UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 22, 2011

MEMORANDUM

Subject: Efficacy Review for EPA Reg. No. 70271-20, Pure Bright Germicidal; DP Barcode: 390541

From: Thao Pham
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Tajah Blackburn, Ph.D., Microbiologist
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

8/24/11

To: Monisha Harris PM32
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: KIK International, Inc.
33 Macintosh Boulevard
Concord, Ontario L4K4L5

Formulation from the Label:

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

I BACKGROUND

The product, Pure Bright Germicidal 160 Bleach (EPA Reg. No. 70271-20), is an EPA-approved disinfectant (bactericide, fungicide, virucide), sanitizer, and deodorizer for use on hard, non-porous surfaces in household, commercial, institutional, animal care, and hospital or medical environments. The product is also approved for use as a laundry sanitizer. In addition to label revisions, the applicant requested to amend the registration of this product to add an alternate formulation. Studies were provided to demonstrate efficacy of the alternate formulation as a disinfectant against *Staphylococcus aureus*, *Salmonella enterica*, *Pseudomonas aeruginosa*, Influenza A virus, Canine parvovirus, and *Trichophyton mentagrophytes*. All other organism data is expected to be bridged. The label makes no claims regarding effectiveness of the product in the presence of light or moderate soil loads. 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 May 26, 2011), EPA Form 8570-1 (Application for Pesticide), EPA Form 8570-27 (Formulator's Exemption Statement), EPA Form 8570-34 (Certification with Respect to Citation of Data), EPA Form 8570-35 (Data Matrix), six studies (MRID 484937-03 through 484937-08), Statements of No Data Confidentiality Claims for all six studies, and the proposed label.

II USE DIRECTIONS

The product is designed for disinfecting and sanitizing hard, non-porous surfaces. The product may be used to treat hard, non-porous surfaces, including: appliances, bathtubs, cages, counter tops, cutting boards (non-porous, plastic), equipment, faucets, floors, furniture, garbage disposals, instruments, kennels, shower curtains (plastic), showers, sinks, toilet bowls, toys, trash bins, trash cans, and walls. The proposed label indicates that the product may be used on hard, non-porous surfaces, including: glass, glazed ceramic, glazed porcelain, glazed tile, linoleum, painted woodwork, and vinyl. Directions on the proposed label provide the following information regarding preparation and use of the product as a disinfectant: Prepare a use solution by mixing ¾ cup of the product with 1 gallon of water (a 1:21.3 dilution). Pre-wash surfaces and rinse. Spray, rinse, or wipe surfaces with use solution. Let stand for 5 minutes (for 10 minutes to disinfect against fungi). Drain or rinse and air dry.

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.

Disinfectants for Use in Hospital or Medical Environments; Confirmatory Efficacy Data Requirements

Under certain circumstances, an applicant is permitted to rely on previously submitted efficacy data to support an application or amendment for registration of a product and to submit only minimal confirmatory efficacy data on his own product to demonstrate his ability to produce an effective formation. Confirmatory data must be developed on the applicant's own finished product. For hospital disinfectants, 10 carriers on each of 2 samples representing 2 different product lots must be tested against *Salmonella enterica* (ATCC 10708, formerly *Salmonella choleraesuis*), *Staphylococcus aureus* (ATCC 6538), and *Pseudomonas aeruginosa* (ATCC 15442) using either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products as Disinfectants Method. Killing on all carriers is required.

Disinfectants for Use as Fungicides (Against Pathogenic Fungi, Using a Modified AOAC Use-Dilution Method)

The effectiveness of liquid disinfectants against specific pathogenic fungi must be supported by efficacy data using an appropriate test. The AOAC Use-Dilution Method may be modified to conform with the appropriate elements in the AOAC Fungicidal Test. The inoculum in the test must be modified to provide a concentration of at least 10^6 conidia per carrier. Ten carriers on each of 2 product samples representing 2 different product lots must be employed in the test. Killing of the specific pathogenic fungi on all carriers is required.

