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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

June 18, 2010

MEMORANDUM

Subject: Efficacy Review for So-White Brand Bleach and Disinfectant;
EPA Reg. No. 9009-15; DP Barcode: D376572

From: Marcie Tidd, Microbiologist
Product Science Branch
Antimicrobials Division (7510P)

Marcie Tidd 7/9/10

Thru: Tajah Blackburn, Team Leader
Product Science Branch
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[Signature]
7/9/10

Emily Mitchell, Chief
Product Science Branch
Antimicrobials Division (7510P)

To: Wanda Henson, Acting PM 32 / Wanda Henson
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: OnLine Packaging, Inc.
4311 Plover Road
Plover, WI 54467

Formulation from the Label:

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Sodium Hypochlorite.....	5.25%
<u>Other Ingredients</u>	<u>94.75%</u>
Total.....	100.00%

I. BACKGROUND

The product, SoWhite Brand Bleach and Disinfectant, (Reg. No. 9009-15) is an EPA registered disinfectant, non-food contact sanitizer, sanitizing rinse, and virucide. The applicant is attempting to add public health pests to the label (data submitted with product 9009-16 though conducted on 9009-15) along with uses consistent with the sodium hypochlorite RED and additional label language taken from other sodium hypochlorite products.

The data package contained a letter from the registrant's representative (dated March 30, 2010), a data citation form, the data matrix, and the proposed label (pinpunched March 31, 2010). The sodium hypochlorite reregistration guidance document (hereafter referred to as the RED), the last approved label for 9009-15 (January 20, 2006), previous efficacy reviews for 9009-16 (DPs 354178 and 364048), as well as the last approved label for 9009-15 were referenced in this review.

II. USE DIRECTIONS

This product is intended for use as a disinfectant, sanitizer, and virucide in residential, commercial and industrial settings. The last approved label contained only directions for the use of the product as a disinfectant and food-contact surface sanitizer for hard non porous surfaces in restaurants and kitchens. The label has expanded from 2 pages to 12 pages and includes directions for use of the product in the following applications.

- Sanitization of Nonporous Non-Food Contact Surfaces

Rinse, Immersion, and Spray Methods: Mix 5oz product with 10 gallons of water (200 PPM available chlorine). Clean equipment surfaces then rinse surfaces thoroughly with (or immerse into) sanitizing solution, maintaining contact with sanitizer for at least 5 minutes. Do not rinse equipment with water after treatment. Spray/Fog method indicates to spray or fog all surfaces until wet allowing excess sanitizer to drain then vacate the area for at least 2 hours.

- Sanitization of Porous Non-Food Contact Surfaces

Rinse, Immersion, and Spray Methods: Mix 15oz product with 10 gallons of water (600 PPM available chlorine). Clean equipment surfaces then rinse surfaces thoroughly with (or immerse into) sanitizing solution, maintaining contact with sanitizer for at least 5 minutes. Do not rinse equipment with water after treatment. Spray/Fog method indicates to spray or fog all surfaces until wet allowing excess sanitizer to drain then vacate the area for at least 2 hours.

- Sanitization of Nonporous Food Contact Surfaces

Prepare a 100 ppm sanitizing solution by thoroughly mixing 3 oz of this product with 10 gallons of water (5 oz product with 10 gallons of water (200 ppm) if no test kit is available). Clean equipment surfaces in the normal manner. Rinse all surfaces thoroughly with the sanitizing solution, maintaining contact with the sanitizer for at least 5 minutes. Do not rinse

equipment with water after treatment. Instructions also appear for immersion, flow/pressure, clean-in-place, and spray/fog methods.

- Sanitization of Nonporous Food Contact Surfaces

Prepare a 600 ppm sanitizing solution by thoroughly mixing 15 oz of this product with 10 gallons of water. Clean equipment surfaces in the normal manner. Rinse all surfaces thoroughly with the sanitizing solution, maintaining contact with the sanitizer for at least 2 minutes. Do not rinse equipment with water after treatment. Instructions also indicate to prepare a 200 ppm sanitizing solution, but do not indicate why, or if this is only when a test kit is available. Instructions also appear for immersion and spray/fog methods.

