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July 3, 2003

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Richard H. Hefter, Chief
High Production Volume Chemicals Branch
U.S. Environmental Protection Agency
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1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460-0001

Document Processing Center (7407M)
EPA East - Room 6428 Attn: Section 8(e)
U.S. Environmental Protection Agency
Office of Pollution Prevention and Toxics
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460-0001

Re: TSCA Section 8(e) Reporting For PFOA

Dear Mr. Hefter:

Our law firm currently serves as class counsel for a group of tens of thousands of citizens whose drinking water is contaminated with ammonium perfluorooctanoate (a/k/a APFO/PFOA/FC-143/C-8) (hereinafter "C-8") released from E.I. duPont de Nemours and Company's ("DuPont's") Washington Works fluoropolymer manufacturing facility along the Ohio River in Wood County, West Virginia. During the course of this lawsuit (styled *Jack W. Leach, et al. v. E.I. duPont de Nemours and Company* (Circuit Court of Wood County, WV, Civil Action No. 01-C-608)) and a prior lawsuit during which we represented members of the Tennant family who claimed that C-8 released from DuPont's Dry Run Landfill in Wood County, West Virginia, caused the death of several hundred head of cattle and other damages, including damage to the Tennant's own health (styled *Wilbur E. Tennant, et al., v. E.I. duPont de Nemours & Co., Inc.* (Case No. CA-6:99-0488 (S.D.W.Va.))), we obtained and reviewed nearly one million pages of documents from DuPont's internal files relating to C-8.

Among the documents obtained from DuPont to date are documents relating to DuPont's pregnancy outcome study among its female workers exposed to C-8 at its Washington Works plant back in 1981, and DuPont's knowledge of the presence of C-8 in public drinking water supplies at levels exceeding DuPont's internal community exposure standards. The Environmental Working Group ("EWG") referenced some of these data in its April 11, 2003,

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letter asking USEPA to investigate DuPont's actions with respect to disclosure of birth defect and drinking water contamination data to USEPA, pursuant to Section 8(e) of TSCA, which your office asked DuPont to explain in your letter dated May 22, 2003. (AR-226-1318)

Because of the potential likelihood of substantial harm to our class members or to the public interest from an incorrect understanding or assessment of the birth defect and drinking water contamination data at issue, we submit the following information obtained from DuPont for consideration in connection with your Agency's evaluation of the statements made by DuPont's counsel on this matter in its June 20, 2003, letter responding to your May 22, 2003, letter:

1. March 20, 1981 - 3M submitted a TSCA Section 8(e) notice to USEPA, attaching its report finding birth defects in the eyes of rat fetuses exposed to C-8. (Exhibit A (EID072034-45)) That same day, 3M notified DuPont of the eye defect findings. (Exhibit B (EID079423))
2. March 25, 1981 - DuPont's Medical Director, Dr. Bruce Karrh, summarized the birth defect data received from 3M and DuPont's knowledge of the pregnancy outcome status of Washington Works employees exposed to C-8 as follows:

At present, about 50 women employees have potential for exposure to C-8 compounds at Parkersburg Of the 50 female employees at Parkersburg, three are pregnant now and 2 probably pregnant. The reproductive capability of the others is unknown at present. One employee who worked in the area had a miscarriage followed immediately by a normal pregnancy with a recent normal outcome. Her potential C-8 exposure throughout both pregnancies was described as "heavy." There was one recent abnormal pregnancy outcome with one female employee at the Plant, but she did not work where there was any possibility of exposure to C-8.

Of the employees presently pregnant, one is in her 7th month, one in her 5th month, one in her 3rd month, and 2 probably just pregnant. One complicating factor is that C-8 is retained in the body for a very long time after exposure ceases.

The plan at present is to convene a meeting after Dr. Staples reviews 3-M's work, probably by March 27. . . . If the 3M study is valid, women of child-bearing potential will probably be excluded from jobs where there is potential for exposure to C-8 compounds,

at least until a no-effect level is determined. . . . Haskell
Laboratory will determine what additional testing needs to be done.

