UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

April 11, 2009

**MEMORANDUM**

Subject: Efficacy Review for EPA File Symbol No. 777-RNI, Gattuso GP
DP Barcode: 362630

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

4/17/09

Thru: Michele Wingfield, Chief
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To: Tracy Lantz PM 34/ Stacey Grisby
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Reckitt Benckiser, Inc.
Morris Corporate Center IV
399 Interspace Parkway
Parsippany, NJ 07054-0225

Formulations from Label

| Active Ingredient(s) | % by wt. |
|---|---|
| Citric Acid | 3.5% |
| Other Ingredients | 96.5% |
| Total | 100.0% |

## I BACKGROUND

The product, Gattuso GP (EPA File Symbol 777-RNI), is a new product. The applicant requested to register the ready-to-use product for use as a disinfectant (bactericide, virucide), sanitizer, and deodorizer on hard, non-porous surfaces in household, institutional, commercial, and hospital or medical environments. The studies in this data package were submitted to the Agency in response to a letter from the Agency to the applicant (dated November 5, 2008). Studies were conducted at Reckitt Benckiser Inc., Microbiology Laboratory, located at One Phillips Parkway, in Montvale, NJ 07645. It appears as though this data package is the result of a study rejected at front-end processing by the Agency. This efficacy study was originally included in the DP# 362066. The Conclusion statement included in DP# 362066 stated that "**the Agency has stated that it would accept these three efficacy studies which utilize a "coarse filtration" step provided that the applicant conducts and submits hospital confirmatory testing without utilizing a "coarse filtration" step. The applicant conducted such testing; however, the laboratory report identified as Volume 21 was rejected by the Agency and is not yet available for review.**"

## II USE DIRECTIONS

The product is designed for disinfecting and sanitizing hard, non-porous surfaces, including: bathtubs, cabinets, 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: enamel, glass, glazed ceramic, glazed porcelain, glazed tile, laminated plastic, linoleum, metal (e.g., chrome, stainless steel), and vinyl. Directions on the proposed label provide 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.

## 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 t5442). 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. 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 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.

## IV SYNOPSIS OF SUBMITTED EFFICACY STUDY

**1. MRID 476883-01 "Hospital Type Disinfectant Efficacy Testing in the Presence of Organic Soil," Test Organisms: *Staphylococcus aureus* (ATCC 6538), Salmonella enterica (ATCC 10708), and Pseudomonas aeruginosa (ATCC 15442) for Formula Number 1333-117A, by Kyle T. Smith. Study conducted at Reckitt Benckiser Inc. Study completion date – January 27, 2009. Amended final report dates – (1) January 27, 2009 and (2) February 26, 2009. Master Schedule No. 2008-0223.**

This study was conducted against *Staphylococcus aureus* (ATCC 6538), *Salmonella enterica* (ATCC 10708), and *Pseudomonas aeruginosa* (ATCC 15442). Three lots (Lot Nos. 1453-108, 1453-110, and 1453-111) 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. All lots were at least 60 days old at the time of testing. The product was received ready-to-use, as a trigger spray. A culture of the challenge microorganism was prepared in accordance with the published AOAC method, with the following exceptions: (1) the culture was incubated for 48±2 hours at a target temperature of 35±2.5°C (which differs from the AOAC method specification of 48 hours for all bacterial cultures except *Pseudomonas aeruginosa*); and (2) the final culture transfer was coarse filtered. Horse serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers (20 mm x 25 mm)/lot/test organism were inoculated with 0.01 mL of the test culture. Inoculum was uniformly spread over the surface of the carriers. The carriers were dried for 40-42 minutes at 32.5-37.5°C (which differs from the AOAC method specification of 30-40 minutes at 37°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. The carriers were allowed to remain wet for 5 minutes at ambient temperature. Following the exposure period, the remaining liquid was drained from each carrier. Individual carriers were transferred to 20 mL of subculture broth to neutralize. Subcultures then were gently agitated or shaken. All subcultures were incubated for at least 46 hours at 32.7-37.9°C (which differs from the AOAC method specification of 48

hours at 37°C). Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for inoculum count, dried recovery carrier count, test system verification (i.e., purity, identity), sterility, and neutralizer efficacy.

