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March 18, 2010

Via Federal Express

Document Processing Center (Mail Code 7407M)
Room 6428
Attention: 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency, ICC Building
1201 Constitution Ave., NW
Washington, DC 20004

Dear 8(e) Coordinator:

8EHQ-06-16436/8EHQ-06-16478

This letter is to inform you of the results of a pilot reproduction study in northern bobwhite quail with the above referenced test substance. This test substance is subject to a Consent Order, PMN P-08-509.

The pilot study evaluated the effects upon adult northern bobwhite quail (*Colinus virginianus*) of dietary exposure to the test substance over a six-week period. Effects on health, weight gain and feed consumption were examined along with the effects of adult exposure to the test substance on the number of eggs laid, normal development of eggs, viability of the embryos, percent hatchability, offspring survival and egg shell thickness.

Three treatment groups, each containing five pairs of northern bobwhite quail, were fed diets containing the test substance at nominal dietary concentrations of 10, 100 or 1000 ppm. A fourth control group, fed non-treated diet, was maintained concurrently with the treatment groups. Results of the analysis of the diet samples verified that the test substance was present at the appropriate concentrations, that the diet mixes were homogeneous, and that the test substance was stable for the length of exposure. The test birds were acclimated to the facilities and study pens prior to initiation of the test. During the study, all adult birds were observed daily for signs of toxicity or abnormal behavior. Adult body weights were measured at test initiation, on Weeks 2, 4, and at adult termination. Feed consumption for each pen was measured weekly throughout the test. At the conclusion of the exposure period, all adult birds were euthanized and necropsied.

Eggs were collected daily from all pens, when available. During Weeks 1 and 2 eggs were counted, then disposed. Eggs produced during Weeks 3 through 6 were counted and those selected for egg shell thickness measurement were removed. The remaining eggs were identified by an alphabetic lot code (Lots A, B, C & D). All eggs laid in a weekly interval were considered as one lot. Cracked or abnormal eggs were recorded and discarded. All eggs not discarded were placed in an incubator. Eggs were candled on Day 12 of incubation to determine embryo viability and on Day 21 to determine embryo survival. On Day 21 of incubation, the eggs were placed in a hatcher and allowed to hatch. All hatchlings, unhatched eggs and egg shells were removed from the hatcher on Day 25 or 26 of incubation. The individual body weight of the surviving hatchlings was determined. Hatchlings were leg banded for identification by pen of origin and then routinely housed according to the appropriate parental concentration grouping in brooding pens until 14 days of age. Offspring were observed daily from hatching until 14 days of age. At 14 days of age, the average body weight by parental pen of all surviving offspring was determined. All eggs laid during the six-week test were used in evaluation of egg production among the test groups. The evaluations of the other reproductive parameters were based on the eggs produced during Weeks 3 through 6 of the test (Lots A – D).

No mortalities occurred during the course of the study. Incidental clinical observations normally associated with penwear were observed during the test. Such observations included foot and head lesions and an ocular injury. Except for the incidental clinical findings, all birds in the 0, 10, 100, or 1000 ppm treatment groups were normal in

appearance and behavior for the duration of the test. When compared to the control group, there were no apparent treatment-related effects upon body weight or feed consumption at the 10, 100 or 1000 ppm test concentrations.

Due to the small sample size and short length of range-finding tests, it is not atypical for variation in egg production to be observed. While reproductive parameters were variable among individuals, when compared to the control group, there appeared to be no treatment-related effects upon reproductive performance at the 10 or 100 ppm test concentrations. However, at the 1000 ppm test concentration there was a slight reduction in viability of embryos, which was also evidenced in reductions in numbers of hatchlings and 14-day old survivors as percentages of eggs set and the maximum set.

When compared to the control group, there appeared to be no treatment-related effects upon egg shell thickness measurements and offspring body weights at the 10, 100 or 1000 ppm test concentrations. At the end of Week 6 (Day 42), all surviving birds were euthanized and subjected to gross necropsy. All findings observed were considered to be incidental and not related to treatment.

The no-observed-effect concentration for northern bobwhite quail exposed to the test substance in the diet during the study was 100 ppm.

This information is submitted in accordance with current guidance issued by EPA indicating EPA's interpretation of Section 8(e) of the Toxic Substances Control Act or, where it is not clear that reporting criteria have been met, it is submitted as a precautionary measure and because it is information in which EPA may have an interest.

Sincerely,

A. Michael Kaplan

A. Michael Kaplan, Ph.D.
Director - Regulatory Affairs

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