UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL
SAFETY AND POLLUTION
PREVENTION

June 20, 2013

**MEMORANDUM**

**Subject:** Efficacy Review for Puma; EPA Reg. No. 5813-100; DP Barcode: D410185.

**From:** Ibrahim Laniyan, Ph.D.
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**Thru:** Mark Perry
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**To:** Jaclyn Pyne / Mike Mendelsohn, Acting PM 32
Regulatory Management Branch I
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**Applicant:** The Clorox Company
c/o PS&RC
P.O. Box 493
Pleasanton, CA 94566-0803

**Formulation from the Label:**

| Active Ingredient | % by wt. |
|---|---|
| Sodium Hypochlorite | 8.25 % |
| Other Ingredients: | 91.75 % |
| Total | 100.00 % |

(Yields 7.85% available chlorine)

## I. BACKGROUND

The product, Puma (EPA Reg. No. 5813-100), is an EPA-approved disinfectant (bactericide, fungicide, virucide), sanitizer, sanitizing rinse, and deodorizer for use on hard, non-porous surfaces in household, commercial, institutional, food preparation, animal care, and hospital or medical environments. The product is also a laundry sanitizer. The applicant requested to amend the registration of this product to: (1) add a new claim for effectiveness as a disinfectant against *Mycobacterium bovis* BCG; (2) revise and add Directions for Use and various marketing claims. Efficacy study provided in the data package was conducted using the product formulated at the lower certified limit. 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 to EPA (dated March 08, 2013), EPA Form 8570-1 (Application for Pesticide), EPA Form 8570-34 (Certification with Respect to Citation of Data), EPA Form 8570-35 (Data Matrix), one study (MRID 490767-01), Statements of No Data Confidentiality Claims for the study, and the proposed label.

## II. USE DIRECTIONS

The product is designed for disinfecting and sanitizing hard, non-porous surfaces. The product is also designed for use as a laundry sanitizer. The product may be used to treat hard, non-porous surfaces, including: appliances, baby bottles, baby toys, bathtubs, bicycles, bidets, brushes, car dashboards, car door handles, changing tables, combs, counter tops, crib bumpers, cutting boards, diaper pails, dishes, faucets, floors, flower pots, furniture, garbage cans, garbage disposals, glassware, golf balls and clubs, grills, handles, high chairs, litter boxes, lunchboxes, outdoor siding, painted cribs, patio furniture, pet bowls, plastic mattress covers, playground sets, play pens, pots and pans, shower curtains, shower doors, showers, sinks, sports equipment, steering wheels, thermometers, toilet bowls, toilets, toys, trash cans, trash compactors, urinals, utensils, wading pools, and walls. The label indicates that the product may be used on hard, non-porous surfaces, including: finished woodwork, glass, glazed porcelain, glazed tile, laminate, linoleum, painted woodwork, plastic (e.g., vinyl), sealed brick, sealed granite, sealed patio stone, stainless steel, and sealed stucco. The label indicates that the product is not for use on aluminum, chipped enamel, non-stainless steel, and silver. Directions on the proposed label provide the following information regarding preparation and use of the product:

> As a disinfectant against *Mycobacterium bovis* BCG: Pre-clean surface prior to disinfection. Prepare a use solution by adding 1 part product and 9 parts water (a 1:10 dilution; ~7850 ppm) or 1 part product and 8 parts water (a 1:9 dilution; ~8700 ppm). Apply use solution and let stand for 10 minutes. Rinse and air dry. Prepare fresh solution daily

## III. AGENCY STANDARDS FOR PROPOSED CLAIMS

**Disinfectants for Use as Tuberculocides (Using the AOAC Tuberculocidal Activity of Disinfectants Test Method):** Disinfectants may bear additional label claims of effectiveness as tuberculocides when supported by appropriate tuberculocidal effectiveness data. Certain chemical classes (i.e., glutaraldehyde and quaternary ammonium compounds) are required to undergo validation testing in addition to basic testing. Products that are formulated with other

chemical groups do not require validation testing. When using the existing or modified AOAC Tuberculocidal Activity Test Methods, 10 carriers for each of 2 samples, representing 2 different product lots, must be tested against *Mycobacterium bovis* BCG (a member of the *Mycobacterium tuberculosis* species complex). Killing on all carriers/slides as demonstrated in Modified Proskauer-Beck Broth, and no growth in any of the inoculated tubes of 2 additional media (i.e., Middlebrook 7H9 Broth Difco B, Kirchners Medium, and/or TB Broth Base) is required.