- Sanitization directions also appear for agricultural uses (including post-harvest protection, food egg sanitization, and fruit & vegetable washing), artificial sand beaches, and dialysis machines.

- Disinfection of Nonporous Non-Food Contact Surfaces

Prepare a 600 PPM solution by thoroughly mixing 15 oz of this product with 10 gallons of water. Clean equipment surfaces in the normal manner. Rinse (or immerse) all surfaces thoroughly with the disinfecting solution, maintaining contact with the solution for at least 5 minutes. Do not rinse equipment with water after treatment.

- Disinfection directions also appear for the following;
 - Kitchen, Dishes, Sinks: $\frac{3}{4}$ cup / 1 quart water, 5 minutes; then 1 Tbsp / gallon rinse
 - Walls, Floors, and other Hard Inanimate Surfaces Not in Direct Contact with Food: 1 cup / gallon, 5 minutes
 - Bathrooms: 1 $\frac{1}{2}$ cups / 2 gallons water, 5 minutes
 - Sewage & Wastewater Effluent Treatment
 - Slime Control in Sewage and Wastewater Treatment
 - Disinfection of Drinking Water
 - Emergency Disinfection after Floods
 - Emergency Disinfection after Main Breaks
 - Farm Premises: 25 oz / 10 gallons water, 10 minutes

In addition, the following uses are being added;

- Public Water System Treatment
- Cooling Tower / Evaporative Condenser Water Treatment
- Pulp and Paper Mill Process Water Systems
- Agricultural Uses
- Asphalt or Wood Roofs and Sidings
- Slime control on Boat Bottoms

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

General or broad-spectrum Disinfectants for Use on Hard Surfaces

Claims of effectiveness as a "general disinfectant" or representations that the product is effective against a broad spectrum of microorganisms are acceptable if the product is effective against both Gram-positive and Gram-negative bacteria. These claims must be substantiated by data derived using the AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products Test (for spray products). The tests require that sixty carriers must be tested with each of 3 samples, representing 3 different batches, one of which is at least 60 days old, against *Salmonella choleraesuis* ATCC 10708 (for effectiveness against Gram-negative bacteria) and *Staphylococcus aureus* ATCC 6538 (for effectiveness against Gram-positive bacteria). [120 carriers per sample; a total of 360 carriers] To pass performance requirements, tests must result in killing in 59 out of each set of 60 carriers to give a 95% confidence level.

Sanitizing Rinses (for previously cleaned, food-contact surfaces)

Efficacy of sanitizing rinses formulated with halide chemical products including; iodophors, mixed halides, and chlorine bearing chemicals must be substantiated with data derived from the AOAC Available Chlorine Germicidal Equivalent Concentration Method. Data from one test on each of 3 samples, representing 3 different batches, one of which is at least 60 days old, against *S. typhi* are required. Test results must show product concentrations equivalent in activity to 50, 100, and 200 ppm of available chlorine. (The reference standard is sodium hypochlorite.)

Sanitizer Test (for inanimate, non-food contact surfaces)

The effectiveness of sanitizers for non-food contact surfaces must be supported by data that show that the product will substantially reduce the numbers of test bacteria on a treated surface over those on an untreated control surface. The test surface(s) should represent the type(s) of surfaces recommended for treatment on the label, i.e., porous or non-porous. Products that are represented as "one-step sanitizers" should be tested with an appropriate organic soil load, such as 5 percent serum. Tests should be performed with each of 3 product samples, representing 3 different product lots, one of which is at least 60 days old against *Staphylococcus aureus* (ATCC 6538) and either *Klebsiella pneumoniae* (aberrant, ATCC 4352) or *Enterobacter aerogenes* (ATCC 13048 or 15038). Results must show a bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes.

IV. SUMMARY OF SUBMITTED STUDIES

No additional studies were provided with this submission. The applicant is citing data sent in with the product, "SoWhite brand Ultra Bleach and Disinfectant" (9009-16). Data for product 9009-16 (a 6% sodium hypochlorite product) were actually conducted on the product, "SoWhite Brand Bleach and Disinfectant" (9009-15), which is the subject of this review.