(Exhibit C (EID096503))

3. March 27, 1981 - DuPont teratologist, Dr. R.E. Staples, and DuPont pathologist, Taisan Chiu, visited 3M to review the 3M rat birth defect study and concluded that the "study was valid and that the observed fetus eye changes were due to the C-8." (Exhibit B (EID079423) and E (EID079758-9)) 3M delivered a hard copy of 3M's final rat birth defect study to DuPont that same day. (Exhibit D (EID079613))

4. March 31, 1981 - DuPont notified its employees that all female workers would be removed from jobs "where there is potential for exposure to C-8" at DuPont's Washington Works. (Exhibit F (EID079212-3)) In standby questions and answers for those employees, DuPont provided the following information:
 1. Q: How many female employees at your Parkersburg Plant may have been exposed to C-8?

A: About sixty worked in areas where there is potential for exposure.

 2. Q: Have you sampled the blood of these employees to determine if they have elevated organic fluoride levels?

A: Some but not all female employees have been sampled as part of our existing programs.

 3. Q: Do they have levels of C-8 above normal?

A: Yes, some do.

 4. Q: Are any of the sixty female employees pregnant?

A: Yes, two that we know of.

 5. Q: Are there any former employees you know of who may have been exposed to C-8 and who are now pregnant?

A: Yes, one that we know of.

(*Id.*, at EID079214)

5. April 1, 1981 - DuPont began identifying female employees potentially exposed to C-8 at its Washington Works Plant for C-8 blood sampling. (Exhibit B, at EID079423)
6. April 2, 1981 - DuPont's Medical Director, Dr. Bruce Karrh, confirmed that DuPont was evaluating "an epidemiology study for reproductive effects from potential exposure to C-8," that "pregnancy outcome can be studied to answer a simple question - does C-8 exposure cause abnormal child," and that Dr. Karrh had asked to delay such a study until after DuPont completed its first pregnancy outcome study at a different facility and until after 3M provided results of its protocol for conducting its own C-8-specific pregnancy outcome study. (Exhibit G (EID096492))
7. April 6, 1981 - DuPont's Medical Director, Dr. Bruce Karrh, sent a memo stating that DuPont Medical had requested on April 2, 1981, that DuPont delay moving forward with a C-8 pregnancy outcome study but "[s]ince then, . . . recently obtained information indicates there may be a need to do such a study. Medical Division epidemiologists are evaluating how such a study can be accomplished and are communicating with Parkersburg Plant personnel to determine the number of people who may be in the group to be studied." (Exhibit H (EID096486))

On that same date, DuPont issued a revised corporate communications package on the C-8 birth defect issue. (Exhibit B at Attachment IV (EID079439-69)) In revised standby questions and answers, DuPont clarified that there are "about 50" women who are potentially exposed to C-8 at the Washington Works plant and provided the following standby question and answer:

"Q. 19. I understand an employee at the Parkersburg plant suffered a miscarriage. Was this related to FC-143 exposure?"

A. 19. We have no information that indicates a higher risk of miscarriage due to exposure to FC-143."

(*Id.*, at EID079455)

8. April 9, 1981 - DuPont prepared a "supplemental communication" to its Washington Work's employees to respond to claims of two birth defects having been reported to DuPont among children born to women exposed to C-8 at the Washington Works plant. In those communication materials, DuPont states:

There have been rumors that two women who worked in Fluoropolymers have had children with birth defects. We are not aware of any human birth defects attributable to FC-143. We do know of two women who worked in this area before or during pregnancy whose children reportedly had defects detected at birth. We became aware of this information after 3M notified us of the animal study. We do not know whether there is a relationship. We are investigating this matter further, and we are considering additional studies.

(Exhibit B, at Attachment V(EID079470)) In formal standby questions and answers on the same issue, DuPont provided the following prepared response:

"Q 01. Is it true that two women who worked in the FC-143 area at your Parkersburg plant have had children with birth defects?

A 01. We are not aware of any human birth defects attributable to ammonium perfluorooctanoate, also known as FC-143. We do know of two women who worked in this area before or during pregnancy whose children reportedly had defects detected at birth. We do not know if there is a relationship. We are investigating this matter further, and we are considering additional studies.

Q 02. Can you be more specific about these two defects?

