UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

MEMORANDUM

DATE: September 30, 2008

SUBJECT: Efficacy Review for Gattuso GP;
EPA File Symbol 777-RNI;
DP Barcode: D354310

FROM: Lorilyn M. Montford 11/4/08
Efficacy **E**valuation Team
Antimicrobials Division (7510P)

THRU: Dr. Tajah Blackburn, Team Leader
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Michele E. Wingfield, Chief
Product Science Branch
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TO: Adam Heyward, PM 34/Stacey Grigsby
Regulatory Management Branch II
Antimicrobials Division (7510P)

APPLICANT: Reckitt Benckiser Inc.
Morris Corporate Center IV
399 Interpace Parkway, P.O. Box 225
Parsippany, NJ 07054-0225

FORMULATION FROM LABEL:

Active Ingredient(s)	% by wt.
Formic Acid	2.85%
Citric Acid	3.50%
Inert Ingredients	93.65%
Total	100.00%

I BACKGROUND

The product, Gattuso GP (EPA File Symbol 777-RNI), is a new product. The applicant requested to register the product as a ready-to-use disinfectant (bactericide, virucide), sanitizer, fungistat/ mildewstat, and deodorizer for use on hard, non-porous surfaces in household, institutional, commercial, and hospital or medical environments. Studies were conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, in Eagan, MN 55121; and Reckitt Benckiser Inc., located at One Philips Parkway, in Montvale, New Jersey 07645.

This data package contained a letter from the applicant to EPA (dated June 19, 2008), EPA Form 8570-1 (Application for Pesticide), EPA Form 8570-4 (Confidential Statement of Formula), EPA Form 8570-34 (Certification with Respect to Citation of Data), EPA Form 8570-35 (Data Matrix), fifteen studies (MRID 474557-18 through 474557-32), Statements of No Data Confidentiality Claims for all fifteen studies, and the proposed label.

Note: EPA Form 8570-4 (Confidential Statement of Formula) contains Confidential Business Information. Data or information claimed by the applicant to be FIFRA confidential has not been included in this efficacy report.

Note: The laboratory studies describe studies conducted for the products, Formula Number 1262-144A and Formula Number 1333-117A. Information in the data package indicates that Formula Number 1262-144A is the basic formulation of the product, Gattuso GP, and Formula Number 1333-117A is an alternate formulation of the product, Gattuso GP.

II USE DIRECTIONS

The product is designed for disinfecting and sanitizing hard, non-porous surfaces such as bathtubs, cabinet, counter tops, faucets, fixtures, floors, shower curtains, shower stalls, showers, sinks, toilet bowl exteriors, urinals, and vanity tops. The proposed label indicates that the product may be used on hard, non-porous surfaces including: chrome, enamel, glass, glazed ceramic, glazed porcelain, glazed tile, laminated plastic, linoleum, stainless steel, and vinyl. Directions on the proposed label provided the following information regarding use of the product: Pre-clean surfaces. Spray surfaces until thoroughly wet. To disinfect, let stand for 5 minutes. To sanitize, let stand for 30 seconds. Wipe off with a clean, damp cloth or sponge. To control mold and mildew, let stand for 3 minutes and then allow to 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 on Hard Surfaces 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. This includes a minor formulation change (e.g., a change in an inert ingredient) in a registered product. 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 choleraesuis* (ATCC 10708), *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.

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.

Sanitizers (For 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. [Testing requirements in EPA DIS/TSS-10 may be used.] 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 Aone-step sanitizers@ should be tested with an appropriate organic soil load, such as 5 percent *s*erum. 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.

Products Controlling Microorganisms of Economic or Aesthetic Significance

Algaecides, slimicides, preservatives, deodorizers, and other products expressly claiming control of microorganisms of economic or aesthetic significance not directly related to human health do not require efficacy data. However, adequate dosage recommendations and complete

directions for use must be provided in labeling.

IV COMMENTS ON THE SUBMITTED EFFICACY STUDIES

1. MRID 474557-18 "Disinfectant Efficacy Testing in the Presence of Organic Soil," for Formula Number 1262-144A, Test Organism: *Staphylococcus aureus* (ATCC 6538), by Kyle T. Smith. Study conducted at Reckitt Benckiser Inc. Study completion date – March 11, 2008. Amended report date – June 19, 2008. Master Schedule No. 2007-01 t1.

This study was conducted against *Staphylococcus aureus* (ATCC 6538). Three lots (Lot Nos. 1333-030, 1333-056, and 1333-058) of the product, Formula Number 1262-144A, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. At least one of the product lots tested (i.e., Lot No. 1333-030) was at least 60 days old at the time of testing. The product was received ready-to-use. A culture of the challenge microorganism was prepared in accordance with the published AOAC method. Horse serum was added to the culture to achieve a 5% organic soil load. Sixty (60) glass slide carriers were inoculated with 0.01 ml of a 48±2 hour old suspension of the test organism. The carriers were dried for 40-65 minutes at 31.6-37.5°C. For each lot of product, separate carriers were sprayed (2-3 pumps) with the product at a distance of 6-8 inches from the carrier surface. Each carrier was exposed to the product for 5 minutes at 21.9-22.6°C. The carriers were transferred to 20 ml of Letheen Broth to neutralize. All subcultures were incubated for at least 68 hours at 32.7-37.9°C, and then examined for the presence or absence of visible growth. Controls included those for test system verification (i.e., purity, identity), sterility, inoculum count, dried recovery carrier count, and neutralizer efficacy.

Note: The study was conducted according to GLP standards with the following exception: an expired reagent (Gram Crystal Violet, C#1202) was used in the Gram stain procedure. The laboratory study stated: "It has been concluded that although an expired reagent was used in the Verification of the Test System Assay, this did not affect the results of each Gram Stain. In addition, sufficient information was provided from the other Test System Verification components to determine that the organism used in each assay was the test system, *Staphylococcus aureus*."