Note: As an interim policy, EPA is accepting studies with dried carrier counts that are at least 10^4 for *Trichophyton mentagrophytes*, *Aspergillus niger*, and *Candida albicans*. EPA recognizes laboratories are experiencing problems in maintaining dried carrier counts at the 10^6 level. This interim policy will be in effect until EPA determines that the laboratories are able to achieve consistent carrier counts at the 10^6 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 484937-03 "AOAC Use-Dilution Method, Test Organism: *Staphylococcus aureus* (ATCC 6538)" for Pure Bright Germicidal 160 Bleach Alternate Formula, by Jill Ruhme. Study conducted at ATS Labs. Study completion date – September 13, 2010. Project Number A09882.

This confirmatory study was conducted against *Staphylococcus aureus* (ATCC 6538). Two lots (Lot Nos. LBK 036-063 and LBK 036-064) of the product, Pure Bright Germicidal 160 Bleach Alternate Formula, were tested using the AOAC Use-Dilution Method as described in the AOAC Official Methods of Analysis, 2006. Use solutions were prepared by adding 6.0 mL of the product and 127.8 mL of filter sterilized tap water (a 1:21.3 dilution). A culture of the challenge microorganism was prepared in accordance with the published AOAC methods. The use solutions were not tested in the presence of a 5% organic soil load. Ten (10) stainless steel penicylinder carriers per product lot were immersed for 15 minutes in a 48-54 hour old suspension of test organism, at a ratio of 1 carrier per 1 mL broth. The carriers were dried for 40 minutes at 35-37°C at 41% relative humidity. Each carrier was placed in 10.0 mL of the use solution for 5 minutes at 19.0°C. [It is unknown whether the tubes containing the use solution were swirled after addition of the carriers, as specified in the AOAC methods.] Following exposure, individual carriers were transferred to 10 mL of Letheen Broth with 0.2% sodium thiosulfate to neutralize. [It is unknown whether tubes containing the neutralizer were shaken thoroughly after addition of the carriers, as specified in the AOAC methods.] All subcultures were incubated for 48±4 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation (both product lots).

2. MRID 484937-04 "AOAC Use-Dilution Method, Test Organism: *Salmonella enterica* (ATCC 10708)" for Pure Bright Germicidal 160 Bleach Alternate Formula, by Jill Ruhme. Study conducted at ATS Labs. Study completion date – September 13, 2010. Project Number A09883.

This confirmatory study was conducted against *Salmonella enterica* (ATCC 10708). Two lots (Lot Nos. LBK 036-063 and LBK 036-064) of the product, Pure Bright Germicidal 160 Bleach Alternate Formula, were tested using the AOAC Use-Dilution Method as described in the AOAC Official Methods of Analysis, 2006. Use solutions were prepared by adding 6.0 mL of the product and 127.8 mL of filter sterilized tap water (a 1:21.3 dilution). Testing was conducted on July 28, 2010 and August 11, 2010. A culture of the challenge microorganism was prepared in accordance with the published AOAC methods. The use solutions were not tested in the presence of a 5% organic soil load. Ten (10) stainless steel penicylinder carriers per product lot were immersed for 15 minutes in a 48-54 hour old suspension of test organism, at a ratio of 1 carrier per 1.0 mL broth. The carriers were dried for 40 minutes at 35-37°C at 39-46% relative humidity. Each carrier was placed in 10.0 mL of the use solution for 5 minutes at 20.0°C. [It is unknown whether the tubes containing the use solution were swirled after

addition of the carriers, as specified in the AOAC methods.] Following exposure, individual carriers were transferred to 10 mL of Letheen Broth with 0.2% sodium thiosulfate to neutralize. [It is unknown whether tubes containing the neutralizer were shaken thoroughly after addition of the carriers, as specified in the AOAC methods.] All subcultures were incubated for ~44 hours at 35-37°C (which differs from the AOAC methods specification of 48±2 hours at 36±1°C). Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation (both product lots).

Note: Testing conducted on July 28, 2010 against one product lot (Lot No. LBK 036-063) showed growth of the test organism in one of ten subculture tubes. Testing was repeated to test for false positives.

Note: Protocol deviations/amendments reported in the study were reviewed.

3. MRID 484937-05 "AOAC Use-Dilution Method, Test Organism: *Pseudomonas aeruginosa* (ATCC 15442)" for Pure Bright Germicidal 160 Bleach Alternate Formula, by Becky Lien. Study conducted at ATS Labs. Study completion date – September 15, 2010. Project Number A09909.