A 02. (Refer question to Dr. Bruce W. Karrh of the Medical Division).

(*Id.*, at EID079472)

9. April 13, 1981 - DuPont Medical Division Epidemiologist, William E. Fayerweather, submitted and circulated among DuPont Medical Division and Business personnel a research proposal entitled "Study of Pregnancy Outcome in Washington Works Employees" (Exhibit I (EID106191-205). See also Exhibit II, at 11-12) The proposal specifically identified its objectives as being to determine

whether: "a. Pregnancy outcome among female Washington Works employees is causally related to their occupational exposure to C-8" and whether: "b. Pregnancy outcome among wives of Washington Works employees is causally related to their husbands' exposure to C-8." (*Id.*, at EID106192). In identifying the "rationale" for the proposed studies, DuPont stated that "exposed female employees and wives of exposed male employees will be studied. Female workers are studied because they may have been exposed to C-8 during or immediately prior to their pregnancies. Wives of male workers are studied because the husbands may somehow bring C-8 home with them and expose their wives at home." (*Id.*, at EID106193) The study proposal defined its "Specific Aims" as follows:

Histories of pregnancy outcome and of potential exposure to C-8 will be ascertained for:

- a. Washington Works active female employees, and
- b. Wives of Washington Works active male employees.

Potential exposure to C-8 will be determined from personal records, medical records, and employee interviews. Pregnancy outcome will be determined via self-administered questionnaires given to female employees and wives of male employees.

If an association is observed between pregnancy outcome and having had potential exposure to C-8, the association will be assessed as to whether it is causal or whether it is due to other confounding factors.

(*Id.*, at EID106193-4) With respect to the statistical significance of any birth defects revealed from the pregnancy outcome study, DuPont provided a table that:

shows the minimum number of births with malformations that must be observed in the study group to say that there is a statistically significant excess ($p < 0.05$). For instance, 2 malformations in 10 exposed live births is a significantly higher rate than a national rate of 2 per 1000. Two malformations per 10 exposed live births is also significantly higher than a plant rate of 0 per 50 nonexposed births.

(*Id.*, at EID106200 (emphasis added), *see also id.*, at EID106205 (Table III))

10. April 14, 1981 - DuPont prepared a memo confirming that it was collecting C-8 C-8 blood samples to "[p]rovide data for pregnancy outcome study and confirm background level," with recognition of potential need for employee communication to "[i]ntroduce and encourage support for the 'pregnancy outcome' study". (Exhibit J (EID090073-5)) DuPont stated at that time, however, that "It is felt that an overall communication of intent of [C-8 blood sampling] program would have a negative impact at this time." (*Id.*, at EID090073)

11. April 15, 1981 - A C-8 pregnancy outcome study questionnaire was drafted and approved by DuPont Medical Director, Dr. Bruce Karrh, and Dr. B. Culpepper. (Exhibit K (EID102437) and Exhibit L (EID106216-23)) In addition to information relating to reproductive/pregnancy issues, DuPont's C-8 pregnancy outcome questionnaire also sought information regarding the following specific medical conditions:
 - Anemia;
 - Sugar diabetes;
 - Thyroid condition;
 - Epilepsy, fits or other neurological conditions;
 - Kidney or bladder condition;
 - Liver condition;
 - Any type of cancer; and
 - Heart condition.

(Exhibit L, at EID106218)

12. April 16, 1981 - DuPont Medical Division personnel, including Dr. B. Culpepper, and business representatives, including H.E. Serenbetz, met and discussed the C-8 pregnancy outcome study. (Exhibit K (EID102437))

13. April 23, 1981 - Another meeting occurred between DuPont Medical Division personnel, including Dr. Bruce Karrh, and business personnel, including H.E. Serenbetz, to discuss the C-8 pregnancy outcome study during which Washington Works plant "pregnancies by year and pay class presented; sample sizes for statistical significance presented." (*Id.*)

