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Document Title	INITIAL SUBMISSION: LTR FRM DUPONT TO USEPA W/SUMMARY RESLTS OF AN IN VITRO MAMMALIAN CHROMOSOME ABERRATION TEST W/ 1,1-DIFLUOROETHANE IN HUMAN PERIPHRL BLOOD LYMPHOCYTES, 091800		
Chemical Category	1,1-DIFLUOROETHANE		

A-03

8EHQ-0900-14783

DuPont Haskell Laboratory
for Toxicology and Industrial Medicine
Elkton Road, P.O. Box 50
Newark, DE 19714-0050

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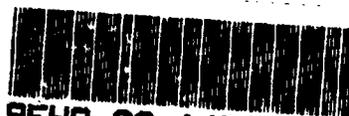
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DuPont Haskell Laboratory.

September 18, 2000

Via Federal Express



8EHQ-00-14783

MR 39492

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Room G99 East Tower
Attention: 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
401 M Street SW
Washington, DC 20460-0001

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Dear 8(e) Coordinator:

1,1-Difluoroethane (HFC-152a)
[CAS # 75-37-6]



This letter is to inform you of the results of an *in vitro* mammalian chromosome aberration test with the above referenced substance, using human peripheral blood lymphocytes (HPBL) in both the absence and presence of an exogenous metabolic activation system (Arochlor®-induced rat liver S9). The chromosome aberration assay was used to evaluate the clastogenic potential of the substance.

A total of four independent tests were conducted. The first test was a 3-hour exposure with and without S9 at dose levels of 35, 50, 70%. The second test 2 was a 3-hour exposure with S9 at dose levels of 0, 35, 50, 70%, and a 19-hour exposure without S9 at dose levels of 35, 50, 70%. The third test was a confirmatory 19-hour exposure without S9 at dose levels of 50, 60, 70%. The test substance is a gas, and the 70% v/v concentration used was the highest attainable in the test system.

No substantial toxicity ($\geq 50\%$ mitotic inhibition) was observed at any dose level under any testing condition. After continuous 19-hour treatment in the absence of S9, the test substance caused statistically significant ($p < 0.01$, Fisher's test) increases in the proportion of metaphase figures containing chromosomal aberrations. The elevated frequencies were observed in the second test at the 70% dose level, and reproduced in the third test at the 60% dose level. Further trend test analysis using Mantel's Test for Trend recorded a statistically significant ($p < 0.05$) dose-response in the second test, but not in the third test. The observed increased chromosome aberration frequencies were considered small, but exceeded the upper 99% confidence limits of the historical control range of the testing facility. In the 3-hour treatment in the absence or presence of S9, the test substance caused no statistically significant increases in the proportion of metaphase figures containing chromosomal aberrations at any tested dose level.

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The test substance was concluded to show statistically significant evidence of clastogenic activity in this test system only after continuous 10-hour treatment in the absence of S9. However, the observed positive responses were weak and considered to be of marginal biological relevance.

Under these experimental conditions, the findings described above are being reported in accordance with the guidance given in the EPA TSCA Section 8(e) Reporting Guide (June 1991).

Sincerely,

A handwritten signature in black ink that reads "A. Michael Kaplan". The signature is written in a cursive style and is followed by a horizontal line.

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

AMK/MD:clp
(302) 366-5760

CERTIFICATE OF AUTHENTICITY

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