

1130-15

02-03-2010

1/9

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

FEB -3 2010

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

Subject: **Burnishine Germicidal Solution**
EPA Registration Number 1130-15
Notification Dated January 6, 2010
EPA Received Date January 7, 2010

Dear Ms. Davis:

This will knowledge receipt of your notification, submitted under the provisions of FIFRA section 3c 9. Based on a review of the submitted material the following comment apply.

Proposed Amendment:

- Add labeling claims against Pandemic 2009 H1N1 Influenza A Virus per EPA's Guidance Document dated 10/21/09

General Comments:

Based on a review of the material submitted, the following comment apply:

The notification is acceptable. A copy has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, please contact Drusilla Copeland at (703) 308-6224.

Sincerely,

Velma Noble
Product Manager (31)
Regulatory Management Branch I

SYMBOL							
SURNAME							
DATE							

United States Environmental Protection Agency 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 <h2 style="text-align: center;">Notification</h2>
--	--	--

Application for Pesticide – Section I

1. Company/Product Number EPA Reg. No. 1130-14 15	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/ Product (Name) Burnishine Germicidal Solution	PM # 31	
5. Name and Address of Applicant (include ZIP Code) Burnishine Products, a Division of the Herbert Stanley Company c/o RegWest Company, LLC 30856 Rocky Road Greeley, CO 80631-9375 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. 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.
--	---

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

**Notification of label revisions to add Pandemic 2009 H1N1 Influenza A Virus claims per PR Notice 95-2.
 and
 Notification of label revision for per PR Notice 2007-4.
 Refer to Reference Label for an illustration of the revisions.**

This notification is consistent with the provisions of PR Notices 95-2 and 2007-4 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 Notices 95-2 and 2007-4 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

1. Material This Product Will Be Packaged In:			
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): _____
*Certification must be submitted		If "Yes" Unit Packaging Wt. No. Per Container	If "Yes" Packaging Wt. 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

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application).		
Name Kim Davis, CC, APC, Manager	Title Consultant/Agent	Telephone No. (Include Area Code) kim@regwest.com (970) 353-0611
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.		6. Date Application Received (Stamped)
2. Signature 	3. Title Consultant/Agent	
4. Typed Name Kim Davis, CC, APC, Manager	5. Date January 6, 2010	

January 6, 2010



Ms. Velma Noble, Product Manager 31
Document Processing Desk – **NOTIF**
Office of Pesticide Programs – **7504P**
U.S. Environmental Protection Agency
One Potomac Yard, South Building, Room S-4900
2777 South Crystal Drive
Arlington, VA 22202

Dear Ms. Noble:

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

On behalf of **Burnishine Products, a Division of the Herbert Stanley Company**, RegWest Company, LLC is submitting the attached materials as a notification of label revision per PR Notices 95-2 (H1N1) and 2007-4* (refillable container disposal directions). RegWest will act as sole agent in this endeavor.

Attached are the following:

1. Application for Pesticide: Notification
2. One **Reference Label** (illustrating the label revisions)
3. Two **New Labels** (incorporating the revisions)

Per the Agency's guidance document entitled "Guidance for Testing and Labeling Claims against Pandemic 2009 H1N1 Influenza A Virus (Formerly called Swine Flu)" and the referenced PR Notice 95-2, we are adding the 'labeling recommendations' as presented in the guidance document. Per PR Notice 2007-4, we are also taking this opportunity to add refillable container disposal directions. All revisions are illustrated on the **Reference 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

A handwritten signature in black ink, appearing to be "Kim Davis", written over a circular scribble.

Kim Davis, CC, APC, Manager
Consultant/Agent

Attachments

cc: BSP – Truax, H.

30856 Rocky Road
Greeley, CO 80631-9375
970-353-0611
970-353-0613 Fax
Kim@regwest.com

5/6

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
Kills Pandemic 2009 H1N1 Influenza Virus* [formerly called "swine flu"]

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	<u>99.692%</u>
Total	100.000%

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

Net Contents: _____ fl. oz. [____ mL]

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

Burnishine Products
755 Tri State Parkway
Gurnee, Illinois 60031
800-837-8140

{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 including gram-negative and gram-positive bacteria, such as *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Salmonella enterica*. 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.