This confirmatory study was conducted against *Pseudomonas aeruginosa* (ATCC 15442). Two lots (Lot Nos. LBK 036-063 and LBK 036-064) of the product, Pure Bright Germicidal 160 Bleach Alternate Formula, were tested using the AOAC Use-Dilution Method as described in the AOAC Official Methods of Analysis, 2006. Use solutions were prepared by adding 7.0 mL of the product and 149.1 mL of filter sterilized tap water (a 1:21.3 dilution). A culture of the challenge microorganism was prepared in accordance with the published AOAC methods. The use solutions were not tested in the presence of a 5% organic soil load. Ten (10) stainless steel penicylinder carriers per product lot were immersed for 15 minutes in a 48-54 hour old suspension of test organism, at a ratio of 1 carrier per 1.0 mL broth. The carriers were dried for 40 minutes at 35-37°C at 41% relative humidity. Each carrier was placed in 10.0 mL of the use solution for 5 minutes at 20.0°C. [It is unknown whether the tubes containing the use solution were swirled after addition of the carriers, as specified in the AOAC methods.] Following exposure, individual carriers were transferred to 10 mL of Letheen Broth with 0.2% sodium thiosulfate to neutralize. [It is unknown whether tubes containing the neutralizer were shaken thoroughly after addition of the carriers, as specified in the AOAC methods.] All subcultures were incubated for ~46.5 hours at 35-37°C. The subcultures were stored for 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 carrier population, purity, sterility, viability, and neutralization confirmation (both product lots).

4. MRID 484937-06 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Influenza A virus" for Pure Bright Germicidal 160 Bleach Alternate Formula, by Shanen Conway. Study conducted at ATS Labs. Study completion date – September 13, 2010. Project Number A09884.

This study was conducted against Influenza A virus (Strain Hong Kong; ATCC VR-544), using RMK cells (Rhesus monkey kidney cells; obtained from ViroMed Laboratories, Inc., Cell Culture Division; maintained in-house) as the host system. Two lots (Lot Nos. LBK 036-063 and LBK 036-064) of the product, Pure Bright Germicidal 160 Bleach Alternate Formula, were tested according to ATS Labs Protocol No. DAC02063010.FLUA.1 (copy provided). Use solutions were prepared by adding 1.00 mL of the product and 21.3 mL of filter sterilized tap water (a 1:21.3 dilution). The stock virus culture contained 1% 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 20.0°C at 40% relative humidity. For each lot of product, separate dried virus films were exposed to 2.00 mL of the use solution for 5 minutes at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Minimum Essential Medium with 1% (v/v) 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 input virus count, dried virus count, cytotoxicity, and neutralization (both product lots). Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

5. MRID 484937-07 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Canine Parvovirus" for Pure Bright Germicidal 160 Bleach Alternate Formula, by Shanen Conway. Study conducted at ATS Labs. Study completion date – October 14, 2010. Project Number A09920.

This study was conducted against Canine parvovirus (Strain Cornell; ATCC VR-2017), using A-72 cells (canine tumor cells; obtained from ViroMed Laboratories, Inc., Cell Culture Division; maintained in-house) as the host system. Two lots (Lot Nos. LBK 036-063 and LBK 036-064) of the product, Pure Bright Germicidal 160 Bleach Alternate Formula, were tested according to ATS Labs Protocol No. DAC02063010.CPV (copy provided). Use solutions were prepared by adding 1.00 mL of the product and 21.3 mL of filter sterilized tap water (a 1:21.3 dilution). The stock virus culture was adjusted to contain 1% 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 20.0°C at 50% relative humidity. For each lot of product, separate dried virus films were exposed to 2.00 mL of the use solution for 5 minutes at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Eagles Minimum Essential Medium with 5% heat-inactivated fetal bovine serum, 10 µg/mL

gentamicin, 100 units/mL penicillin, 2.5 µg/mL fungizone, and 10 mM HEPES. A-72 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. On the final day of incubation, a hemagglutination assay was performed on the culture using swine red blood cells at 2-8°C. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization (both product lots). Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

Note: The laboratory reported a failed study set up on August 6, 2010. In the study, a recoverable virus titer of at least 10^4 was not achieved. The laboratory did not accept the assay. These data were not used to evaluate efficacy of the product. Testing was repeated on August 27, 2010. See page 8 and Attachment I of the laboratory report.

