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March 25, 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



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Dear 8(e) Coordinator:



8 8 1 0 0 0 0 2 0 5

Diphenylguanidine  
CAS # 102-06-7

This letter is to inform you of the results of two pre-1977 (1940 and 1941) toxicity studies which we recently became aware of with the test substance referenced above.

#### Acute Oral Approximate Lethal Dose in Rats:

A group of five rats were given 1.00 cc of a 5% suspension of the test substance in agar. Based on body weight the dose levels ranged from 198 to 282 mg/kg (more details are not available). One rat showed labored breathing 5 minutes after treatment and became weak in the hind legs. This rat developed convulsive movements in 10 minutes, and progressed into a coma with cyanosis, and dying within 15 minutes after treatment. Gross pathological examination revealed the stomach was distended and the mucosa was slightly edematous. There was slight edema of the duodenum, the lungs were normal, but the cardiac muscles were very flaccid. The other rats developed dyspnea in 5-17 minutes and showed periods of alternating quiet and restlessness. The breathing returned to normal in about 3 hours. One of these rats was given a second dose of 0.5 cc of the 5% suspension in agar. Muscular twitching was noted 2 hours after the additional dose which lasted for about 5 minutes. The surviving animals showed no further signs of toxicity and when autopsied 28 days after treatment showed no significant pathology. A sixth rat was given an oral dose of a 7.5% suspension of the test substance in agar (341 mg/kg). Dyspnea developed immediately followed by restlessness and weakness in the hind legs. Convulsive movements were noted after 14 minutes and the rat became cyanotic within 16 minutes and comatose a minute later when the convulsive movements ceased. The coma lasted for about one and one-half hours. The rat slowly returned to normal the day after dosing and an autopsy 28 days after dosing showed no significant pathological changes.

#### Skin Irritation and Sensitization in Guinea Pigs:

Two groups of animals were used to determine skin irritation and dermal sensitization. One group of 7 guinea pigs was placed on a diet of rabbit chow, plus daily carrot and cabbage greens. The other group of 8 guinea pigs was placed on a diet of rabbit chow, plus 50 mg of vitamin C per animal.

An initial patch test was made to establish the irritating effect of the test substance and to serve as a control. All patch tests were made on the skin of the back, 24 hours after depilation with barium sulfide paste and through washing. The test substance paste was applied to a 6 mm square area on the hairless backs. The skin was read 24 hours after contact. Attempts were made to sensitize the animals by giving subcutaneous injections of a 0.2 cc of a 2% suspension of the test substance in saline, 3 times a week for a period of 2 weeks. After a rest period of 11 days following the last injection, a second patch test was made in exactly the same manner as the initial test and the reaction recorded. Following this test, 7 animals were selected from the prior study (3 from the greens group and 4

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from the vitamin supplement group) and given a series of intraperitoneal injections with 0.2 cc of a 2% suspension of the test substance in saline three times a week for two weeks. After a rest period of 11 days, the patch test was repeated and reactions recorded.

After the initial patch test, no animals in the greens group had any reaction. One animal had slight erythema in the vitamin supplement group. In the initial sensitization test one animal in the greens group had very slight erythema and in the vitamin supplement group, no reactions were noted. In the intraperitoneal sensitization test all 3 green diet animals experienced definite erythema. For the 4 vitamin supplement diet animals, 2 experienced slight erythema, 1 experienced very slight erythema and 1 had no reaction.

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 handwritten signature in cursive script that reads "A. Michael Kaplan".

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

AMK/LAB: clp  
(302) 366-5260