UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

June 17, 2008

MEMORANDUM

Subject: Efficacy Review for EPA Reg. No. 9009-16, SoWhite Brand Ultra Bleach and Disinfectant; DP Barcode: 350969

From: Tajah L. Blackburn, Ph.D., Microbiologist
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Product Science Branch
Antimicrobials Division (7510P)
6/17/08

Thru: Michele Wingfield, Chief
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To: Emily Mitchell Pm 32/ Thomas Luminello
Regulatory Management Branch II
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Applicant: OnLine Packaging, Inc.
Plover, WI 54457

Formulations from Label

Active Ingredient(s)	% by wt.
Sodium Hypochlorite	6.0%
Other Ingredients	94.0
Total	100.0%

I BACKGROUND

The product, SoWhite Brand Ultra Bleach and Disinfectant (EPA Reg. No. 9009-16), is a registered disinfectant for use on hard, non-porous surfaces in household environments. The product can also be added to laundry washing machines. [The last-accepted label (dated August 26, 2004) does not list microorganisms against which the product disinfects and does not identify whether the product is for use as a laundry deodorizer, sanitizer, or disinfectant.] The applicant requested to add new claims and additional use sites. Studies were conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, in Eagan, MN 55121.

This data package contained a letter from the applicant's representative to EPA (dated March 12, 2008), three studies (MRID 473774-01 through -03), Statements of No Data Confidentiality Claims for all three studies, and the proposed label.

Note: The laboratory reports describe studies conducted for the product, SoWhite 5.25% Bleach. The data package does not contain any information to confirm that the tested product, SoWhite 5.25% Bleach, is a use solution of the product, SoWhite Brand Ultra Bleach and Disinfectant, which is the subject of this efficacy report.

II USE DIRECTIONS

The proposed label indicates that the product is for use in disinfecting countertops, cups, dishes, equipment, floors, showers, sinks, teapots, toilets, tubs, and walls. The proposed label indicates that the product is for sanitizing dialysis machines, eating and drinking utensils, garbage cans, milking equipment, sickroom equipment, tableware, and toilets. The product label indicates that the product may be used on hard, non-porous surfaces including: enamel, ceramic tile, porcelain, and vinyl. Directions on the proposed label provided the following information regarding preparation and use of the product as a disinfectant:

> For Kitchens, Dishes, and Sinks – Dilute 0.25 cup of the product per quart of water (a 1:16 use solution; ~3800-PPM available chlorine). Clean items. Soak items in disinfecting solution for 10 minutes. Rinse with a 200-PPM available chlorine use solution. Let air dry.
>
> For Walls, Floors, and Other Surfaces – Dilute 0.75 cup of product per gallon of water (a 1:21 use solution; ~2900-PPM available chlorine). Prewash surfaces. Rinse. Spray, rinse, or wipe surfaces with disinfecting solution. Let stand for 10 minutes. Drain and air dry.
>
> For Non-Porous, Non-Food Contact Surfaces – Dilute 13 ounces of the product with 10 gallons of water (a 1:98 use solution; 600-PPM available chlorine). Clean equipment in the normal manner. Rinse all surfaces with the disinfecting solution. Maintain contact with the use solution for at least 10 minutes. Do not rinse with water.

For Bathrooms – Dilute 1.5 cups of the product with 2 gallons of water (a 1:21 use solution; ~2900-PPM available chlorine). Spread disinfecting solution on clean surface. Let stand for 10 minutes. Drain.

III AGENCY STANDARDS FOR PROPOSED CLAIMS

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments

The effectiveness of disinfectants for use on hard surfaces in hospital or medical environments 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 as Disinfectants Method (for spray products). Sixty carriers must be tested with each of 3 product samples, representing 3 different product lots, one of which is at least 60 days old, against *Salmonella enterica* (ATCC 10708; formerly *Salmonella choleraesuis*), *Staphylococcus aureus* (ATCC 6538), and *Pseudomonas aeruginosa* (ATCC 15442). To support products labeled as "disinfectants," killing on 59 out of 60 carriers is required to provide effectiveness at the 95% confidence level.

Virucides

The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level.

IV COMMENTS ON THE SUBMITTED EFFICACY STUDIES

1. MRID 473774-01 "AOAC Use-Dilution Method," Test Organisms: *Staphylococcus aureus* (ATCC 6538) and *Salmonella enterica* (ATCC 10708) for SoWhite 5¼% Bleach, by Becky Lien. Study conducted at ATS Labs. Study completion date – February 28, 2008. Project Number A05813.

