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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

8810000028/S

8EHQ-09-17699

Dear 8(e) Coordinator:

Epsilon-Caprolactam
CAS # 105-60-2

This letter is to inform you of the results of several pre-1977 (1952-1953) toxicity studies (subchronic inhalation, skin sensitization and a human patch test) which we recently became aware of with the test substance referenced above.

A series of subchronic inhalation tests was conducted on groups of animals including, 6 guinea pigs, 6 rats, 2 rabbits and 4 mongrel dogs. One dog was exposed for 43 six-hour exposures; the 2 dogs for 67 six-hour exposures and the last dog for 72 six-hour exposures. Three guinea pigs, 3 rats and 1 rabbit received 67 six-hour exposures and three guinea pigs, 3 rats and 1 rabbit received 72 six-hour exposures. All exposures were to fumes of ε-caprolactam at concentrations that ranged from an average of 0.444 mg/L for exposure 1 through 43 to an average of 1.02 mg/L for exposures 44 through 73; composition of the fume, generated by heating ε-caprolactam in air, was not evaluated.

A skin sensitization test was conducted on guinea pigs and dogs at the end of their inhalation exposure regiment. Observations were made one-hour, 24-hours and 48-hours after patch application.

A human patch test was conducted to determine whether or not Type 6 nylon containing 3-5% water-extractable ε-caprolactam and dimers produced primary skin irritation and/or sensitization for workers in the workplace.

The results indicate that repeated exposures to ε-caprolactam fumes may cause skin sensitization in dogs and guinea pigs, mild damage to rabbit eyes, changes in blood pressure and/or pulse in two of the exposed dogs and aggravation of gastro-intestinal disorders as was noted by one particularly nervous dog and one normal dog. The fumes seemed to aggravate open sores, and especially infections and soreness of the eyes. Two of the four dogs were timid and fearful by nature but these dogs did display occasional muscular tremors, and one of these two dogs after the 46th and 67th exposure displayed severe muscular tremors, weakness, coughing with a white dense froth around the mouth. In both instances, the dogs were normal the next morning. One of the dogs had a significant lowering of systolic pressure and pulse pressure but otherwise no other significant changes in weight, blood sugar, cholesterol, BUN, thymol turbidity or hematology. Gross pathology suggested that 2 of the dogs showed an indication either acute duodenitis or gastroenteritis. However, microscopic examination revealed no changes that were attributable to ε-caprolactam.

Subchronic exposure resulted in one rabbit with slight corneal damage and mild irritation of the conjunctiva in both eyes of the 2 rabbits. No gross or microscopic pathology was observed in the rats or rabbits. Guinea pigs showed microscopic pathology as follows: one had lung reaction to foreign body and kidney showed evidence of regeneration of tubules; another had nephritis, and the third displayed consolidation of the apex of the right lung. No other gross or microscopic changes were detected in the remaining 3 guinea pigs.

Company Sanitized

While Type 6 nylon (polycaprolactam) caused neither primary irritation nor allergic sensitization in the 204 human subjects tested, guinea pigs and dogs exposed to ε-caprolactam fumes by inhalation acquired a mild skin sensitization.

Sincerely,