The following data are cited on the product's data matrix.

Studies	MRID
AOAC Use Dilution Test: <i>Staphylococcus aureus</i> (ATCC 6538); <i>Salmonella enterica</i> (ATCC 10708)	473774-01
AOAC Virucidal Efficacy: Influenza A virus (ATCC VR-544, strain Hong Kong)	473774-03
AOAC Virucidal Efficacy: Rhinovirus type 37 (ATCC VR-1147, strain 151-1)	473774-02
AOAC Fungicidal Test: <i>Trichophyton mentagrophytes</i> (ATCC 9533)	477191-02
AOAC Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces: <i>Staphylococcus aureus</i> (ATCC 6538); <i>Enterobacter aerogenes</i> (ATCC 13048)	477191-01

V. RESULTS & CONCLUSIONS

1. In an efficacy review dated July 14, 2008 (T. Blackburn), the following data on product 9009-15 were reviewed.

Claims and Organisms	MRID	Status
General Disinfectant: <i>Staphylococcus aureus</i> (ATCC 6538); <i>Salmonella enterica</i> (ATCC 10708)	473774-01	Acceptable at a 600 ppm* available chlorine level (tested at 7.5 oz / 5 gallons of water, ~1:85.3) with a 5 minute contact time in the presence of a 5% organic soil load
Virucidal Efficacy: Influenza A virus (ATCC VR-544, strain Hong Kong)	473774-03	
Virucidal Efficacy: Rhinovirus type 37 (ATCC VR-1147, strain 151-1)	473774-02	

*Submitted studies state that the product was tested at a ready-to-use dilution. The efficacy study references a letter from the registrant (dated June 20, 2008), which states that MRID Nos. 473774-01, 473774-02, and 473774-03 were diluted according to directions for use, which are to add 7.5 oz product per 5 gallons of water resulting in a 600 ppm available chlorine.

2. In an efficacy review dated May 13, 2009 (T. Blackburn), the following data on product 9009-15 were reviewed.

Claims and Organisms	MRID	Status
Fungicidal Activity: <i>Trichophyton mentagrophytes</i> (ATCC 9533)	477191-02	Acceptable at <u>full strength</u> *, 5 minute contact time in the presence of a 5% organic soil load
Non-Food Contact Surface Sanitization: <i>Staphylococcus aureus</i> (ATCC 6538); <i>Enterobacter aerogenes</i> (ATCC 13048)	477191-01	Acceptable at <u>full strength</u> *, 5 minute contact time in the presence of a 5% organic soil load

*At the current time, no documentation is available to indicate that the product was diluted at the time of testing, and laboratory reports indicate that the product was tested in a ready-to-use format. The referenced efficacy review noted this deficiency and a June 29, 2009 email from Wanda Henson to the applicant's representative reiterated this information.

VI. RECOMMENDATIONS

Regarding Cited Data

1. The proposed label claims that the product is a disinfectant (against *Salmonella enterica* and *Staphylococcus aureus*) and virucide (against Influenza A and Rhinovirus type 37) on non-porous non-food contact surfaces at a dilution of 15 oz of product per 10 gallons of water (600 ppm available chlorine) with a 5 minute contact time. Though the product was tested in a 5% soil load, directions indicate that surfaces should be cleaned in the normal manner prior to treatment. These claims (as listed under "Disinfection of Nonporous Non-Food Contact Surfaces") are acceptable as they are supported by the cited data. ✓

Note: Multiple use directions for disinfection are present on the label. Under the Disinfection header (1st paragraph, page 9) the text indicates to "Follow directions for use in the "DISINFECTING WALLS, FLOORS, AND OTHER INANIMATE SURFACES" section below." These directions dictate that the user should use the product at five times the ppm level at which efficacy was demonstrated. Having multiple use directions with differing dilutions and contact times is confusing to the end user and may result in the product not being applied properly. The applicant needs to simplify use directions with one main set for disinfection of hard, non-porous surfaces which reflects testing conditions (i.e. 600 ppm, 5 minute contact time). ✓

