

1130-15

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

NOV 10 2004

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

Ms. Kim Davis  
Consultant for,  
Burnishine Products,  
a division of Herbert Stanley Company  
c/o RegWest Company  
30856 Rocky Road  
Greeley, CO 80631-9375

Subject: Burnishine Germicidal Solution  
EPA Registration Number 1130-15  
Your Notification Dated October 8<sup>th</sup>, 2004  
EPA Received Dated October 12<sup>th</sup>, 2004

The notification referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act(FIFRA), as amended, to add the claim for Canine Parvovirus(5 minute contact time) to the product labeling, is acceptable.

Your notification has been made part of the permanent records for this file.

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

Sincerely,

A handwritten signature in cursive script, appearing to read "M Swindell".

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

October 8, 2004



Ms. Sherada Hobgood  
 Document Processing Desk - **NOTIF**  
 Office of Pesticide Programs – **7504C**  
**U.S. Environmental Protection Agency**  
 1801 South Bell Street  
 Crystal Mall #2, Room 266A  
 Arlington, VA 22202-4501

Dear Ms. Hobgood:

**Subject:** Burnishine Products, a Division of the Herbert Stanley Company  
 Burnishine Germicidal Solution  
 EPA Reg. No. 1130-15

On behalf of its client, **Burnishine Products, a Division of the Herbert Stanley Company**, RegWest Company, LLC is submitting the attached materials as notification of label revision per PR Notice 98-10 and DIS/TSS-16. RegWest Company will act as sole agent in this endeavor.

Attached are the following items:

1. Application for Pesticide: Other
2. One **Reference Label** (illustrates the changes)
3. Two **New Labels** (incorporate the changes)

We are adding the claim for Canine Parvovirus (5 minute contact time) on pages 2 and 3 of the draft labeling. We are submitting this via notification based on point number 7 of DIS/TSS-16 which states:

*Efficacy data will not be required for those organisms which are solely pathogenic for animals.*

We do have the data, and once the Agency provides acceptance of the notification intend to submit the required documents and data to the State of California for approval on the market label.

Please contact me at (970) 353-0611 or kim@regwest.com if you have any questions or require additional information.

Regards,  
**RegWest Company, LLC**

Kim Davis, CC, APC, Manager  
 Consultant/Agent

Attachments

pc: BSP – DeMasi, C.

30856 Rocky Road  
 Greeley, CO 80631-9373  
 970-353-0611  
 970-353-0613 Fax  
 Kim@regwest.com

United States <b>Environmental Protection Agency</b> 1200 Pennsylvania Avenue, N.W. Washington, DC 20460-0001	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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**Application for Pesticide – Section I**

1. Company/Product Number <b>EPA Reg. No. 1130-15</b>	2. EPA Product Manager <b>Marshall Swindell</b>	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/ Product (Name) <b>Burnishine Germicidal Solution</b>	PM # <b>33</b>	
5. Name and Address of Applicant (Include ZIP Code) <b>Burnishine Products,          a Division of the Herbert Stanley Company          c/o RegWest Company, LLC          30856 Rocky Road          Greeley, CO 80631-9375</b>		6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3)(b)(i) my product is similar or identical in composition and labeling to:  EPA Reg. No. _____  Product Name _____

**Section – II**

<input type="checkbox"/> Amendment – Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input checked="" type="checkbox"/> Notification – Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other – Explain below.
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**Explanation:** Use additional page(s) if necessary. (For Section I and Section II.)


**Submit label revision notification to add the Canine Parvovirus claim per PR Notice 98-10 and Dis/TSS-16.**

*This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR § 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to the EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR § 152.46 this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.*

**Section – III**

<b>1. Material This Product Will Be Packaged In:</b>			
Child Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify): _____
* <b>Certification must be submitted</b>		If "Yes" Unit Packaging Wgt.    No. Per Container	If "Yes" Packaging Wgt.    No. Per Container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container	
5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling Accompanying Product			
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Stenciled <input type="checkbox"/> Paper glued <input type="checkbox"/> Other _____			

**Section - IV**

<b>1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application).</b>		
Name <b>Kim Davis, CC, APC, Manager</b>	Title <b>Consultant/Agent</b>	Telephone No. (Include Area Code) <b>(970) 353-0611 / kim@regwest.com</b>
<b>Certification</b>		6. Date Application Received <b>(Stamped)</b>
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		
2. Signature 	3. Title <b>Consultant/Agent</b>	
4. Typed Name <b>Kim Davis, CC, APC, Manager</b>	5. Date <b>October 8, 2004</b>	

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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 <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%
<b>Other Ingredients</b> .....	<b>78.692%</b>
Total .....	<b>100.000%</b>

**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

**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, *Pseudomonas aeruginosa* ATCC 15442, Rhinovirus ATCC VR-286 (associated with common colds), *Salmonella choleraesuis* ATCC 10708 and *Staphylococcus aureus* ATCC 6538 in the presence of a 5% organic soil load.

**[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 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 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.

**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, <i>Pseudomonas aeruginosa</i> , Rhinovirus, <i>Salmonella choleraesuis</i> and <i>Staphylococcus aureus</i>	3 minutes
<i>Aspergillus niger</i> , <i>Candida albicans</i> , Vancomycin-resistant <i>Enterococcus faecalis</i> (VRE), and <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 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 preclean 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