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Salmonella enterica* (ATCC 10708). Three lots (Lot Nos. N259-RO, M252s, and K211) of the product, SoWhite 5¼% Bleach, were tested using the AOAC Use-Dilution Method as described in the AOAC Official Methods of Analysis, 15th Edition, 1990. At least one of the product lots tested (i.e., Lot No. K211) was at least 60 days old at the time of testing. Testing was conducted on January 18, 2008 and February 14, 2008. The

product was received ready-to-use. Fetal bovine serum was added to the cultures to achieve a 5% organic soil load. Sixty (60) stainless steel penicylinder carriers per product lot per microorganism were immersed in a 48-54 hour old suspension of the test organism, at a ratio of 1 carrier per 1 ml broth. The carriers were dried for 40 minutes at 36°C at 30-32% relative humidity. Each carrier was exposed to 10 ml of the product for 5 minutes at 19.0-20.0°C. After exposure, individual carriers were transferred to 10 ml of Letheen Broth containing 0.1% sodium thiosulfate to neutralize. At least 30 minutes after subculture of the first carrier, individual carriers were transferred from primary subcultures tubes to secondary subculture tubes of 10 ml of Letheen Broth containing 0.1% sodium thiosulfate. Subcultures were incubated for 46-46.25 hours at 35-37°C. The subcultures were stored for 1-2 days at 2-8°C prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

Note: Testing performed on January 18, 2008 did not demonstrate expected efficacy results against *Staphylococcus aureus* for one product lot (i.e., Lot No. N259-R). On February 14, 2008, testing was repeated to test for potential false positive.

2. MRID 473774-02 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Rhinovirus type 37" for SoWhite 5.25% Bleach, by Mary J. Miller. Study conducted at ATS Labs. Study completion date – January 24, 2008. Project Number A05770.

This study was conducted against Rhinovirus type 37 (Strain 151-1; ATCC VR-1147), using MRC-5 cells (human embryonic lung cells; ATCC CCL-171; propagated in-house) as the host system. Two lots (Lot Nos. N259-RO and M252s) of the product, SoWhite 5.25% Bleach, were tested according to ATS Labs Protocol No. ONL01112907.R37 (copy provided). The product was received ready-to-use. The stock virus culture contained 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.1°C at 54% relative humidity. For each lot of product, separate dried virus films were exposed to 2.0 ml of the product for 5 minutes at 20.1°C. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. Each virus-disinfectant mixture was immediately passed through a Sephadex column, and diluted serially in Minimum Essential Medium supplemented with 10% heat-inactivated fetal bovine serum, 10 µg/ml gentamicin, 100 units/ml penicillin, and 2.5 µg/ml amphotericin B. MRC-5 cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 31-35°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for dried virus counts, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

3. MRID 473774-03 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Influenza A virus" for SoWhite 5.25% Bleach, by Mary J. Miller. Study conducted at ATS Labs. Study completion date – January 25, 2008. Project Number A05771.

This study was conducted against Influenza A virus (Strain Hong Kong; ATCC VR-544), using Rhesus monkey kidney cells (RMK cells; originally obtained from ViroMed Laboratories, Inc., Cell Culture Division; maintained in-house) as the host system. Two lots (Lot Nos. N259-RO and M252s) of the product, SoWhite 5.25% Bleach, were tested according to ATS Labs Protocol No. ONL01112907.FLUA (copy provided). The product was received ready-to-use. The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.1°C at 52% relative humidity. For each lot of product, separate dried virus films were exposed to 2.0 ml of the product for 5 minutes at 20.1°C. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. Each virus-disinfectant mixture was immediately passed through a Sephadex column, and diluted serially in Minimum Essential Medium supplemented with 1% heat-inactivated fetal bovine serum, 10 µg/ml gentamicin, 100 units/ml penicillin, and 2.5 µg/ml amphotericin B. RMK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for dried virus counts, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

V RESULTS

MRID Number	Organism	No. Exhibiting Growth/ Total No. Tested			Carrier Population (CFU/ carrier)
		Lot No. N259-RO	Lot No. M252s	Lot No. K211	
473774-01	*Staphylococcus aureus* Test Date: 1/18/08	1°=0/60 2°=2/60	1°=0/60 2°=1/60	1°=1/60 2°=1/60	1.17×10^7
	Staphylococcus aureus Test Date: 2/14/08	1°=0/60 2°=1/60	---	---	5.8×10^6
	Salmonella enterica	1°=0/60 2°=0/60	1°=0/60 2°=0/60	1°=0/60 2°=0/60	5.0×10^6