2. The proposed label claims that the product is a fungicide against *Trichophyton mentagrophytes* (Athlete's Foot Fungus) (page 9), although there are no specific fungicidal directions listed. Text following the claim indicates to "Follow directions for use in the "DISINFECTING WALLS, FLOORS, AND OTHER INANIMATE SURFACES." In these directions, the product is diluted 1 cup to gallon of water. In testing, the lab report indicated that the product was tested in a ready-to-use format, and this data was previously deemed unacceptable in the May 13, 2009 efficacy review. Remove all fungicidal claims (including references to *T. mentagrophytes* from the product label unless clarification can be made on the product's dilution at the time of testing. X

3. The proposed label claims that the product is a sanitizer on nonporous non-food contact surfaces (page 5) at a 5 oz per 10 gallon of water dilution (200 ppm) with a contact time of 5 minutes on precleaned surfaces. Cited data against *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048) indicates that the product was tested in a ready-to-use format. The May 13, 2009 efficacy review deemed this data unacceptable for the label claims being made. The product files contain no information from the registrant clarifying the product's dilution at the time of testing. However, current label directions regarding sanitization of nonporous non-food contact surfaces are in agreement with the RED and may remain on the label. The applicant will not be allowed to make claims for sanitization against *S. aureus* or *E. aerogenes* until clarification on the tested use dilution is provided. X

Regarding Proposed Labeling

1. On page 3, instructions are listed for "Household / Laundry Use." The label does not state whether this is for cleaning or sanitizing. The applicant must clarify this and move directions to the appropriate section. If this section is dedicated to cleaning instructions, an appropriate header must be added. The RED specifies directions for laundry sanitizers, and the label needs to match these use directions.
2. On page 3, the bolded statement in the middle of the page is out of place, "Use this product to clean and deodorize trash and garbage cans and other surfaces. After washing and rinsing, apply a solution containing $\frac{3}{4}$ cup of this product in 1 gallon of water. Allow surfaces to remain wet for 5 minutes. SANITIZATION." Remove the phrase "SANITIZATION" and move these directions to an appropriate place on the label under the correct heading.
3. On page 6, directions for toilet bowls (unspecified if cleaning or sanitization) and sanitization and deodorization of garbage cans appear under the header for Sanitization of Porous Non-Food Contact Surfaces. Move these directions to an appropriate section and label the intended use for toilet bowls.
4. On page 7, directions for "Sanitizing Tableware in Low Temperature Dishwashing Machine" appear. According the RED, "Sanitizers used in automated systems may be used for general cleaning but may not be re-used for sanitizing purposes."
5. On page 7, directions for "Sanitizing of Porous Food Contact Surfaces" include directions for making a 200 ppm solution under rinse and immersion methods. This is in disagreement with the RED, which specifies only a 600 ppm solution. Delete directions for a 200 ppm solution.
6. On page 8, separate directions for Post-Harvest Protection of potatoes and disinfection of leafcutting bee cells.
7. On page 9, at least 4 different use dilutions appear for disinfection. Combine these into one main disinfection direction set, and separate those for any unique surface so to clarify the label for the end user.
8. On page 12, delete all unqualified claims for germs until fungicidal data is deemed acceptable.
9. The proposed label does not list use sites (i.e. floors, walls, counters), surface types (i.e. stainless steel, glass) or use areas (i.e. residential, institutional, industrial) for which "non-porous surfaces" (under disinfection directions) would be present. The applicant needs to revise the label to meet DIS/TSS-15 label guidelines.

Note to PM

Use directions are disorganized and vary widely throughout the label. I strongly recommend that the applicant organize the label into distinct sections for cleaning, sanitizing, and disinfecting and that contact times and dilutions are standardized for each.

On page 8, directions for sanitization of "Artificial Sand Beaches" appear. This use is not included in the RED. Is this a new use, and if so, is it acceptable?