2. MRID 474557-19 "Disinfectant Efficacy Testing in the Presence of Organic Soil," for Formula Number 1262-144A, Test Organism: *Salmonella enterica* (ATCC t0708), by Kyle T. Smith. Study conducted at Reckitt Benckiser Inc. Study completion date – March 11, 2008. Master Schedule No. 2007-0116.

This study was conducted against *Salmonella enterica* (ATCC 10708). Three lots (Lot Nos. 1333-036, 1333-056, and 1333-058) of the product, Formula Number 1262-144A, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. Each of the three product lots tested was at least 60 days old at the time of testing. The product was received ready-to-use. A culture of the challenge microorganism was prepared in accordance with the published AOAC method. Horse serum was added to the culture to achieve a 5% organic soil load. Sixty (60) glass slide carriers were inoculated with 0.01 ml of a 48±2 hour old suspension of the test organism. The carriers were dried for 40-42 minutes at 33.5-35.1°C. For each lot of product, separate carriers were sprayed (2-3 pumps) with the product at a distance of 6-8 inches from the carrier surface. Each carrier was exposed to the product for 5 minutes at 21.6-21.9°C. The carriers were

transferred to 20 ml of Letheen Broth to neutralize. All subcultures were incubated for at least 69 hours at 33.9-35.8°C, and then examined for the presence or absence of visible growth. Controls included those for test system verification (i.e., purity, identity), sterility, inoculum count, dried recovery carrier count, and neutralizer efficacy.

3. MRID 474557-20 "Disinfectant Efficacy Testing in the Presence of Organic Soil," for Formula Number 1262-144A, Test Organism: *Pseudomonas aeruginosa* (ATCC 15442), by Kyle T. Smith. Study conducted at Reckitt Benckiser Inc. Study completion date – March 11, 2008. Master Schedule No. 2007-0117.

This study was conducted against *Pseudomonas aeruginosa* (ATCC 15442). Three lots (Lot Nos. 1333-030, 1333-056, and 1333-058) of the product, Formula Number 1262-144A, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. Each of the three product lots tested was at least 60 days old at the time of testing. The product was received ready-to-use. A culture of the challenge microorganism was prepared in accordance with the published AOAC method. Horse serum was added to the culture to achieve a 5% organic soil load. Sixty (60) glass slide carriers were inoculated with 0.01 ml of a 48±2 hour old suspension of the test organism. The carriers were dried for 39-41 minutes at 32.7-34.3°C. For each lot of product, separate carriers were sprayed (2-3 pumps) with the product at a distance of 6-8 inches from the carrier surface. Each carrier was exposed to the product for 5 minutes at 21.6-21.9°C. The carriers were transferred to 20 ml of Letheen Broth to neutralize. All subcultures were incubated for at least 69 hours at 33.5-35.4°C, and then examined for the presence or absence of visible growth. Controls included those for test system verification (i.e., purity, identity), sterility, inoculum count, dried recovery carrier count, and neutralizer efficacy.

4. MRID 474557-21 "Inactivation of Influenza A (H1N1/Avian Flu) in the Presence of Organic Matter," for Formula Number 1262-144A, by Kelly Whitehead. Study conducted at Reckitt Benckiser Inc. Study completion date – March 11, 2008. Master Schedule No. 2007-0129.

This study was conducted against Influenza A virus (ATCC VR-98; Strain A/Malaya/ 302/ 54), using Rhesus monkey kidney cells (RMK cells; obtained from ViroMed Laboratories, Minneapolis, MN) as the host system. Two lots (Lot Nos. 1333-030 and 1333-056) of the product, Formula Number 1262-144A, were tested according to Reckitt Benckiser Inc.'s protocol "Inactivation of Influenza A virus (H1N1/Avian flu) in the Presence of Organic Matter" (copy provided). The product was received ready-to-use. The stock virus culture contained at least a 5% organic soil load. Films of virus were prepared by spreading 0.3 ml of virus inoculum uniformly over the bottoms of separate sterile polystyrene Petri dishes. The virus films were dried 43-59 minutes at 25.5°C at 20.44-23.38% humidity. For each lot of product, separate dried virus films were sprayed (2-3 pumps) with the product at a distance of 6-8 inches from the carrier surface. Each carrier remained exposed to the product for 30 seconds at 19.2-20.3°C. Following exposure, the plates were neutralized with 2.0 ml of fetal bovine serum. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed through individual Sephadex columns, and diluted serially in Minimum Essential Medium supplemented with gentamicin. RMK cells in multi-well culture dishes were inoculated in quadruplicate with 0.2 ml of the dilutions. The plates were re-fed using 1-2 ml of Minimum Essential Medium supplemented with gentamicin and 1% serum. The cultures were incubated for 7 days at 35.8-36.2°C in 1.941-8.271% CO_2. Following incubation, the cultures were examined for the presence or absence of cytopathic effects (i.e., cellular detachment,

degeneration of the cell sheet, giant cell/syncytia formation) and cytotoxicity. Controls included those for host cell viability, dried virus count, cytotoxicity, and neutralization effectiveness. Viral and cytotoxicity titers were calculated by the method of Reed and Muench.

5. MRID 474557-22 "Inactivation of Influenza A Virus (Human Flu) in the Presence of Organic Matter" for Formula Number 1262-144A, by Kelly Whitehead. Study conducted at Reckitt Benckiser Inc. Study completion date – March 18, 2008. Master Schedule No. 2007-0130.

This study was initiated via Reckitt Benckiser Inc.'s protocol "Inactivation of Influenza A virus (Human flu) in the Presence of Organic Matter." The study included an amendment, dated December 7, 2007, serving to terminate the study. The study was sent to an external facility, ATS Labs, due to time constraints. No testing was performed and no data were generated.