6. MRID 484937-08 "AOAC Fungicidal Use-Dilution Method, Test Organism: *Trichophyton mentagrophytes* (ATCC 9533)" for Pure Bright Germicidal 160 Bleach Alternate Formula, by Lynsey Wieland. Study conducted at ATS Labs. Study completion date – October 29, 2010. Project Number A10251.

This study was conducted against *Trichophyton mentagrophytes* (ATCC 9533). Two lots (Lot Nos. BLK 040 001 and BLK 040 002) of the product, Pure Bright Germicidal 160 Bleach Alternate Formula, were tested using the AOAC Use-Dilution Method (modified for fungi) as described in the AOAC Official Methods of Analysis, 2006. Use solutions were prepared by adding 6.0 mL of the product and 127.8 mL of filter sterilized tap water (a 1:21.3 dilution). A culture of the challenge microorganism was prepared. The use solutions were not tested in the presence of a 5% organic soil load. Ten (10) stainless steel penicylinder carriers per product lot were immersed for 15 minutes in a 10-day old suspension of test organism, at a ratio of 1 carrier per 1.0 mL suspension. The carriers were dried for 40 minutes at 35-37°C at 52.44% relative humidity. Each carrier was placed in 10.0 mL of the use solution for 10 minutes at 19.5°C. [It is unknown whether the tubes containing the use solution were swirled after addition of the carriers, as specified in the AOAC methods.] Following exposure, individual carriers were transferred to 10 mL of Sabouraud Dextrose Broth with 0.1% sodium thiosulfate to neutralize. [It is unknown whether tubes containing the neutralizer were shaken thoroughly after addition of the carriers, as specified in the AOAC methods.] Carriers were transferred from primary subculture tubes into individual secondary subculture tubes containing 10 mL of Sabouraud Dextrose Broth with 0.07% Lecithin and 0.5% Tween 80 at least 30 minutes following the first transfer. All subcultures were incubated for 10 days at 25-30°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation (both product lots).

V RESULTS

MRID Number	Organism	No. Exhibiting Growth/ Total No. Tested		Carrier Population (CFU/ carrier)
		Lot No. LBK 036-063	Lot No. LBK 036-064	
5-Minute Exposure Time				
484937-03	*Staphylococcus aureus*	0/10	0/10	1.81×10^7
484937-04	*Salmonella enterica* Test Date: 7/26/2010 Test Date: 8/11/2010	 1/10 0/10	 0/10 ---	 1.70×10^6 6.3×10^5
484937-05	*Pseudomonas aeruginosa*	0/10	0/10	6.2×10^6

MRID Number	Organism	No. Exhibiting Growth/ Total No. Tested		Carrier Population (CFU/ carrier)
		Lot No. BLK 040 001	Lot No. BLK 040 002	
10-Minute Exposure Time				
484937-08	*Trichophyton mentagrophytes*	1°=0/10 2°=0/10	1°=0/10 2°=0/10	6.6×10^5

MRID Number	Organism	Results			Dried Virus Count
			Lot No. LBK 036-063	Lot No. LBK 036-064	
5-Minute Exposure Time					
484937-06	Influenza A virus	10^{-1} to 10^{-8} dilutions	Complete inactivation	Complete inactivation	$10^{6.5}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
484937-07	Canine parvovirus	10^{-1} to 10^{-8} dilutions	Complete inactivation	Complete inactivation	$10^{4.5}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	$\leq 10^{0.5}$	

VI CONCLUSIONS

1. The submitted confirmatory efficacy data support the use of 1:21.3 dilution of the product, Pure Bright Germicidal 160 Bleach Alternate Formula, as a disinfectant with bactericidal activity against the following microorganisms on pre-cleaned, hard, non-porous surfaces for a 5-minute contact time:

Staphylococcus aureus	MRID 484937-03
Salmonella enterica	MRID 484937-04
Pseudomonas aeruginosa	MRID 484937-05

Complete 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 on one product lot against *Salmonella enterica* to evaluate for false positives. The registrant will need to verify the analysis for the testing of the false positive Neutralization confirmation testing showed positive growth of the microorganisms. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth.

