 1-800-535-5053 for emergency medical treatment information.]</p>	

{The First Aid statements' grid format will be used if market label space permits; otherwise a paragraph format will be used.}

Physical or Chemical Hazards

Do not use or store near heat or open flame.

[] Denotes alternate/optional language

{ } Denotes language that does not appear on market labeling