6. MRID 474557-23 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces" for Formula Number 1262-144A, Test Organism: Influenza A virus (Hong Kong), by Mary J. Miller. Study conducted at ATS Labs. Study completion date – January 8, 2008. Study Identification Number A05675.

This study was conducted against Influenza A virus (ATCC VR-544; Strain Hong Kong), using Rhesus monkey kidney cells (RMK cells; obtained from ViroMed Laboratories, Inc.; maintained in-house) as the host system. Two lots (Lot Nos. 1333-056 and 1333-058) of the product, Formula Number 1262-144A, were tested according to ATS Labs Protocol No. REK01112707.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 dried for 20 minutes at 20.0°C at 54% relative humidity. For each lot of product, five separate dried virus films were sprayed (3 pumps) with the product at a distance of 6-8 inches from the carrier surface. Each carrier remained exposed to the product for 30 seconds at 20.0°C. Just prior to the termination of the exposure time, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed through individual Sephadex columns, 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 count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

Note: The aliquot of low titer stock virus used for the neutralization control contained approximately 316 infectious units, which is a higher number of units than typically used.

7. MRID 474557-24 "Inactivation of Poliovirus Type 1 in the Presence of Organic Matter," for Formula Number 1262-144A, by Kelly Whitehead. Study conducted at Reckitt Benckiser Inc. Study completion date – March 18, 2008. Master Schedule No. 2007-0139.

This study was conducted against Poliovirus type 1 (ATCC VR-192; Strain Chat) using cultures of Vero cells (obtained from ViroMed Laboratories, Minneapolis, MN) as the host

system. Three lots (Lot Nos. 1333-030, 1333-056, and t333-058) of the product, Formula Number 1262-t44A, were tested according to Reckitt Benckiser Inc.'s protocol, "Inactivation of Poliovirus type 1 in the Presence of Organic Matter" (copy provided). The product was received ready-to-use. Testing was conducted on December 12, 2007 and January 11, 2008. The stock virus culture was adjusted to contain at least 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.3 ml of virus inoculum uniformly over the bottoms of separate sterile polystyrene Petri dishes. The virus films were dried for 44-72 minutes at 25.2-25.6°C at 27.48-31.80% humidity. For the each lot of product, separate dried virus films were sprayed (2-3 pumps) with the product at a distance of 6-8 inches from the carrier surface. Each virus film was exposed to the product for 5 minutes at 19.8-20.8°C. Following exposure, the plates were neutralized with 2.0 ml of fetal bovine serum. The plates were then scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed through individual Sephadex columns, and diluted serially in Minimum Essential Medium supplemented with gentamicin. Vero cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated for 5 days at 36.5-37.0°C in 3.340-7.464% CO_2. The cultures were examined for the presence or absence of cytopathic effects (i.e., refractile rounding and sloughing) and cytotoxicity. Controls included those for host cell viability, dried virus count, cytotoxicity, and neutralization effectiveness. Viral and cytotoxicity titers were calculated by the method of Reed and Muench.

Note: The laboratory reported a failed trial set up on December 12, 2007. In that trial, 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 January 11, 2008. See page 12 and Attachment 3 of the laboratory study.

8. MRID 474557-25 "Inactivation of Human Respiratory Syncytial Virus (RSV) in the Presence of Organic Matter," for Formula Number 1262-144A, by Kelly Whitehead. Study conducted at Reckitt Benckiser Inc. Study completion date – March 18, 2008. Master Schedule No. 2007-0128.

This study was initiated via Reckitt Benckiser Inc.'s protocol "Inactivation of Human Respiratory Syncytial Virus (RSV) in the Presence of Organic Matter." Assays were set up on December 3, 2007 and December 19, 2007. The study included an amendment, dated January 3, 2008, serving to terminate the study. The study was sent to an external facility, ATS Labs, due to time constraints. No conclusions were made because the host cells were not healthy confluent cells at the end of either assay.

Note: Further investigation, by the laboratory, revealed that bacterial or fungal contamination was not the cause. The laboratory concluded that other possible causes could be mycoplasma, other virus contamination or, more likely, cell death due to apoptosis (e.g., end of life cycle/ too many passages).

9. MRID 474557-26 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces" for Formula Number 1262-144A, Test Organism: Respiratory Syncytial Virus, by Mary J. Miller. Study conducted at ATS Labs. Study completion date – January 30, 2008. Study Identification Number A05772.

This study was conducted against Respiratory syncytial virus (ATCC VR-26; Strain Long), using human larynx carcinoma (Hep-2 cells; obtained from ViroMed Laboratories, Inc.;

maintained in-house) as the host system. Two lots (Lot Nos. 1333-056 and 1333-058) of the product, Formula Number 1262-144A, were tested according to ATS Labs Protocol No. REK01010208.RSV (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 dried for 20 minutes at 20.2°C at 50% relative humidity. For each lot of product, five separate dried virus films were sprayed (3 pumps) with the product at a distance of 6-8 inches from the carrier surface. Each carrier remained exposed to the product for 5 minutes at 20.2°C. Just prior to the termination of the exposure time, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed through individual Sephadex columns, and diluted serially in Eagle's Minimum Essential Medium supplemented with 2% heat-inactivated fetal bovine serum, 10 µg/ml gentamicin, 100 units/ml penicillin, 2.5 µg/ml Fungizone, 10 µg/ml vancomycin, 2 mM L-glutamine, and 10 mM HEPES. Hep-2 cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 31-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 9 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

10. MRID 474557-27 "Inactivation of Human Rotavirus in the Presence of Organic Matter" for Formula Number 1262-144A, by Kelly Whitehead. Study conducted at Reckitt Benckiser Inc. Study completion date – March 18, 2008. Master Schedule No. 2007-0127.