2. The submitted efficacy data (MRID 484937-08) support the use of a 1:21.3 dilution of the product, Pure Bright Germicidal 160 Bleach Alternate Formula, as a disinfectant with fungicidal activity against *Trichophyton mentagrophytes* on pre-cleaned, hard, non-porous surfaces for a 10-minute contact time. Complete killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganism. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth.

3. The submitted efficacy data support the use of a 1:21.3 dilution of the product, Pure Bright Germicidal 160 Bleach Alternate Formula, as a disinfectant with virucidal activity against the following microorganisms on hard, non-porous surfaces in the presence of a 1% organic soil load for a 5-minute contact time:

Influenza A virus	MRID 484937-06
Canine parvovirus	MRID 484937-07

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

VII RECOMMENDATIONS

1. The proposed label claims that a 1:21.3 dilution of the product, Pure Bright Germicidal 160 Bleach Alternate Formula, is an effective disinfectant against the following microorganisms on pre-cleaned, hard, non-porous surfaces for a 5-minute contact time:

Pseudomonas aeruginosa
Salmonella enterica
Staphylococcus aureus

Influenza A virus
Canine parvovirus

These claims are acceptable as they are supported by the submitted data.

2. The proposed label claims that a 1:21.3 dilution of the product, Pure Bright Germicidal 160 Bleach Alternate Formula, is an effective disinfectant against *Trichophyton mentagrophytes* on pre-cleaned, hard, non-porous surfaces for a 10-minute contact time. This claim is acceptable as it is supported by the submitted data.

3. The following revisions to the proposed label are recommended:

- Under the "Environmental Hazards" section on the proposed label, change "public waters" to read "other waters."

- On page 9 of the proposed label, change "ceramic tile and vinyl flooring" to read "glazed ceramic tile and vinyl flooring." Ceramic tile is a porous surface.

- On page 9 of the proposed label under the "Kitchen: Clean and disinfect" section, change "Wash, rinse, or wipe surfaces and then apply disinfecting solution" to read "Pre-clean surfaces with soap or detergent and then apply disinfecting solution." Efficacy testing (for the alternate formula) was not conducted in the presence of a light or moderate organic soil load; therefore, rinsing alone is not sufficient.

- On page 9 of the proposed label under the "[To Disinfect] Bathroom" section, change "Wash, rinse, or wipe surfaces and then apply disinfecting solution" to read "Pre-clean surfaces with soap or detergent and then apply disinfecting solution." Efficacy testing (for the alternate formula) was not conducted in the presence of a light or moderate organic soil load; therefore, rinsing alone is not sufficient.

- On page 9 of the proposed label under the "[To Disinfect] Kitchens and Bathrooms" section, change "Wash surfaces with water" to read "Pre-clean surfaces with soap or detergent and then apply disinfecting solution." Efficacy testing (for the alternate formula) was not conducted in the presence of a light or moderate organic soil load; therefore, washing with water is not sufficient.

- On page 9 of the proposed label under the "Disinfect Hard Non-porous Surfaces" section, change "Wash, rinse, or wipe surfaces and then apply disinfecting solution" to read "Pre-clean surfaces with soap or detergent and then apply disinfecting solution." Efficacy testing (for the alternate formula) was not conducted in the presence of a light or moderate organic soil load; therefore, rinsing alone is not sufficient.

- On page 9 of the proposed label under the "Disinfecting Children's Hard Non-porous Furniture and Toys" section, change "Wash all surface thoroughly" to read "Wash all surfaces thoroughly with soap or detergent." Efficacy testing (for the alternate formula) was not conducted in the presence of a light or moderate organic soil load.

- On page 9 of the proposed label under the "Sickroom Equipment" section, change "Wash all surface thoroughly" to read "Wash all surfaces thoroughly with soap or detergent." Efficacy testing (for the alternate formula) was not conducted in the presence of a light or moderate organic soil load.