14. April 28, 1981 - DuPont's Haskell Laboratory began its own study on C-8 birth defects in rats, stating that "[i]n the interim, our standard of 0.-0.4 ppm total organic fluorides will continue to be used as a blood level that will not mandate removal of females from the work place." (Exhibit M (EID096481))
15. May 8, 1981 - DuPont calculated "abnormal pregnancy outcome rates . . . for entire company, 1979-1980." (Exhibit K (EID102437))
16. May 14, 1981 - The first set of formal C-8-specific blood results for female Washington Works employees were provided by DuPont's Haskell Laboratory to the Medical Director of DuPont's Washington Works plant, Dr. Younger Power. (Exhibit N (EID713271-3)). The results reflected testing of 48 women at the Parkersburg facility, including "Employee W"^{1/} with a C-8 blood result of 0.048 ppm. (*Id.*, at EID713272) The C-8 blood results for 15 of the 48 women exceeded 0.4 ppm. (*Id.*)
17. May 15, 1981 - "Informed consent and confidentiality of data package [s]" were sent to DuPont's Medical Director, Dr. Bruce Karrh, in connection with the C-8 pregnancy outcome study. (Exhibit K (EID102437))
18. May 19, 1981 - DuPont's Haskell Laboratory forwarded additional C-8-specific blood data results to Dr. Younger Power, Medical Director for DuPont's Washington Works plant. (Exhibit O (EID713274-5)) The data contained sample results for an additional 13 women, including "Employee X" with a C-8 blood result of 2.5 ppm, along with the results of C-8 detected in "cord blood" of "Baby Y" (detected at 0.055 ppm) and C-8 blood results for mother, "Employee Y," of 0.070 ppm."^{2/} (*Id.*, at EID713275) The C-8 blood results for 8 of the 13 women, including "Employee X," exceeded 0.4 ppm. (*Id.*)

^{1/} Although we are submitting copies of the DuPont documents that have the employee names redacted to protect their privacy, we have obtained non-redacted versions from DuPont that confirm that the four employees we reference in this letter as "Employee W," "Employee X," "Employee Y," and "Employee Z" are, in fact, the individuals being referenced in the documents.

^{2/} The non-redacted version of Exhibit O indicates that the last C-8 blood result in the chart (0.055 ppm) is from "cord blood" and for a "baby" with the same last name as Employee Y, whose C-8 blood results are provided in the immediately preceding entry on the chart (0.070 ppm).

19. May 26, 1981 - DuPont summarized its "C-8 program status" in a memorandum indicating that previous communications to employees had indicated that DuPont had planned "some follow-up to see if birth defects may have resulted from exposure to C-8" and that "[a]lthough these programs are either just underway or still in the discussion stage, a status report is in order." (Exhibit P (EID090076)) With respect to the status to C-8 blood sampling results, a "summary of sampling results available through May 14" was attached at Attachment III, which summarized C-8 levels detected among workers at other DuPont facilities, C-8 levels detected among 56 "current Washington Works female employees," and "births and pregnancies" among those Washington Works female employees. (*Id.*, at EID090083-5)

Among the information presented with respect to such "births and pregnancies" is a reference to "Child- 4 months. One nostril and eye defect" and a "0.048 ppm C-8 blood level, which corresponds with the 0.048 C-8 blood level reported for "Employee W. " (*Compare id.*, at EID090083 with Exhibit N, at EID713272. *See also* Exhibit R, at EID079375). The "births and pregnancies" chart also references another "Child-2 plus years. Unconfirmed eye and tear duct defect" and a 2.5 ppm C-8 blood level, which corresponds with the 2.5 ppm C-8 blood level reported for Washington Works "Employee X". (*Compare* Exhibit P, at EID090083 with Exhibit O, at EID713275. *See also* Exhibit R, at EID079375). Although C-8 blood results were reported for "umbilical cord blood" with respect to a separate "normal child," no information is provided with respect to whether any C-8 had been detected in the blood of the two children with reported birth defects.

20. July 16, 1981 - DuPont's Haskell Laboratory forwarded to Dr. Younger Power, Medical Director for DuPont Washington Works, additional C-8 blood sampling data, including results from several men^{3/} and results for the baby of "Employee W"^{4/} indicating a C-8 blood level of 0.012 ppm, which corresponds with the results DuPont listed for the baby born to Washington Works "Employee W," which DuPont had identified as a baby born with "one nostril and eye defect", (*see* Exhibit Q (at EID713277), P (at EID090083), and R (at EID079375). The C-8

^{3/} The non-redacted version of this document confirms male names for at least 10 of the employees sampled.