This study was initiated via Reckitt Benckiser Inc.'s protocol "Inactivation of Human Rotavirus in the Presence of Organic Matter." The study included an amendment, dated December 7, 2007, serving to terminate the study. The study was sent to an external facility, ATS Labs, due to time constraints. No conclusions were made because the host cells were not healthy confluent cells at the end of the assay.

11. MRID 474557-28 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces" for Formula Number 1262-144A, Test Organism: Rotavirus, by Mary J. Miller. Study conducted at ATS Labs. Study completion date – February 6, 2008. Study Identification Number A05676.

This study was conducted against Rotavirus (Strain WA; obtained from the University of Ottawa, Ontario, Canada), using Rhesus monkey kidney cells (MA-104 cells; obtained from Diagnostic Hybrids Inc., Athens, OH; propagated in-house) as the host system. Two lots (Lot Nos. 1333-056 and 1333-058) of the product, Formula Number 1262-144A, were tested according to ATS Labs Protocol No. REK01112707.ROT (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 dried for 20 minutes at 20.1°C at 43% relative humidity. For each lot of product, five separate dried virus films were sprayed (3 pumps) with the product at a distance of 6-8 inches from the carrier surface. Each carrier remained exposed to the product for 5 minutes at 20.1°C. Just prior to the termination of the exposure time, the plates were scraped with a cell scraper to re-suspend the

contents. The virus-disinfectant mixtures were passed through individual Sephadex columns, and diluted serially in serum-free Minimum Essential Medium supplemented with 10 µg/ml gentamicin, 100 units/ml penicillin, 2.5 µg/ml amphotericin B, 2.0 mM L-glutamine, and 0.5 µg/ml trypsin. Following titration, the 10^{-2} dilution of each replicate was passed through an individual Sephadex column to aid in removing the cytotoxic effects of the product to the indicator cell cultures. MA-104 cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The inoculum was allowed to adsorb for 60 minutes. Post-adsorption, test medium was added to each well and the cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 6 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

Note: The laboratory reported a failed trial set up on January 2, 2008. In that trial, a 3-log reduction in titer beyond the cytotoxic level was not demonstrated. These data were not used to evaluate efficacy of the product. Testing was repeated on January 24, 2008. See page 8 and Attachment I of the laboratory study.

12. MRID 474557-29 "Sanitization Study: Quantitative Reduction of Bacteria on a Non-Food Contact Surface" for Formula Number 1262-144A, Test Organism: *Salmonella enterica* (ATCC 10708), by Kyle T. Smith. Study conducted at Reckitt Benckiser Inc. Study completion date – March 11, 2008. Master Schedule No. 2007-0134.

This study was conducted against *Salmonella enterica* (ATCC 10708). Three lots (Lot Nos. 1333-030, 1333-056, and 1333-058) of the product, Formula Number 1262-144A, were tested. The laboratory study referenced a modification of ASTM Standard Method E1153-87 (Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces). The product was received ready-to-use. Testing was conducted on November 29, 2007 and December 4, 2007. A culture of the challenge microorganism was prepared in accordance with the published AOAC method. Horse serum was added to the culture to achieve a 5% organic soil load. Five sterile glass slide carriers per product lot were inoculated with 0.02 ml of a 24±2 hour old suspension of the test organism. The carriers were dried for 40 minutes at 35.4-35.8°C. For each lot of product, separate carriers were sprayed (2-3 pumps) with the product at a distance of 6-8 inches from the carrier surface. Each carrier was exposed to the product for 30 seconds at 21.9°C. Following exposure, individual carriers were transferred to 20 ml of D/E Broth to neutralize. All subcultures were incubated for at least 50 hours at 34.3-36.2°C. Following incubation, colonies were counted. Controls included a non-active control and those for test system verification (i.e., purity, identity), sterility, inoculum count, dried recovery carrier count, and neutralizer efficacy.

Note: The laboratory reported a failed trial set up on November 29, 2007. In that trial, the non-active control and dried recovery carrier control values were below the required minimum range of 1×10^4 CFU/carrier. In addition, it was determined that 10 ml of the neutralizing medium (i.e., D/E Broth) was insufficient in neutralizing the product. The laboratory did not accept the assay. These data were not used to evaluate efficacy of the product. Testing was repeated on December 4, 2007. See page 15 and Appendix B of the laboratory study.

13. MRID 474557-30 "Sanitization Study: Quantitative Reduction of Bacteria on a Non-Food Contact Surface," for Formula Number 1262-144A, Test Organisms: *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048), by Kyle T. Smith. Study conducted at Reckitt Benckiser Inc. Study completion date – March 11, 2008. Master Schedule No. 2007-0135.

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048). Three lots (Lot Nos. 1333-030, 1333-056, and 1333-058) of the product, Formula Number 1262-144A, were tested. The laboratory study referenced a modification of ASTM Standard Method E1153-87 (Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces). Each of the three product lots tested was at least 60 days old at the time. The product was received ready-to-use. Cultures of the challenge microorganisms were prepared in accordance with the published AOAC method(s). Horse serum was added to the culture to achieve a 5% organic soil load. Five sterile glass slide carriers per product lot were inoculated with 0.03 ml of a 24-hour old suspension of a test organism. The carriers were dried for 51-55 minutes at 35.1-35.4°C. For each lot of product, separate carriers were sprayed (2-3 pumps) with the product at a distance of 6-8 inches from the carrier surface. Each carrier was exposed to the product for 30 seconds at 21.9-22.3°C. Following exposure, individual carriers were transferred to 20 ml of D/E Broth to neutralize. All subcultures were incubated for at least 68 hours at 29.4-36.2°C. Following incubation, colonies were counted. Controls included a non-active control and those for test system verification (i.e., purity, identity), sterility, inoculum count, dried recovery carrier count, and neutralizer efficacy.