MRID Number	Organism	Results			Dried Virus Count ($TCID_{50}$/0.1 ml)
			Lot No. N259-RO	Lot No. M252s	
473774-02	Rhinovirus type 37	10^{-1} to 10^{-6} dilutions	Complete inactivation	Complete inactivation	$10^{4.75}$
		$TCID_{50}$/0.1 ml	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
473774-03	Influenza A virus	10^{-1} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	$10^{5.5}$
		$TCID_{50}$/0.1 ml	$\leq 10^{0.5}$	$\leq 10^{0.5}$	

VI CONCLUSIONS

Note: The data package does not contain any information to confirm that the tested product, SoWhite 5.25 Bleach, is a use solution of the product, SoWhite Brand Ultra Bleach and Disinfectant, which is the subject of this efficacy report. Information regarding the tested product is required before claims are accepted.

1. The submitted efficacy data support the use of SoWhite 5.25% Bleach (relation to SoWhite Brand Ultra Bleach and Disinfectant unknown) as a disinfectant against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load for a contact time of 5 minutes at full strength:

Salmonella enterica	MRID 473774-01
Staphylococcus aureus	MRID 473774-01

Acceptable killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. [Note that repeat testing was conducted against *Staphylococcus aureus* to evaluate for false positives.] At least one of the product lots tested was at least 60 days old at the time of testing. Neutralization confirmation testing showed positive growth of the microorganisms. The viability controls were positive for growth. The purity controls were reported as pure. The sterility controls did not show growth.

2. The submitted efficacy data support the use of SoWhite 5.25% Bleach (relation to SoWhite Brand Ultra Bleach and Disinfectant unknown) as a disinfectant with virucidal activity against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load for a contact time of 5 minutes at full strength:

Rhinovirus type 37	MRID 473774-02
Influenza A virus	MRID 473774-03

Recoverable virus titers of at least 10^4 were achieved. Cytotoxicity was not observed. Complete inactivation (no growth) was observed in all dilutions tested.

VII RECOMMENDATIONS

Note: The data package does not contain any information to confirm that the tested product, SoWhite 5.25 Bleach, is a use solution of the product, SoWhite Brand Ultra Bleach and Disinfectant, which is the subject of this efficacy report. Information regarding the tested product is required before claims are accepted.

A. Recommendations Regarding Use of the Product as a Disinfectant

1. The proposed label claims that the product, SoWhite Brand Ultra Bleach and Disinfectant, is an effective disinfectant on pre-cleaned, hard, non-porous surfaces against *Salmonella enterica*, *Staphylococcus aureus*, Influenza A virus, and Rhinovirus type 37. The label suggests a 10-minute contact time at 600-PPM available chlorine (and higher concentrations). The label is silent regarding virucidal use directions for Influenza A and Rhinovirus. .

2. The proposed label claims that the product is an effective disinfectant for kitchen, dishes, and sinks. [See page 9 of the proposed label.] The disinfectant instructions specify use of a 1:16 use solution (~3800-PPM available chlorine) for 10 minutes on pre-cleaned items, followed by a rinse step using a solution of 200-PPM available chlorine. These conditions differ from the last-accepted label and the efficacy data provided. The last-accepted label indicates use of a 1:21 use solution (~2900-PPM available chlorine) for 5 minutes to disinfect kitchen sinks and countertops. The efficacy data provided support use of the tested product at full strength (available chlorine not specified) for 5 minutes. This inconsistency must be addressed. It would be preferable if all disinfectant applications had the same conditions (i.e., contact time, available chlorine), as appropriate.

3. The proposed label claims that the product is an effective disinfectant for walls, floors, and other hard surfaces not in direct contact with food. [See page 9 of the proposed label.] The disinfectant instructions specify use of a 1:21 use solution (~2900-PPM available chlorine) for 10 minutes. These conditions differ from the last-accepted label and the efficacy data provided. The last-accepted label indicates use of a 1:21 use solution (~2900-PPM available chlorine) for 5 minutes. The efficacy data provided support use of the tested product at full strength (available chlorine not specified) for 5 minutes. This inconsistency must be addressed.

