

**TSCA NON-CONFIDENTIAL BUSINESS INFORMATION**

DOCUMENT DESCRIPTION	DOCUMENT CONTROL NUMBER	DATE RECEIVED
8EHQ-09-17773	88100000102	12/16/09

COMMENTS:

**ORIGINAL**

**DOES NOT CONTAIN CBI**

MR# 323 428

8EHQ-1209-17773A

88100000102



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09 DEC 16 AM 11:38

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December 15, 2009

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:

Aluminum Hydroxide Oxide  
1318-23-6

This letter is to inform you of the results of a pre-1977 (1963) subchronic dermal toxicity study which we recently became aware of with the test substance referenced above.

A 21-day skin absorption test on abraded skin of male rabbits and a 90-day on intact skin of male and female rabbits were conducted. Two grams/kg of the colloidal solution were gently rubbed into the clipped skin on the backs of the rabbits five times per week. The rabbits were weighed three times per week and examined on treatment days for clinical signs of toxicity. Analyses were made on blood collected from the ear vein prior to the start of treatment and after the last treatment (red and white cell counts, differential white cell count, hemoglobin and hematocrit). In the 90-day study blood was also analyzed after 6 weeks of treatment. Urine analysis was carried out at comparable times and included a measure of volume, concentration as milliosmols per liter and protein. Semi-quantitative tests for sugar, acetone, bilirubin and urobilinogen were also made. Color, appearance, and pH were noted and sediment was examined microscopically. After final treatment, one rabbit in each group of the 21-day test and one male and one female in each group from the 90-day test were submitted for gross and microscopic evaluation. The remaining rabbits were put on a 14-day recovery and then treated similarly.

The dose levels in the 21-day study (2 male rabbits/group) were 0, 100, 200 or 300 mg/kg of body weight and % solutions of the test substance were 0, 5, 10 or 15%. For the 90-day study (2 male and 2 female rabbits/group), doses were 0, 25, 50, 100, 200 or 300 mg/kg of body weight and % solutions of the test substance were 0, 1.25, 2.5, 5.0, 10 or 15%, respectively.

The test substance when rubbed into abraded skin for 15 treatments and into intact skin for 65 treatments produced no evidence of systemic toxicity. Irritation of the skin (faint erythema and scaliness to strong erythema and very scaly) was observed and was dose related, but after the initial skin accommodation, which occurred after the 4<sup>th</sup> treatment, it was believed largely due to physical trauma from the film which formed on the skin during treatment and from friction caused by the rubbing of the thickly matted fur. No significant abnormalities were observed in either the blood or urine of the treated rabbits. Pathological lesions found in the kidneys, liver, duodenum, and lungs of the control and treated rabbits were considered coincidental. No significant lesions were detected histologically in the brain, spleen, bone marrow, stomach, thymus, pancreas, adrenals, pituitary, testes, ovaries and uterus. Histologically the changes observed on abraded skin after three weeks were those of the adaptation to both the test substance and to abrasion. The mild hyperplasia of the epidermis commonly seen after adaptation to the chemical was observed in only one of the four rabbit at the 10% level and killed immediately after the 65<sup>th</sup> treatment.

**CONTAINS NO CB!**

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". The signature is written in black ink and is positioned above the typed name.

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

AMK: clp  
(302) 366-5260