14. MRID 474557-31 "Hospital Type Disinfectant Efficacy Testing in the Presence of Organic Soil," for Formula Number 1333-117A, by Kyle T. Smith. Study conducted at Reckitt Benckiser Inc. Study completion date – April 3, 2008. Master Schedule No. 2008-0044.

This confirmatory study was conducted against *Staphylococcus aureus* (ATCC 6538), *Salmonella enterica* (ATCC 10708), and *Pseudomonas aeruginosa* (ATCC 15442). Three lots (Lot Nos. 1333-173, 1333-175, and 1333-176) of the product, Formula Number 1333-117A, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. The product was received ready-to-use. Cultures of the challenge microorganisms were prepared in accordance with the published AOAC method(s). Horse serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers were inoculated with 0.01 ml of a 48±2 hour old suspension of a test organism. The carriers were dried for 40-42 minutes at 33.9-34.8°C. For each lot of product, separate carriers were sprayed (2-3 pumps) with the product at a distance of 6-8 inches from the carrier surface. Each carrier was exposed to the product for 5 minutes at 22.1-22.9°C. The carriers were transferred to 20 ml of Letheen Broth to neutralize. All subcultures were incubated for at least 67 hours at 33.5-35.5°C, and then examined for the presence or absence of visible growth. Controls included those for test system verification (i.e., purity, identity), sterility, inoculum count, dried recovery carrier count, and neutralizer efficacy.

15. MRID 474557-32 "Fungistatic Activity in the Presence of Organic Soil" for Formula Number 1262-144A, Test Organism: *Aspergillus niger* (ATCC 6275), by Kyle T. Smith. Study conducted at Reckitt Benckiser Inc. Study completion date – March 11, 2008. Master Schedule No. 2007-0125.

This study was conducted against *Aspergillus niger* (ATCC 6275). Three lots (Lot Nos. t333-030, 1333-056, and 1333-058) of the product, Formula Number t262-t44A, were tested using the EPA Hard Surface Mildew Fungistatic Test Method. The product was received ready-to-use. A 1 ml aliquot of a standardized conidial suspension was added to 20 ml of Czapek Dox Broth. This suspension was supplemented with horse serum to achieve a final concentration of 5% (v/v) horse serum. Sterile 25 mm^2 glazed ceramic tiles (t0 per treatment) were sprayed (2-3 pumps) with the product at a distance of 6-8 inches from the carrier surface. Each carrier remained exposed to the product for 3 minutes at 2t.6-2t.9°C. Following treatment, the tiles were dried for 40-42 minutes at 34.7-35.8°C. Following the drying period, the surfaces of each test tile and each untreated control tile were inoculated with 0.0t ml of the conidial suspension using a sterile inoculating loop. The tiles were returned to 34.3-35.t°C and dried for 40 minutes. Each tile (treated side up) was placed in an individual Petri dish containing 2% water agar. The plates and tubes were incubated at 24.6-25.3°C. The tiles were examined for the presence or absence of fungal growth after 7 days, 12 hours, and 7 minutes of incubation. When no growth was visually observed, a magnified examination was performed. Controls included those for spore suspension count, test system verification (purity and identity), and sterility.

V RESULTS

MRID Number	Organism	No. Exhibiting Growth/ Total No. Tested				Dried Recovery Carrier Count (CFU/ Carrier)
		Lot No. t333-030	Lot No. 1333-036	Lot No. t333-056	Lot No. 1333-058	
474557-18	*Staphylococcus aureus*	0/60	---	0/60	0/60	$1.36 \times t0^6$ to 5.5×10^6
474557-19	*Salmonella enterica*	---	t/60	0/60	0/60	4.1×10^4 to 2.61×10^5
474557-20	*Pseudomonas aeruginosa*	1/60	---	0/60	0/60	1.12×10^6 to 8.3×10^6

MRID Number	Organism	No. Exhibiting Growth/ Total No. Tested			Dried Recovery Carrier Count (CFU/ Carrier)
		Lot No. 1333-173	Lot No. t333-175	Lot No. t333-176	
474557-31	*Staphylococcus aureus*	0/10	0/10	0/10	8.7×10^5 to 1.12×10^6
474557-31	*Salmonella enterica*	0/10	0/10	0/10	1.61×10^5 to 6.0×10^5
474557-31	*Pseudomonas aeruginosa*	0/10	0/10	0/10	5.0×10^5 to 1.28×10^6

MRID Number	Organism	Results				Dried Virus Control
			Lot No. 1333-030	Lot No. 1333-056	Lot No. 1333-058	
474557-21	Influenza A virus (H1N1/ Avian flu)	10^{-1} to 10^{-2} dilutions	Cytotoxicity		---	$10^{7.17}$ ID_{50}/ 0.2 ml
		10^{-3} to 10^{-5} dilutions	Complete inactivation		---	
		ID_{50}/0.2 ml	$\leq 10^{2.5}$		---	
		Log reduction	≥4.67 log10		---	
474557-23	Influenza A virus (Hong Kong)	10^{-1} dilution	---	Cytotoxicity		$10^{5.96}$ $TCID_{50}$/0.1 ml
		10^{-2} to 10^{-7} dilutions	---	Complete inactivation		
		$TCID_{50}$/0.1 ml	---	$\leq 10^{1.5}$	$\leq 10^{0.5\text{-}1.5}$*	
		Log reduction	---	≥4.46 log10		
474557-24	Poliovirus type 1	10^{-2} to 10^{-5} dilutions	Complete inactivation			$10^{7.33}$ ID_{50}/ 0.1 ml
		ID_{50}/0.1 ml	$\leq 10^{1.5}$	$\leq 10^{1.5}$	$\leq 10^{1.5}$	
474557-26	Respiratory syncytial virus	10^{-1} to 10^{-6} dilutions	---	Complete inactivation		$10^{4.62}$ $TCID_{50}$/0.1 ml
		$TCID_{50}$/0.1 ml	---	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
474557-28	Rotavirus	10^{-1} dilution	---	Cytotoxicity		$10^{5.74}$ $TCID_{50}$/0.1 ml
		10^{-2} to 10^{-7} dilutions	---	Complete inactivation		
		$TCID_{50}$/0.1 ml	---	$\leq 10^{1.5}$	$\leq 10^{1.5}$	
		Log reduction	---	≥4.24 log10		

*A $TCID_{50}$/0.1 ml of $\leq 10^{0.5}$ for Replicate #5 was reported.