^{4/} The non-redacted version of this document references a male name and a reference to an "infant" with the same last name as "Employee W" next to the 0.012 ppm C-8 blood test result.

blood results also confirmed levels of C-8 in the blood of 7 of the employees sampled at levels exceeding 0.4 ppm C-8 in blood. (Exhibit Q, at 713277)

21. July 22, 1981 - A meeting occurred among DuPont Medical Division personnel, including Dr. B. Culpepper, and business personnel, including H.E. Serenbetz, in which Mr. Serenbetz announced that all further work on the C-8 pregnancy outcome study was now "on-hold." (Exhibit K (EID102437))
22. September 16, 1981 - A DuPont employee updated by hand DuPont's May 14, 1981 chart summarizing "birth and pregnancies" among female Washington Works employees to incorporate the C-8 blood results received in July of 1981. (Exhibit R (EID079371-5))^{5/} With respect to results of 1.5 ppm C-8 in blood originally reported in May of 1981 for an individual who was "5 months pregnant," the handwritten notes from September of 1981 indicate that that individual, "Employee Z," was now "on pregnancy leave." (*Id.*, at EID079375)
23. October 20, 1981 - DuPont's Haskell Laboratory forwarded to the Washington Works' Medical Director, Dr. Younger Power, additional C-8 blood sampling results, including new C-8 blood results for "Employee Z" indicating 1.0 ppm C-8 in her blood and 0.43 ppm C-8 in the "cord blood" for a "baby" with the same last name as "Employee Z." (Exhibit S (EID713278-9))^{6/} Both of those results, along with the results from 7 of the other employees tested, exceeded 0.4 ppm C-8 in blood.
24. December 15, 1981 - DuPont released a "C-8 Status Report" to its Washington Work's employees in which DuPont stated that, upon review of additional studies being performed by DuPont and 3M on the ability of C-8 to cause birth defects un animals, DuPont was taking the position that "it does not seem that the observed effects in the eyes of the unborn rats were due to C-8." (Exhibit T (EID089462))
25. December 18, 1981 - A DuPont Washington Works employee informed DuPont's corporate office in Wilmington that two female employees at the Washington

^{5/} Although the original version of Exhibit R produced by DuPont contains the employee names and employee I.D. numbers, we have redacted that information in the copy attached hereto.

^{6/} Again, the names are confirmed in the non-redacted versions of the documents produced by DuPont.

Works had raised questions after receiving DuPont's December 15, 1981, memo in which DuPont stated that it now believed C-8 did not cause birth defects. According to the Washington Works employee:

Two of them had questions that we could not answer . . . The first person has a child with birth defects around the eye. She would like to know if the 3M studies found any malformations other than right in the eye. She is especially concerned about the eyelid. She would also like to be able to read the reports from the DuPont animal studies herself. The second person has a child with 0.4 ppm C-8 in its blood. She would like to know what is the safe blood level for her and the baby. She would also like to know if the baby's liver is more susceptible to damage by C-8 than that of an adult and what signs and symptoms she should be alert to. Lastly, she would like to know if the studies showed any other embryological effects.

(Exhibit U (EID079544))

26. February 4, 1982 - 3M and DuPont scientists, including R.E. Staples and Gerry Kennedy, met to discuss additional C-8 birth defect rat studies recently conducted by the companies, along with the results of an additional rabbit study soon to be completed by 3M, all of which the companies agreed should be interpreted as being "negative" for birth defects. (Exhibit V (EID071712)) During that meeting, DuPont and 3M agreed to inform both company's employees of the companies' view of the additional C-8 birth defect work in animals on March 3, 1982, and to meet with USEPA to present their joint interpretation of the animal birth defect data during the week of March 10, 1982. (*Id.*, at EID071713)
27. March 3, 1982 - DuPont notified all of its employees that DuPont had determined that, because "C-8 has not been shown to produce teratogenic effects in the several animal studies, we conclude that female employees of childbearing capability no longer need to be excluded from areas where there is potential for exposure to C-8. All employees both male and female, are now eligible to work in Teflon." (Exhibit W (EID089464)) There is no reference in the employee communication to the data DuPont had obtained with respect to human eye defects, pregnancy outcome, or C-8 blood levels among its Washington Works employees and children.