4. The proposed label claims that the product is an effective disinfectant for pre-cleaned, non-porous, non-food contact surfaces. [See pages 9 and 10 of the proposed label.] The disinfectant instructions specify use of a 1:98 use solution (600-PPM available chlorine) for 10 minutes. These conditions differ from the last-accepted label and the efficacy data provided. The last-accepted label indicates use of a 1:21 use solution (~2900-PPM available chlorine) for 5 minutes. The efficacy data provided support use of the tested product at full strength (available chlorine not specified) for 5 minutes. This inconsistency must be addressed.

5. The proposed label claims that the product is an effective disinfectant for toilets. [See page 10 of the proposed label.] The disinfectant instructions specify use of 0.5 cup of bleach for 10 minutes. These conditions differ from the last-accepted label. The last-accepted label indicates use of 1 cup of bleach for 10 minutes. This inconsistency must

be addressed. Furthermore, these use-directions are inconsistent with the Guidance for the Reregistration of Pesticide Products Containing Sodium and Calcium Hypochlorite Salts as the Active Ingredient.

6. The proposed label includes a new claim that the product is an effective disinfectant against mold and mildew on bathroom surfaces for a 10-minute contact time at a 1:21 use solution (~2900-PPM available chlorine). [See page 10 of the proposed label.] Data have not been provided to support mold and mildew claims. All relevant references must be deleted from the proposed label.

7. The proposed label includes a new claim that the product is an effective disinfectant of drinking water (emergency/public/individual/system). [See page 10 of the proposed label.] Data have not been provided to support this new claim. All relevant references must be deleted from the proposed label. These claims are consistent with the Guidance for the Reregistration of Pesticide Products Containing Sodium and Calcium Hypochlorite Salts as the Active Ingredient.

8. The proposed label includes a new claim that the product is an effective disinfectant on farm premises for a 10-minute contact time at a 1:60 use solution (1000-PPM available chlorine). [See page 12 of the proposed label.] These conditions differ from the last-accepted label and the efficacy data provided. The last-accepted label indicates use of a 1:21 use solution (~2900-PPM available chlorine) for 5 minutes on pre-cleaned, non-porous, non-food contact surfaces. The efficacy data provided support use of the tested product at full strength (available chlorine not specified) for 5 minutes. This inconsistency must be addressed. These claims are consistent with the Guidance for the Reregistration of Pesticide Products Containing Sodium and Calcium Hypochlorite Salts as the Active Ingredient.

9. The proposed label now includes special instructions for cleaning and decontamination against HIV on surfaces in the presence of a 5% organic soil load. [See page 12 of the proposed label.] The disinfectant instructions specify a 5-minute contact time at a 1:6 use solution (10,000-PPM available chlorine). Data have not been provided to support these instructions, HIV claims, or use of the product in healthcare settings. All relevant references must be deleted from the proposed label.

10. The proposed label now includes special instructions for cleaning and decontamination against *Mycobacterium tuberculosis* (Tb) on hard, non-porous surfaces in the presence of a moderate amount of organic soil. [See page 12 of the proposed label.] The disinfectant instructions specify a 5-minute contact time at a 1:6 use solution (10,000-PPM available chlorine). Data have not been provided to support these instructions, Tb claims, or use of the product in healthcare settings. All relevant references must be deleted from the proposed label.

B. Recommendations Regarding Use of the Product as a Sanitizer

1. The proposed label includes a claim that the product may be used to sanitize laundry. [See page 5 of the proposed label.] The last-accepted label describes an application for laundry usage; however, the last-accepted label does not identify whether the product is for use as a laundry deodorizer, sanitizer, or disinfectant. These claims are consistent

with the Guidance for the Reregistration of Pesticide Products Containing Sodium and Calcium Hypochlorite Salts as the Active Ingredient.

2. The proposed label includes new claims that the product is an effective sanitizer for use on non-porous, non-food contact surfaces. [See pages 5 through 6 of the proposed label]. These claims are consistent with the Guidance for the Reregistration of Pesticide Products Containing Sodium and Calcium Hypochlorite Salts as the Active Ingredient. The listing of toilet bowls, sickroom equipment, and garbage cans is not consistent with Guidance for the Reregistration of Pesticide Products Containing Sodium and Calcium Hypochlorite Salts as the Active Ingredient.

3. The proposed label includes new claims that the product is an effective sanitizer for use on non-porous, food contact surfaces. [See pages 7 through 9 of the proposed label]. These claims are consistent with the Guidance for the Reregistration of Pesticide Products Containing Sodium and Calcium Hypochlorite Salts as the Active Ingredient. However claims to sanitize milking equipment are not consistent with the Guidance for the Reregistration of Pesticide Product Containing Sodium and Calcium Hypochlorite Salts as the Active Ingredient.