MRID Number	Organism	Lot No.	Geometric Mean Surviving	Parallel Control	Percent Reduction
			(CFU/ carrier)		
474557-29	*Salmonella enterica*	1333-030	1.0×10^1	3.9×10^4	>99.9
		1333-056	1.0×10^1	3.9×10^4	>99.9
		1333-058	1.0×10^1	3.9×10^4	>99.9
474557-30	*Staphylococcus aureus*	1333-030	1.0×10^1	2.34×10^7	>99.9
		1333-056	1.0×10^1	2.34×10^7	>99.9
		1333-058	1.0×10^1	2.34×10^7	>99.9
	Enterobacter aerogenes	1333-030	1.32×10^1	1.65×10^5	>99.9
		1333-056	1.51×10^1	1.65×10^5	>99.9
		1333-058	1.51×10^1	1.65×10^5	>99.9

MRID Number	Organism	No. Exhibiting Growth/ Total No. Tested			Control Tiles
		Lot No. 1333-030	Lot No. 1333-056	Lot No. 1333-058	
474557-32	*Aspergillus niger*	0/10	0/10	0/10	10/10*

* At least 50% fungal growth on each untreated control tile was observed.

VI CONCLUSIONS

A. Conclusions Regarding Use of the Product as a Disinfectant

1. The submitted efficacy data do not support the use of the product, Gattuso GP (also referred to as Formula Number 1262-144A), as a disinfectant with bactericidal activity against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load for a 5-minute contact time:

Staphylococcus aureus	MRID 474557-18
Salmonella enterica	MRID 474557-19
Pseudomonas aeruginosa	MRID 474557-20

AOAC method deviations were cited regarding culture preparation, carrier drying, and subculture incubation. The culture preparation deviation (i.e. coarse filtered) is considered significant, and warrants rationale from registrant explaining the deviation from the method and feasibility. These deviations (culture preparation, carrier drying time, and subculture incubation) were not included in the Protocol Deviation sections. Additionally, **the registrant must provide rationale for the utilizing the Hard Surface Carrier Test method to the filtration step, and not continuing beyond this step (i.e. development of standard curve, etc.).** Lastly, the Hard Surface Carrier Test method was the basis of the filtration step; however this method was not mentioned as a reference.

Rationale provided by Diane Bosenberg (Reckitt Benckiser), emailed on September 29, 2008, to support data (EPA Reg. No. 777-99) with the identical issues, provided the following rationale:

"As per our conversation, I am responding back to your email from September 22, 2008 regarding the AOAC method deviations cited in the efficacy data presented for support of the Amendment on EPA Registration Number 777-99, OPP Decision Number D-397979.

As discussed, these deviations have been in place in our Microbiology laboratory for many years (some as far back as 10 years). They have been disclosed in our protocols and final reports during this time without issue. Also, they are explained in detail in our Microbiology SOPs which have been reviewed during our EPA audits without comment. The original registration for EPA Registration Number 777-99 was done in the same manner and was approved. Considering that these deviations to the AOAC method are standard practice and are disclosed in all of our documentation, we do not consider them deviations that need to be explained in the Protocol Deviations section.

In addition, as you know, the Germicidal Spray Products as Disinfectants method is currently under review and is being updated through US EPA (in conjunction with AOAC) and industry collaboration with the intention of harmonizing the language to be in line with the Use-dilution Method as revised and published in 2006. The test parameter changes are to include ranges where appropriate for things such as time and temperature. As revised, these modifications are more in line with Reckitt Benckiser standard practices as reported in MRID Numbers 474759-03, 04, 05, 06 and 07.

The deviations you cite in your email include: culture preparation, carrier drying and subculture incubation. This document will provide you with additional information on each of these points.

Culture Preparation:

The culture preparation information regarding the coarse filtration step is contained in our protocol under the section titled "Preparation of Test Culture / Addition of Organic Load". The specific directions state to "Pour the test culture through a sterile funnel containing coarse filtration medium to remove any particulates." Our standard practice is to use sterile glass wool as the filtration medium. Our SOP states:

> *Prior to the addition of organic soil, the test organism is coarse filtered through glass wool. In many laboratories, it is common practice to allow the test organism to sit prior to testing to allow for any extraneous organic matter to settle, and to be separated from the test organism that will be used for testing. In our laboratory, coarse filtering the test organism is performed to provide this result. Coarse filtering has not been shown to cause any change to the test organism, and inoculum and dried recovery control counts are routinely within the expected and acceptable ranges.*

This method of culture preparation removes any particulates, organism clumping and is a way to remove the pellicle from *Pseudomonas aeruginosa* cultures without the need for additional manipulation. We routinely see consistent and reproducible dried carrier counts using this technique (i.e. 10^5 to $10^{6/7}$). As an additional step in the test, the organism is verified for growth characteristics, purity and identity.

The current AOAC method 961.02 (Germicidal Spray Products as Disinfectants) states to

> "Thoroughly shake 48 h nutrient broth cultures of *S. choleraesuis* and *S. aureus* and let settle 10 min."