28. March 12, 1982 - DuPont and 3M scientists met with USEPA's Office of Toxic Substances to discuss the companies' interpretation of their C-8 animal birth defect studies. (Exhibit X (EID071705-6)) During the meeting, 3M provided copies of its additional rat and rabbit birth defects studies to USEPA and DuPont provided copies of its two rat birth defect studies. Although a DuPont memorandum summarizing the contents of the discussions with US EPA indicates that the companies discussed the animal studies with USEPA, there is no reference to any mention of DuPont's C-8 human pregnancy outcome study or any of the human birth defect data. (*Id.*)

According to DuPont:

A few of the EPA people seemed to find it hard to understand how highly positive findings with good dose-response relationship could subsequently turn out to be negative. I don't think [3M] completely convinced the sceptics by their response, which including the factor of bias through not examining the slides blind. . . . EPA officials said that there is no mechanism for withdrawing an 8e notification or for EPA to declare it not a cause for concern. However, the 3M and DuPont reports of studies on FC-143 will be placed in the same file as the 8e notice, and should anyone ask about the 8e notice on FC-143, he will be told about the conclusions of the reports.

(*Id.*, at EID071706)

29. March 16, 1982 - DuPont notified USEPA's Office of Toxic Substances that, according to DuPont's animal studies, "C-8 does transfer across the placenta of the rat." (Exhibit Y (EID071704)) In that letter, DuPont made no mention of its finding of C-8 in the blood and cord blood of human babies born to its own female employees exposed to C-8 at the Washington Works. (*Id.*)
30. November 1982 - DuPont's Medical Director, Dr. Bruce Karrh, advised DuPont's business representative that:

I recommend that available practical steps be taken to reduce this [C-8]exposure because: Our knowledge of the chronic health effects to low levels of C-8 is quite limited; C-8 is retained in the blood for a long time, creating a concern in other areas such as blood donations, etc.; All employees, not just Teflon area workers, are exposed; and There is obviously great potential for current or future

exposure of members of the local community from emissions leaving the [Washington Works] Plant perimeter.

(Exhibit Z (EID096449-50))

31. March 1984 - DuPont detected C-8 in the public drinking water supplies of both the Lubeck Public Service District ("LPSD"), which was drawing water from wells immediately adjacent to the southwestern border of DuPont's Washington Works Plant in West Virginia, and the Little Hocking Water Association, which was drawing water from wells in Ohio located northeast of the Plant, across the Ohio River. (Exhibit AA (EID079096-100)) C-8 was detected as high as 1.5 ppb in the LPSD water supply and as high as 0.6-0.8 ppb in the Little Hocking Ohio water supply. (*Id.*, at EID079098.01)
32. June 12, 1987 - After additional C-8 water testing again detected C-8 in the LPSD public water supply at 1.9 ppb, (Exhibit BB (EID079091-4)), DuPont employee H.A. Smith, with the Washington Works Plant's Safety, Energy & Environmental Affairs Manufacturing Division, requested that Gerry Kennedy of DuPont's Haskell Laboratory "establish an acceptable level for C-8 in blood, and an acceptable level for C-8 in community drinking water." (Exhibit CC (EID079034))
33. June 25, 1987 - Gerry Kennedy of DuPont's Haskell Laboratory advised H. A. Smith that "[a]n acceptable level for ammonium perfluorooctanoate (C-8) in the blood of workers would be 0.5 ppm" and that "[a]n acceptable level for community drinking water would be 5 ppb." (Exhibit DD (EID078779-80)) With respect to the 5 ppb drinking water limit, Mr. Kennedy cautioned that it "doesn't take into account the time factor (worker exposed 8 hours, not-exposed 16 hours, etc. whereas drinking water intake could be anytime during 16 hours, off 8 hours, etc.)." (*Id.*, at EID078780)
34. April 1991 - After DuPont confirmed through additional public water supply sampling activities that the levels of C-8 had increased to around 2.7 ppb, a DuPont employee asked that a specific request be made to DuPont's "Acceptable Exposure Limits" Committee ("AEL Committee") "to establish a CEG for ammonium perfluorooctanoate in drinking water," pursuant to the guidelines established by DuPont's Haskell Laboratory for setting "Community Exposure Guidelines." (Exhibit EE (EID072215) It was requested that the AEL Committee set the CEG for C-8 in community drinking water after considering "the actual health effects to residents adjacent to our Washington Works Plant from exposure to C-8," and on the assumption that "the value we will get will be based on 20% of