5/6

[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, Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Pandemic 2009 H1N1 Influenza A Virus*, Polio I Virus, *Pseudomonas aeruginosa*, Rhinovirus (associated with common colds), Rotavirus Strain WA, *Salmonella enterica* and *Staphylococcus aureus* in the presence of a 5% organic soil load; and *Staphylococcus aureus* (MRSA).

[Effective in 5 minutes against:] [Kills] *Acinetobacter baumannii*, *Aspergillus niger*, *Candida albicans*, *Escherichia coli* O157:H7, Vancomycin-resistant *Enterococcus faecalis* (VRE), *Trichophyton mentagrophytes* and Canine Parvovirus in the presence of a 5% organic soil load.

[Effective in 6 minutes against:] [Kills] *Mycobacterium bovis* BCG (Tuberculosis) 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)

Use Burnishine Germicidal Solution [this product] on all hard, non-porous environmental surfaces/articles including: Chrome, Formica® Brand, glass, painted surfaces, plastics (such as polycarbonate, polyvinylchloride, polypropylene and polystyrene), Plexiglas®, glazed 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.

Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by Influenza A Virus*. This product, Burnishine Germicidal Solution, is a broad-spectrum hard surface disinfectant that has been shown to be effective against Influenza Strain A2/HK virus* and Avian Influenza A Virus* and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called "swine flu").

This product has demonstrated effectiveness against Influenza A Virus* and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 Influenza virus*.

This product has demonstrated effectiveness against Influenza Strain A2/HK virus* and Avian Influenza A Virus* and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called "swine flu").

General Cleaning, Precleaning and Deodorizing

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.

Disinfection of 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 6 minutes, turn off clipper/shear, then wipe dry with a clean, soft cloth. Lubricate as per clipper/shear manufacturer's instructions.

Disinfection of 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 6 minutes. Remove shear/implement and wipe dry; no rinsing necessary. Use fresh solution when immersion tank [bowl] [sink] solution becomes diluted or visibly soiled.

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 6 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, waterers and other equipment which may contact food or water with soap or detergent, and rinse with potable water before reuse.

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 6 minutes. Allow surfaces to air dry.

To Disinfect Hard, Nonporous, Surfaces/Articles

To Disinfect *Acinetobacter baumannii*, *Aspergillus niger*, Avian Influenza A Virus, *Candida albicans*, Canine Parvovirus, *Escherichia coli* O157:H7, Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Herpes Simplex II, HIV-1 (AIDS Virus), Influenza Strain H2/HK, *Mycobacterium bovis* BCG, Polio I Virus, *Pseudomonas aeruginosa*, Rhinovirus, Rotavirus Strain WA, *Salmonella enterica*, *Staphylococcus aureus*, *Staphylococcus aureus* (MRSA), *Trichophyton mentagrophytes* and Vancomycin-resistant *Enterococcus faecalis* (VRE): Using Burnishine Germicidal Solution [this product] as is (do not dilute), apply solution to thoroughly wet the precleaned surfaces. Allow to remain wet for 6 minutes 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.

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 and/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 6-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.

8
9

{For non-refillable non-household/residential use products (5 gal or less capacity):}

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:** Nonrefillable container; do not reuse or refill this container. Promptly clean container after emptying. Triple rinse (or equivalent) the plastic container after emptying. Triple rinse as follows: Empty the remaining contents into application equipment and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap; shake for 10 seconds. Follow pesticide disposal instructions for rinsate. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Offer the container 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.

Batch [Lot] Code [Number]: _____

{For non-refillable non-household/residential use products (greater than 5 gallons capacity):}

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:** Nonrefillable container; do not reuse or refill this container. Offer for recycling, if available. Triple rinse (or equivalent) container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

Batch [Lot] Code [Number]: _____

{For refillable non-household/residential use products:}

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:** Refillable container; refill this container with only quaternarium ammonium product. Do not reuse this container for any other purpose. Cleaning before refilling is the responsibility of the refiller. Cleaning the container before final disposal is the responsibility of the person disposing of the container. To clean the container before final disposal, empty the remaining contents from this container into application equipment or a mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times.

{For non-refillable household/residential use products:}

Storage: Store in original container in a cool, well ventilated, locked storage area. **Disposal:** Nonrefillable container; do not reuse or refill this container. Offer for recycling, if available, otherwise put in trash.

Batch [Lot] Code [Number]: _____

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 and before eating, drinking, chewing gum or using tobacco. Remove contaminated clothing and wash clothing before reuse.

9/2

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.• Immediately rinse skin 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.
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 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