

October 30, 2007

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
1201 Constitution Ave., NW
Washington, DC 20460

07:00 - 1 10 6:05



Company Sanitized

Dear 8(e) Coordinator:

8EHQ-06-16436/8EHQ-06-16478
Perfluorinated Aliphatic Carboxylic Acid, Ammonium Salt

This letter is to inform you of the results of an acute eye irritation test, an acute dermal toxicity study, and a combined *in vivo* micronucleus and chromosome aberration assay in bone marrow cells from male and female ICR mice with the R&D test substance referenced above.

Acute Eye Irritation Test:

An aliquot of 0.1 mL of test substance was administered to 1 eye of 1 rabbit. The treated and control eye remained unwashed following treatment. The conjunctiva, iris, and cornea of the treated eye were evaluated and scored according to a numerical scale approximately 1, 24, and 28 hours following administration of the test substance.

Brown and white discoloration of the conjunctiva membrane, which appeared to look like necrosis, was observed at 1, 24, and 28 hours after instillation of the test substance. Corneal opacity (score of 2), iritis (score of 1), conjunctival chemosis (score of 2 or 4), and discharge (score of 2 or 3) were also observed. Fluorescein stain examinations were positive for corneal injury. The rabbit was euthanized the day after treatment.

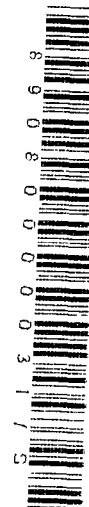
Acute Dermal Toxicity Test:

A single dose of the test substance was applied to the shaved, intact skin of 5 male and 5 female rats at a dose of 5000 mg/kg of body weight. The application site was covered with a semi-occlusive dressing for 24 hours, after which the test substance was removed. The rats were observed for 14 days following application. The rats were necropsied to detect grossly observable evidence of organ or tissue damage at the end of the 15-day test period.

No deaths occurred. The rats exhibited no clinical signs of systemic toxicity during the study. Four rats exhibited wet fur (perineum, inguen) and/or yellow-stained fur/skin (perineum, inguen) after test substance removal. These clinical signs are commonly seen in wrapped rats and therefore are not considered test substance related. High posture observed in a rat on test day 4 was not considered test substance related because it was only observed in a single animal. Hair loss observed in 1 rat was considered incidental. The rats exhibited no body weight losses. No erythema or edema was observed on the test site of male rats. All female rats exhibited erythema (score of 2) but no edema on the test site the day after application of the test substance. No erythema was observed by 2 days after application. Hyperkeratosis was observed on the test site of 8 rats, and ulceration was observed on the test site of 3 rats during the study. All dermal effects cleared by 13 days after application. No gross lesions were observed at necropsy.

Combined *In Vivo* Micronucleus and Chromosome Aberration Assay:

The test substance was evaluated for clastogenicity in a combined *in vivo* micronucleus and chromosome aberration assay in bone marrow cells from male and female ICR mice. The test substance, and the control substances were administered once by oral intubation, and animals were sacrificed 24 or 48 hours after the



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treatment. The test substance was delivered in water. Concurrent negative (vehicle) controls were included at both sacrifice time points, as well as a positive cyclophosphamide control at the 24-hour sacrifice time point.

A pilot toxicity study was initially conducted. Two male mice each were dosed at 1, 10, 100 or 1000 mg/kg while five male and five female mice were dosed at 2000 mg/kg of the test substance. Mortality was observed in 4/5 males and 4/5 females at 2000 mg/kg. Piloerection was seen in 1/2 males at 1 mg/kg, in all males at doses ≥ 10 mg/kg and in all females at 2000 mg/kg. Lethargy and cool to the touch were noted in all males at 1000 and 2000 mg/kg and in all females at 2000 mg/kg. No appreciable changes occurred in the mean group animal body weights of males at doses ≤ 100 mg/kg. Appreciable reductions in the mean group animal body weights of up to 10.9% and 8.6% occurred in males at 1000 and 2000 mg/kg, respectively, and of up to 12.6% in females at 2000 mg/kg. In order to further assess toxicity of the test substance, a toxicity study was performed.

In the toxicity study, male and female mice (5/sex/group) were dosed at 1200, 1400, 1600 or 1800 mg/kg. Mortality was observed in 1/5 males at 1400 mg/kg, 2/5 males and 1/5 females at 1600 mg/kg and 3/5 males and 2/5 females at 1800 mg/kg. Lethargy and piloerection were seen in all males and all females at all doses. No appreciable changes in the mean group animal body weights of males or females occurred at any of the doses. Based upon these results, the high dose for the definitive micronucleus study was set at 1300 mg/kg, which was estimated to be the maximum tolerated dose.

The definitive micronucleus assay consisted of seven groups, each containing 5 male and 5 female mice. Mice in five of these groups were treated either with the controls (vehicle or positive) or the test substance at 325, 650 or 1300 mg/kg and were euthanized 24 hours after treatment. Mice in the other two groups were treated either with the vehicle control or the test substance at 1300 mg/kg and were euthanized 48 hours after treatment. An additional group of 5 male and 5 female mice were treated with the test substance at 1300 mg/kg to be used as replacement animals for the high dose in the event of mortality. Animals were observed for signs of toxicity during the course of the study. From each animal, at the time of euthanasia, bone marrow from one femur was collected and processed for micronucleus analysis and the bone marrow from the other femur was processed for analysis of chromosome aberrations.

Mortality was observed in 3/15 males and 1/15 females at 1300 mg/kg. Piloerection was seen in all males and all females treated with the test substance. Lethargy was noted in 2/5 males at 650 mg/kg and all males and all females at 1300 mg/kg. All males and all females treated with the control substances appeared normal following dose administration. The *in vivo* mouse micronucleus and chromosome aberration test results were negative.

Under these experimental conditions, the findings described above appear to be reportable, based upon EPA's TSCA Section 8(e) reporting criteria.

Sincerely,