Taking this and the ongoing method revision, if you were to follow the methods Testing Disinfectants against *Salmonella choleraesuis* (955.14) or Testing Disinfectants against *Staphylococcus aureus* (955.15) for test culture preparation, the directions state to:

> "Using a Vortex-style mixer, mix nutrient broth test cultures 3 – 4 s and let stand 10 min at room temperature before continuing. Remove the upper portion of each culture, leaving behind any debris or clumps, and transfer to a sterile flask ..."

The current AOAC method 964.02 (Testing Disinfectants against *Pseudomonas aeruginosa*) states:

> "The pellicle from the 48 – 54 h cultures must be removed from the broth before mixing on a Vortex mixer either by decanting the liquid aseptically into a sterile tube or by gently aspirating the broth away from the pellicle using a pipet. ... Using a Vortex-style mixer ..."

We maintain that our method of filtration of the culture through sterile glass wool is equivalent to allowing the cultures to sit undisturbed, removing the upper portion and using that for testing purposes.

Carrier Drying and Subculture Incubation:

The carrier drying information is contained in our protocol in "Drying the Inoculated Test Surface". The specific directions state to

> "Place the petri dishes containing the inoculated slides into a 35±2.5^{0}C incubator, and dry for 40 – 42 minutes."

The subculture Incubation information is contained in the protocol in "Incubation". The specific directions state

> "The target temperature and duration for incubation of the test materials is 35±2.5^{0}C for a minimum of 46 hours."

Our SOP states:

> *Incubation temperatures will be 35 ± 2.5°C when the method specifies 37°C. Incubation temperature of 25 ± 2.5°C or 30 ± 2.5°C will be used for assays using fungi or other test systems requiring lower temperatures. Incubation duration will be over two or more nights. Incubators used in this test method are set and controlled at a set temperature range of 35 ± 2.5°C, 30 ± 2.5°C or 25 ± 1°C for optimal cultivation of organisms. These temperature ranges are monitored by the REES Series II PC Environmental Monitoring*

System (refer to SOP NO. M/V 78). The AOAC Germicidal Spray Products Method does not provide an incubation duration range. A precise 48 hour incubation is too rigid a time to read test results. Incubation over two nights is acceptable when growth controls are positive for bacteria. Fungi testing will require a longer incubation period according to the growth requirements of the organism being tested and can also be determined by sufficient growth of controls. Extended incubation provides a tougher criteria for the test substance, since sub-lethally injured organisms would have longer to recover and multiply. Extended incubation is acceptable as long as the subculture media does not evaporate or otherwise deteriorate, preventing observation of results.

The incubation time for the test materials is more specific in the protocol (i.e. ≥46 hours) than stated in the SOP (i.e. over two or more nights). The drying and incubation times are recorded in the raw data as time start and time end so the exact duration can be ascertained and reported.

When performing these methods, it is apparent that it is impossible to be as exact as the method specifies (i.e. 48 hours at 37°C). This necessitated the addition of ranges for time and temperature as stated in Reckitt Benckiser's SOPs. The time and temperature ranges for drying and incubation were determined by our laboratory to be optimal for the test organisms. Considering the expanded temperature range and drying and incubation time of the revised methods, our standard procedures are more in line with the method modifications and standard industry practices.

To ensure accuracy, all of the Microbiology laboratory equipment is monitored for environmental conditions using the REES Series II PC Environmental Monitoring System. This system allows for more precise data recording and collection throughout any given time period / study. The REES is a computerized system where through a series of probes which are connected to a centralized computer system, accurate information can be obtained about the specific conditions of that equipment. The system has the ability to scan the equipment for the set parameters (i.e. temperature / humidity) every 1.6 seconds and then records that information. Currently the system is set to record the temperature of the incubators at 1 hour intervals. Since the system is continuously scanned, if the temperature deviates from the set range, the system begins recording the temperature every minute until the parameters are once again met. This way we can monitor how long a temperature excursion occurred and determine its impact on the study. Most laboratories record temperatures using mercury thermometers at specific times of the day which does not allow for temperature fluctuations to be captured and is only a moment in time for a study that incubates over the course of several days.

In conclusion, all of the changes that we have made over the years have been done with much internal scrutiny and deliberation. I understand that you are putting these submissions under additional scrutiny due to the ATP program and industry inquiries. As I indicated to you, we intend to disclose our deviations during the workshop being planned between US EPA and industry. We stand behind our deviations as good science and have always thought of these deviations as ways to move the methods forward to current day technologies."

The registrant must submit confirmatory data consistent with the AOAC Germicidal Spray Products test (i.e. without the filtration step). The Agency has determined that utilizing the coarse filtration for particulate removal is a significant deviation. As this is a long-standing practice at Reckitt-Benckiser, the Agency will require the submission of confirmatory data for these bacteria.

2. The submitted confirmatory efficacy data (MRID 474557-31) do not support the use of the alternate formulation of the product, Gattuso GP (also referred to as Formula Number 1333-117A), as a disinfectant with bactericidal activity against *Staphylococcus aureus*, *Salmonella enterica*, and *Pseudomonas aeruginosa* on hard, non-porous surfaces in the presence of a 5% organic soil load for a 5-minute contact time. Consistent with the observation noted above, **the registrant must submit confirmatory data consistent with the AOAC Germicidal Spray Products test (i.e. without the filtration step). The Agency has determined that utilizing coarse filtration for particulate removal is a significant deviation. As this is a long-standing practice at Reckitt-Benckiser, the Agency will require the submission of confirmatory data for these bacteria, only.**

3. The submitted efficacy data support the use of the product, Gattuso GP (also referred to as Formula Number 1262-144A), 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 the contact time specified:

Influenza A virus (H1N1/Avian flu)	30 seconds	MRID 474557-21
Influenza A virus (Hong Kong)	30 seconds	MRID 474557-23
Poliovirus type 1	5 minutes	MRID 474557-24
Respiratory syncytial virus	5 minutes	MRID 474557-26
Rotavirus	5 minutes	MRID 474557-28

Recoverable virus titers of at least 10^4 were achieved. In studies against Rotavirus and Influenza A virus (Hong Kong), cytotoxicity was observed in the 10^{-1} dilutions. Cytotoxicity was observed in the 10^{-1} to 10^{-2} dilutions in studies against Influenza A virus (H1N1/Avian flu). Complete inactivation was indicated in all higher dilutions tested. At least a 3-log reduction in titer was demonstrated beyond the cytotoxic level.