## IV. BRIEF DESCRIPTION OF THE DATA

**Note**: Titration of the tested product lots 12SUK06, 12SUK07, and 12SUK08 by ATS labs resulted in the following concentrations of sodium hypochlorite: 6235 ppm, 6248 ppm, and 6115 ppm.

**1. MRID 490767-01 "AOAC Tuberculocidal Activity of Disinfectants" for Puma, F2009.0092 by Matthew Sathe. Study conducted at ATS Labs. Study completion date – January 23, 2013. Project Number A14116.**

This study was conducted against *Mycobacterium bovis* BCG. Three lots (Lot Nos. 12SUK06, 12SUK07, and 12SUK08) of the product, Puma, F2009.0092, were tested using the ATS Labs protocol CX180925.TB (copy provided). A use-dilution of the product was prepared using 20.0 ml of test substance and 180.0 ml of 100 ppm AOAC synthetic hard water (titrated 101 ppm) (1:10 dilution defined as 1 part test substance + 9 parts diluent). Porcelain penicylinder carriers were immersed for 15 minutes in a 24 days old broth culture of the test organism at a ratio of one carrier per one ml culture. The carriers were dried for 30 minutes at 35-37°C at 56.0% relative humidity. For each product lot, 10 contaminated carriers were transferred to individual tubes containing 10 ml of the product. The carriers were exposed to the product for 9 minutes 45 seconds at room temperature (20.0°C). Following exposure, each carrier was transferred to 10 ml of neutralizer. After at least 10 minutes, each carrier was transferred to a tube containing 20 ml of Modified Proskauer-Beck Broth (MPB). From each tube of neutralizer, 2 ml aliquots were subcultured to individual tubes containing 20 ml of Middlebrook 7H9 Broth and 2 ml aliquots were subcultured to individual tubes containing 20 ml of Kirchner's Medium (KM). All tubes used for primary and secondary transfers were incubated for 60 days at 35-37°C and examined for the presence or absence of visible growth at 32 days and 60 days of incubation. When no growth was observed, culture tubes were incubated an additional 30 days. All plates were incubated for 18 days at 35-37°C. Controls included those for carrier counts, viability, neutralizer effectiveness, sterility, and confirmation of the challenge microorganism. The reported average Colony Forming Units (CFU) per carrier, for the test microorganism, is: ***Mycobacterium bovis* BCG 3.4 x $10^5$**.

## V. RESULTS

| MRID # 490767-01 | Results: No. Exhibiting Growth/Total No. Tested | | | | | | | | | | Average Dried Carrier Count (CFU/carrier) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Lot | 12SUK06 | | | 12SUK07 | | | 12SUK08 | | | |
| | Day | 32 | 60 | 90 | 32 | 60 | 90 | 32 | 60 | 90 | |
| *Mycobacterium bovis* BCG | MPB | 0/10 | 0/10 | 0/10 | 0/10 | 0/10 | 0/10 | 0/10 | 0/10 | 0/10 | 3.4 x $10^5$ |
| | 7H9 | 0/10 | 0/10 | 0/10 | 0/10 | 0/10 | 0/10 | 0/10 | 0/10 | 0/10 | |
| | KM | 0/10 | 0/10 | 0/10 | 0/10 | 0/10 | 0/10 | 0/10 | 0/10 | 0/10 | |

## VI. CONCLUSION

1. The submitted efficacy data (MRID Nos. 4900767-01) **support** the use of 1:10 dilution of the product, Puma, as a disinfectant with tuberculocidal activity, on **pre-cleaned** hard, non-porous surfaces for 9 minutes 45 seconds, at room temperature (20.0°C).

## VII. LABEL

1. The proposed label claims **are acceptable** regarding the use of Puma at 1:10 or 1:9 dilution in 100 ppm hard water, to disinfect **pre-cleaned** hard, non-porous surfaces against *Mycobacterium bovis* BCG, for a 10-minute contact time, at room temperature, as supported by the submitted efficacy data.

2. The applicant must make the following changes to the proposed label, as appropriate:

- On pages 25 of the proposed label, under "Cold & Flu", **add** "**Treated**" to "**Hard non-porous surfaces**" to read "**on Treated Hard Non-porous Surfaces**".

- On pages 31 of the proposed label, **remove exposure reduction claim**.

- On page 38 of the proposed label, under "Crop/Site: Rice Seed Treatment", change "**sterilization**" to "**disinfection**".