4. The proposed label includes new claims that the product is an effective sanitizer for use on porous surfaces. [See pages 6 and 8 of the proposed label.] These claims are consistent with the Guidance for the Reregistration of Pesticide Products Containing Sodium and Calcium Hypochlorite Salts as the Active Ingredient.

5. The proposed label includes a new claim that the product may be used to sanitize dialysis machines. [See page 9 of the proposed label.] These claims are consistent with the Guidance for the Reregistration of Pesticide Products Containing Sodium and Calcium Hypochlorite Salts as the Active Ingredient.

C. Miscellaneous Recommendations

1. The proposed label includes a new claim that the product will control fungus and mildew on asphalt or wood roofs and sidings. [See page 5 of the proposed label.] These claims are consistent with the Guidance for the Reregistration of Pesticide Products Containing Sodium and Calcium Hypochlorite Salts as the Active Ingredient.

2. The proposed label claims that the product may be used to deodorize. In accordance with DIS/TSS-15 requirements, the proposed label must be revised to include adequate dosage recommendations and complete directions for use of the product as a deodorizer.

3. The following changes are required on the proposed label:

- Add page numbers to the proposed label.

- On page 2 of the proposed label under the "Physical or Chemical Hazards" section, change "Extend contact" to read "Extended contact."

- On page 2 of the proposed label, change "ENVIRONMENAL HAZARDS" to read "ENVIRONMENTAL HAZARDS".

- On page 3 of the proposed label, remove claims for "Algaecide and Slimicide" as this is inconsistent with the document, Guidance for the Reregistration of Pesticide Products Containing Sodium and Calcium Hypochlorite Salts as the Active Ingredient.

- On pages 3 and 11 of the proposed label, change "hypo chlorinate" to "hypochlorinate"

- On page 4 of the proposed label, change "lowdown" to "blowdown"

- On page 3 of the proposed label, change "NEW TANKS. BASINS, ETC." to read "NEW TANKS, BASINS, ETC."

- On page 3 of the proposed label under the "New Tanks, Basin, Etc." section, change "43 oz." to read "45 oz." to be consistent with instructions provided in the "Existing Equipment" section.

- On page 5 of the proposed label, re-word the "Asphalt or Wood Roofs and Sidings" section as follows: "To control fungus and mildew, first remove all physical soil by brushing and hosing roofs and sidings with clean water. Prepare a solution containing 5000-PPM available chlorine by mixing 11 oz. of this product per gallon of water. Brush or spray roof or sidings with the 5000-PPM solution. After 30 minutes, rinse by hosing with clean water. [Not for use in California.]"

- On page 5 of the proposed label under the "Laundry Usage" section, the use directions are not consistent with the Guidance document for Sanitization of Laundry, Hand Washing, and Stain Removal.

- On page 5 of the proposed label, under the "Laundry Usage" section, change "SoWhite Ultra Bleach" to read "SoWhite Brand Ultra Bleach and Disinfectant" or "product."

- On page 6 of the proposed label, change "SANITIZATION OP POROUS NON-FOOD CONTACT SURFACES" to read "SANITIZATION OF POROUS NON-FOOD CONTACT SURFACES".

- On page 6 of the proposed label, place the following section heading : "INDIVIDUAL WATER SYSTEMS: DRILLED, DRIVEN & BORED WELLS" under the heading for "Disinfection of Drinking Water (Emergency/Public/Individual Systems)"

- On page 6 of the proposed label, the directions for toilet bowls, sickroom equipment, and garbage cans are not consistent with the Guidance document.

- On page 7 of the proposed label, include the statement "Rinse system with potable water prior to use" at the conclusion of use directions for "FLOW/PRESSURE METHOD" and "CLEAN-IN-PLACE METHOD"

- On page 7 of the proposed label, the directions "To Sanitize Milking Equipment" are not included in the Guidance document.

- On page 9 of the proposed label, change "20 gallons" to "200" gallons to yield a 25 PPM solution.

- On page 9 of the proposed label, change "porcelain" to read "glazed porcelain" and change "enamel" to read "baked enamel." Porcelain and enamel are porous surfaces.

- On page 9 of the proposed label, change "DISINFECTING WALLS, FLOORS. AND...." to read "DISINFECTING WALLS, FLOORS, AND...."

- On page 10 of the proposed label under the "Immersion Method" subheading, change "allow the sanitizer to drain" to read "allow the disinfectant to drain."