Protocol amendments: An additional control assay, Test system Viability, was added to the test procedure; (2) the section Media and Test Substance Water Quality was added to the protocol; (3) the following section was removed from the protocol, "Sterile funnels with coarse filtration medium (e.g. glass wool, cotton, gauze). This item was not used in the study as the test systems were not be coarse filtered prior to testing; (4) In the Preparation of Test Culture section, a step for the *Pseudomonas aeruginosa* culture was inadvertently left out. For *Pseudomonas aeruginosa*, after the 48±2 hour incubation, the test tube or bottles were not be shaken. The culture was decanted into a sterile vesicle, leaving the pellicle behind. The preparation was continued as described for the other 2 test systems, using the decanted *Pseudomonas aeruginosa* culture; and (5) The original protocol was amended on November 20th, 2008 for the following reason: Page 14 of 14 is the Approval and Signature" page of the protocol. On 11/20/2008, an error was noticed in the Approval title on this page. The title read "Protocol Amendment Approval". This is incorrect, as the document approved was the original protocol for M.S. 2008-0223. This title was changed to read "Protocol Approval".

Protocol deviations: The protocol stated that the target incubation temperature for the test materials was 35±2.5°C. The test materials were incubated from 11/19/2008 through 11/21/2008 for a total incubation time of 48 hours, 53 minutes. For a period of 47 minutes on 11/21/2008, the incubation temperature fell below the above stated range, and was recorded to be between 32.2 and 32.4°C. After that time period, the temperature went back into range, and remained there for the duration of the test material incubation. The protocol also stated that incubation temperatures out of the acceptable range would be considered a protocol deviation, but would be deemed acceptable if the Dried Recovery Control values were with the expected range ($\geq 10^4$ organisms per carrier). Each of the 3 Dried Recovery Control values for each of the 3 test systems was within this expected range. Therefore, it has been concluded that this protocol deviation did not impact the integrity of this study, or the results obtained.

## V RESULTS

| MRID Number | Organism | No. Exhibiting Growth/ Total No. Tested | | | Dried Recovery Carrier Count (CFU/ Carrier) |
|---|---|---|---|---|---|
| | | Lot No. 1453-108 | Lot No. 1453-110 | Lot No. 1453-111 | |
| 476883-01 | *Staphylococcus aureus* | 0/10 | 0/10 | 0/10 | $1.76 \times 10^6$ to $2.44 \times 10^6$ |
| | *Salmonella enterica* | 0/10 | 0/10 | 0/10 | $7.7 \times 10^5$ to $1.03 \times 10^6$ |
| | *Pseudomonas aeruginosa* | 0/10 | 0/10 | 0/10 | $1.20 \times 10^5$ to $4.2 \times 10^6$ |

## VI CONCLUSION

1. The submitted confirmatory efficacy data (MRID 476883-01) do now demonstrate that the product, Gattuso GP formulated without formic acid (also referred to as Formula Number 1333-117A), is an effective disinfectant 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. Testing was done without the **"coarse filtration" step as directed by the Agency.** Complete killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Test system verification confirmed that the cultures were acceptable for use in the studies. Sterility controls did not show growth. Neutralizer efficacy testing showed positive growth of the microorganisms.

## VII RECOMMENDATION

1. The proposed label claims are acceptable regarding the use of the product, Gattuso GP, as a disinfectant against *Staphylococcus aureus*, *Salmonella enterica*, and *Pseudomonas aeruginosa* on pre-cleaned, hard, non-porous surfaces for a 5-minute contact time. These claims are now supported by the submitted confirmatory data.

2. Proposed claims, (from prior submission DPs 354310 and 362066), against Influenza A virus (H1N1/Avian Flu) for 30 seconds (MRID No. 476702-15), and Poliovirus type 1 for 5 minutes (MRID No. 476702-16) are now acceptable. The Agency's request for submission of confirmatory data was addressed in the current data package.