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Hoechst Celanese

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Department of
Environmental Health
and Safety (EHS)

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FLWP

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July 23, 1990

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Document Processing Center (TS-790)
U.S. Environmental Protection Agency
Office of Toxic Substances
401 M Street, S.W.
Washington, DC 20460

Attention: TSCA 8(e) Coordinator

Dear Sir or Madam:

Hoechst Celanese Corporation is submitting the following preliminary information concerning a chronic skin-painting study with an organic acid, acrylic acid (CAS Registry Number 79-10-7), in two strains of mice under current notification guidelines of Section 8(e) of the Toxic Substances Control Act. The information was initially provided to Hoechst Celanese Corporation on July 13, 1990 by a third party through a consultant.

According to the third party, male and female mice (50 mice/group) of two strains, C3H/HeN Hsd BR and Hsd:(ICR)BR, were on test for approximately 21 months at the []. The mice were treated topically, three times per week, with 25 or 100 ul of acetone (vehicle controls) or with 25 or 100 ul of 1% (v/v) acrylic acid in acetone for 6 weeks or continuously until the study termination. Mice from groups treated for only 6 weeks continued to be observed and to have the hair shaved from their backs weekly for the remainder of the study (i.e., similar to the mice treated for the duration of the study). All were examined for skin irritation, clinical signs, and tumors. One group of each sex/strain was treated with 25 ul of 0.1% (w/w) benzo(a)pyrene (BaP) in acetone (positive control) 3 times per week.

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According to the third party, there was no definitive evidence that acrylic acid treatment had a carcinogenic effect on any organ system, including the treatment area skin, in male and female ICR mice. Likewise, there was no definitive evidence that acrylic acid treatment had a carcinogenic effect in any organ system, including the treatment area skin, in male C3H mice. For the female C3H mice, the results were essentially the same except that there appeared to be increased frequencies of lymphosarcoma in the high dose treated group compared to the concurrent controls. Pathology was performed by [] and reviewed by []

Based on their reviews, mice treated with 100 ul acrylic acid for approximately 21 months had a lymphosarcoma incidence of 6/50; the group treated with 100 ul acrylic acid for 6 weeks and held for approximately 21 months had a lymphosarcoma incidence of 2/50. The incidence in the corresponding acetone control was apparently zero. The draft information and literature references (1) report the spontaneous frequency of lymphosarcomas in untreated female C3H mice greater than 18 months of age to be approximately 10%. According to the third party, the laboratory which performed the study concludes that acrylic acid is not carcinogenic. We have recently received this information and have not had time to fully evaluate it, but we are making the Agency aware for independent consideration.

Assuming that we confirm all of these results, we do not believe that an elevation relative only to concurrent controls seen in one tumor type in one sex/strain of mice is by itself biologically significant. It is also important to note that there was no evidence of dermal carcinogenicity from acrylic acid in this study according to the third party. This would confirm an earlier chronic skin-painting study with male C3H mice (2). Another chronic skin-painting study in female ICR mice (3) had suggested the potential for dermal carcinoma and leukemia, but the study was reported only as an abstract and was apparently never published in a peer-reviewed journal. This study (3) was discussed in the Celanese Corporation (now known as Hoechst Celanese Corporation) submission to EPA of March 14, 1986, file number 8EHQ-0386-0592. Finally, in a drinking water study with rats, acrylic acid was not carcinogenic (4).

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These data are still preliminary. If the Agency would like any additional information or assistance in regard to this matter, please contact Dr. Michele R. Sullivan, Director of Product Safety and Risk Assessment, at the address on this letterhead or call (201) 231-4480.

Sincerely,

Michele R. Sullivan for J. Engelman

Susan P. Engelman
Vice President
Environmental, Health and
Safety Affairs

- (1) Frith, C.H. and Willey, L.D. "Morphologic classification and correlation of incidence of hyperplastic and neoplastic hematopoietic lesions in mice with age." J. Gerontology 36:534-545(1981).
- (2) DePass, L.R., Fowler, E.H. Meckley, D.R. and Weil, C.S. "Dermal oncogenicity bioassays of acrylic acid, ethyl acrylate, and butyl acrylate." J. Toxicol. Environ. Health 14:115-120(1984).
- (3) Cote, I.L., Hochwalt, A., Seidman, I., Budzilovich, G., Solomon, J.J. and Segal, A. "Acrylic acid: skin carcinogenesis in ICR/HA mice." New York University Medical Center. Abstract in The Toxicologist 6(1):233(1986).
- (4) BASF. "Carcinogenicity study of acrylic acid in drinking water." Unpublished report(1988).

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