- On page 10 of the proposed label, change "ceramic tile" to read "glazed ceramic tile." Ceramic is a porous surface.

- On page 10 of the proposed label under the "Sewage & Wastewater Effluent Treatment" section, correct the wording of the first sentence so that it makes sense.

- On page 11 of the proposed label under the "Individual Systems: Dug Wells" section, change "sanitizing solution" to read "disinfecting solution" in two places.

- On page 11 of the proposed label under the "Basins, Tanks, Flume, Etc." section, change "asdetermined" to read "as determined."

- On page 11 of the proposed label, change "NDIVIDUAL WATER SYSTEMS: FLOWING ARTESION WELLS" to read "INDIVIDUAL WATER SYSTEMS: FLOWING ARTESION WELLS." Furthermore, move the directions for this application under the section entitled, "Disinfection of Drinking Water (Emergency/Public/Individual Systems)"

4. On the label, in numerous areas, change "prewash" to "preclean".

D. Marketing Claims

1. The claims (1) "Kills 99.9% of common household germs" and (2) "Kills 99.9% of the bacteria and viruses commonly found in kitchens, bathrooms, restrooms, households, homes, and offices are not acceptable. These claims have not been demonstrated utilizing actual efficacy data, but rely on the Guidance document. Therefore these quantitative claims are not acceptable.

2. Change the claim "Kills viruses that cause the colds and flu" to "Kills viruses that cause the colds and flu on treated surfaces".

3. The designation for *Salmonella choleraesuis* has been changed to *Salmonella enterica*.

4. Change the claim "Kills *Salmonella enterica*, Influenza A, and Rhinovirus type 37" to "Kills Salmonella enterica, Influenza A, and Rhinovirus type 37on treated surfaces".

5. Change the claim "Effective against *Salmonella enterica*, Influenza A, and Rhinovirus type 37" to "Effective against *Salmonella enterica*, Influenza A, and Rhinovirus type 37" on treated surfaces."

6. Change the claim "Kills surface germs and bacteria (including *Salmonella enterica*, Influenza A, and Rhinovirus type 37" to "Kills *Salmonella enterica*, Influenza A, and Rhinovirus type 37 on treated surfaces".

7. The use of the word "germs" must meet the following criteria;

Criteria for a Germs Claim

A. In order to make a qualified "germ" claim on a product label, a product must be registered as a general purpose/broad spectrum disinfectant product with additional label claims against one of the two classes of organisms listed below:

- Fungi - One pathogenic fungi (usually *Trichophyton mentagrophytes*) that is representative of the use sites listed for the product.
- Viruses - One enveloped and/or non-enveloped virus that is representative of the use sites listed for the product.
- All studies to support disinfectant, fungicidal, and virucidal claims must be conducted according to EPA guidelines.
- The front panel of the label for a qualified public health "germ" claim must contain a designator that refers the user to the qualified statements. A qualified statement is one that clearly describes the type of "germ" the product is efficacious against. When the word "germ" is used on the front panel of a label, an asterisk is required to indicate that there is clarifying language elsewhere on the label.

  Examples: Front panel - Kills germs*
  Back panel - Kills *Salmonella choleraesuis* and *Staphylococcus aureus*
  and (list virus or fungi)

B. In order to make an unqualified "germ" claim on a label, a product must have public health data developed using current EPA guidelines for all three of the major classes of organisms:

- Bacteria - meet the general purpose/broad spectrum disinfectant performance standard per EPA guidelines.
- Fungi - One pathogenic fungi (usually *Trichophyton mentagrophytes*) that is representative of the use sites listed for the product. Studies to be conducted according to EPA guidelines.
- Viruses - One enveloped and non-enveloped virus that is representative of the use sites for the product. Studies to be conducted according to EPA guidelines.

- The claim "germs" can be used without descriptors of the type of organism. No asterisk is required. The claim can appear on the front or back/side panel of a label. However, specific organisms must still be listed on the label.

  Examples: Kills Germs
  Kills germs in the bathroom and/or kitchen

- Qualified statements are optional and can be added to the product label, if desired.

8. Remove the following claims from the label,

   --Removes bacteria from your children's toys
   --Removes germs that detergent leaves behind

Other than the unqualified use of the term "germs", these claims are too ambiguous and imply heighten efficacy.

9. Remove the claim, "Protects against Mold and Mildew" as this has not been supported.

10. ATCC designation numbers are required in one of the following locations:

- on the data matrix;
- on the master label (as optional text) with the listing of the organisms claimed; or
- as the final page of the master label (as optional text).