

1130-15

9-4-2003

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## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SEP -4 2003

**Burnishine Products**

a Division of the Herbert Stanley Company  
c/o Reg West Company  
Greeley, CO 80631-9375

Attention: Ms. Kim Davis

Subject: **Burnishine Germicidal Solution**  
EPA Registration No. 1130-15  
Amendment Application Date: May 2, 2003  
EPA Received Date: May, 2003

The amendment referred to above, submitted in connection with registration under FIFRA sec. 3(c)(7)(A), is acceptable provided that you:

1. Submit and/or cite all data or material required for registration/reregistration of your product under FIFRA sec. 3(c)(5) or FIFRA sec.4 when the Agency requires all registrants of similar products to submit such data.

2. The Agency previously informed you that the test methodology of the submitted efficacy data deviated slightly for standard procedures. You subsequently modified your labeling to agree with the modified test procedure (see our letter dated March 12, 2003). As this product is identical in formulation to other EPA registered products, and your data does show effectiveness, the Agency will accept this amended product using your data under the condition that you conduct and submit Confirmatory efficacy data in accordance with Antimicrobial Division's DIS/TSS 5 Enclosure by March 30, 2004. The Agency must determine that the data is acceptable or the amended label will expire on August 31, 2004.

## CONCURRENCES

SYMBOL							
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If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

3. Submit two copies of your final printed labeling before you release the product for shipment. Refer to the A-79 Enclosure for further description of final printed labeling.

A stamped copy of the label is enclosed for you records.

If you have any question or comments concerning this letter, please contact me at (703) 308 6341 or Portia Jenkins at (703) 308-6230.

Sincerely,



Marshall Swindell  
Product Manager (33)  
Regulatory Management Branch I  
Antimicrobials Division (7510C)

Enclosure

# 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 <sub>14</sub> , 30% C <sub>16</sub> , 5% C <sub>12</sub> , 5% C <sub>18</sub> )	
dimethyl benzyl ammonium chloride .....	0.154%
n-Alkyl (68% C <sub>12</sub> , 32% C <sub>14</sub> ) dimethyl ethylbenzyl	
ammonium chloride .....	0.154%
Isopropanol .....	21.000%
Other Ingredients .....	78.692%
Total .....	100.000%

**Keep Out of Reach of Children**

**CAUTION**

See side panel[s] for additional precautionary statements.

Net Contents: \_\_\_\_\_ oz.

EPA Reg. No. 1130-15

EPA Est. 1130-IL-1

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

SEP 4 2003

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**Burnishine Products**  
Division of The Herbert Stanley Company  
[1100 Lakeside Drive]  
Gurnee, Illinois 60031  
800-837-8140  
www.burnmedical.com

Side Panels}

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this 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. Ready-to-use. For the reasonable person who wants to be sure.

**[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] Hepatitis B Virus (DHBV), Polio I Virus ATCC VR-58 and Rhinovirus ATCC VR-286 (associated with common colds) in the presence of a 5% organic soil load.

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- [Effective in 5 minutes against:] [Kills] *Aspergillus niger* ATCC 10535, *Candida albicans* ATCC 10231, Vancomycin-resistant *Enterococcus faecalis* (VRE) ATCC 51299 and *Trichophyton mentagrophytes* ATCC 9533 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, Canine Distemper ATCC VR-128, *Klebsiella pneumoniae* ATCC 4352, *Pseudomonas aeruginosa* ATCC 15442, Pseudorabies virus ATCC VR-135, *Salmonella choleraesuis* ATCC 10708, *Staphylococcus aureus* ATCC 6538 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)

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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 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 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, critical care areas, emergency rooms, exercise/physical therapy areas, exam rooms, intensive care units, isolation areas, kitchens, laboratories, locker rooms, neonatal units, nurseries, offices, operating rooms/theaters, orthopedics areas, patient care areas, radiology rooms, recovery rooms, respiratory therapy areas, restrooms, shower areas, sickrooms, storage areas, surgical centers/suites 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 disinfection or decontamination 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.

### 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. **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
Hepatitis B Virus (DHBV), Polio I Virus and Rhinovirus	3 minutes
<i>Aspergillus niger</i> , <i>Candida albicans</i> , <i>Vancomycin-resistant Enterococcus faecalis</i> (VRE) and <i>Trichophyton mentagrophytes</i>	5 minutes
<i>Mycobacterium bovis</i> BCG (Tuberculosis)	6 minutes
Adenovirus Type 5, Canine Distemper, <i>Klebsiella pneumoniae</i> , <i>Pseudomonas aeruginosa</i> , <i>Pseudorabies virus</i> , <i>Salmonella choleraesuis</i> , <i>Staphylococcus aureus</i> and <i>Vaccinia virus</i>	10 minutes

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

Kills 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 unexpected 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 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 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 second, let air dry. Although efficacy at a 30 second contact time has been shown to be adequate against HIV-1 (AIDS virus) this contact time would not be sufficient for other organisms. 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 pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

{For non-household/domestic use products:}

### Storage and Disposal

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 large quantity of water. The plastic container should be triple rinsed (or equivalent). 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, dispose of it 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

<b>If Inhaled</b>	<ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li> </ul>
<b>If on Skin or Clothing</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> </ul>
<b>If in Eyes</b>	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> </ul>

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.]

{The First Aid statements' grid format will be used unless market label space is sufficient; 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

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