In studies against Poliovirus type 1 and Respiratory syncytial virus, cytotoxicity was not observed. Complete inactivation (no growth) was indicated in all dilutions tested.

B. Conclusions Regarding Use of the Product as a Sanitizer

1. The submitted efficacy data do not support the use of the product, Gattuso GP (also referred to as Formula Number 1262-144A), as a sanitizer against the following microorganisms on hard, non-porous, non-food contact surfaces in the presence of a 5% organic soil load for a 30-second contact time:

Salmonella enterica	MRID 474557-29
Enterobacter aerogenes	MRID 474557-30

At least a 99.9% reduction in population over the parallel control within 5 minutes (actually within 30 seconds) was observed. At least one of the product lots tested against *Staphylococcus aureus* and *Enterobacter aerogenes* was at least 60 days old at the time of testing. Neutralizer efficacy testing showed positive growth of the microorganisms. **Dried recovery carrier counts and non-active control counts were < 7.5 x 10^5, as consistent with ASTM 1153; briefly, "an average of at least 7.5 x 10^5 organisms must have survived on the inoculated control squares for the test to be valid."**

2. The submitted efficacy data support the use of the product, Gattuso GP (also referred to as Formula Number 1262-144A), as a sanitizer against *Staphylococcus aureus* (MRID 474557-30) on hard, non-porous, non-food contact surfaces in the presence of a 5% organic soil load for a 30-second contact time. At least a 99.9% reduction in population over the parallel control within 5 minutes (actually within 30 seconds) was observed. At least one of the product lots tested against *Staphylococcus aureus* and *Enterobacter aerogenes* was at least 60 days old at the time of testing. Neutralizer efficacy testing showed positive growth of the microorganisms. **Dried recovery carrier counts and non-active control counts were ≥ 7.5 x 10^5, as consistent with ASTM 1153.**

C. Conclusions Regarding Use of the Product as a Fungistat

1. The submitted efficacy data (MRID 474557-32) do not currently support the use of the product, Gattuso GP (also referred to as Formula Number 1262-144A), as a fungistat against *Aspergillus niger* on hard, non-porous surfaces in the presence of a 5% organic soil load for a contact time of 3 minutes. Although no growth was observed 7 days, 12 hours, and 7 minutes after treatment, it does not appear that the plates were incubated at a minimum of 95% relative humidity. [The laboratory study did not report incubation humidity conditions.] Testing was conducted on 3 product lots. Untreated control tiles exhibited growth of *Aspergillus niger* on at least 50% of the untreated tile surface. Test system verification controls verified the identity of the challenge microorganism. Sterility controls did not show growth. Unless plates were incubated at a minimum of 95% relative humidity, fungistat claims are not supported by the submitted data and must be deleted from the proposed label. This information is required.

VII RECOMMENDATIONS

1. The proposed label are unacceptable regarding use of the product, Gattuso GP, as a disinfectant against the following microorganisms on pre-cleaned, hard, non-porous surfaces for the contact time listed:

Staphylococcus aureus	5 minutes
Salmonella enterica	5 minutes
Pseudomonas aeruginosa	5 minutes

Confirmatory data, as outlined in the Conclusions section, must be submitted to the Agency.

2. Until the disinfectant confirmatory efficacy data is submitted to the Agency, the proposed label claims are unacceptable regarding use of the product, Gattuso GP, as a disinfectant with virucidal claims against the following microorganisms on pre-cleaned, hard, non-porous surfaces for the contact times listed:

Avian influenza A virus (H1N1)	30 seconds
Influenza A virus (Hong Kong)	30 seconds
Poliovirus type 1	5 minutes
Respiratory syncytial virus	5 minutes
Rotavirus WA	5 minutes

Confirmatory data, as outlined in the Conclusions section, must be submitted to the Agency.

3. The proposed label claims are unacceptable regarding use of the product, Gattuso GP, as a sanitizer against the following microorganisms on pre-cleaned, hard, non-porous, non-food contact surfaces for a 30-second contact time:

Salmonella enterica
Enterobacter aerogenes

Dried recovery carrier counts and non-active control counts were < 7.5×10^5, as

consistent with ASTM 1153; briefly, "an average of at least 7.5 x 10^5 organisms must have survived on the inoculated control squares for the test to be valid." Acceptable data was generated, with valid carrier counts, for *Staphylococcus aureus*. **To support non-food contact sanitization claims, acceptable efficacy data is required for *Staphylococcus aureus* and *Enterobacter aerogenes* or *Klebsiella pneumoniae*.**

4. The proposed label claims are unacceptable regarding use of the product, Gattuso GP, as a fungistat against *Aspergillus niger* on pre-cleaned, hard, non-porous surfaces for a 3-minute contact time. As discussed in the "Conclusions" section of this efficacy report, incubation humidity conditions were not reported. Unless plates were incubated at a minimum of 95% relative humidity, fungistat claims are not supported by the submitted data and must be deleted from the proposed label. This information is required.

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

   - Under the surface types listed on page 8 of the proposed label, change "Enamal" to read "Baked enamel."

   - Under the "Unqualified metal surface" statement on page 8 of the proposed label, change "otherwise enters" to read "otherwise enter."