total intake allocated to water; and 80% to air since our CEG for C-8 has already been established for air" and DuPont's own, internal air modeling already had confirmed that nearby residents would be exposed to C-8 through the Washington Works' air emissions. (*Id.*)

35. June 11, 1991 - DuPont's AEL Committee selected 1 ppb as the CEG for C-8 in community drinking water, assuming potential community exposure through both air and drinking water. (Exhibit FF (EID097177-85) DuPont defined the purpose of its CEG at that time as follows:

CEGs are exposure guidelines that are expected to be without any effect to members of the community during continuous 24-hour a day exposure to a chemical or physical agent. CEGs may be recommended for air or water or both. As with AELs, CEGs are recommended based on the best available information from industrial experience, animal toxicity studies, controlled human exposure studies, and epidemiological findings. However, because of the variability of sensitivities of members of the community (*e.g.*, the infirm, the old, the young, pregnant females, etc), versus the healthy worker involved with an AEL, a larger uncertainty factor needs to be used in extrapolating these data to a CEG.

(*Id.*, at EID097179)

36. September 1991 - DuPont reviewed additional public drinking water results from the summer of 1991 confirming C-8 in the LPSD public drinking water supplied by the LPSD's original wells as high as 3.9 ppb, and as high as 2.4 ppb in the LPSD's new wells, now located "2.7 miles south-southwest of Washington Works." (Exhibit GG (DE000245-56)
37. Although the C-8 Assessment of Toxicity Team ("CAT Team") established under a November 2001 Consent Order between DuPont and the State of West Virginia announced that it had selected a 150 ppb "screening level" for C-8 in drinking water in May of 2002, DuPont has not changed its internal 1 ppb CEG for C-8 in community drinking water since 1991 and, with respect to the relationship between that CEG and "screening levels," DuPont used its CEGs to calculate a 3 ppb

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"preliminary screening level for C-8 in groundwater used as drinking water"
(assuming no exposure to C-8 in air) that it submitted to USEPA in June of 1999
in connection with its Washington Works Plant. (Exhibit HH, at 24)

Very truly yours,



Robert A. Bilott

RAB:mdm

Enclosures

cc: Dr. Charles M. Auer (USEPA OPPT) (w/o encls.) (letter by telecopy)
Mary Dominiak (USEPA OPPT) (for inclusion in AR-226) (w/encls.) (letter by telecopy)
Jennifer Seed (USEPA) (w/encls.) (letter by telecopy - enclosures by hard copy)
R. Edison Hill, Esq. (w/ encls.)
Larry A. Winter, Esq. (w/ encls.)
Gerald J. Rapien, Esq. (w/o encls.)

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March 20, 1981

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Office of Toxic Substances (WH-557)
Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Gentlemen:

Subject: Section 8(e) Toxic Substances Control Act (TSCA)
Perfluoroalkane Carboxylic Acids and Corresponding
Ammonium Carboxylates

Please find attached 3M Report entitled "Oral Rangefinder Study of T-2998CoC in Pregnant Rats", dated March 12, 1981. Preliminary information from this study has indicated that oral dosing of the subject ammonium carboxylate mixture produces the described teratogenic effects. This Report and the findings described in the article published in the August 1980 American Industrial Hygiene Journal and referenced as part of BERQ-1180-03760, request us to submit this information pursuant to Section 8(e) of TSCA and EPA's statement of interpretation published in the FEDERAL REGISTER, March 16, 1978.

Perfluoroalkane ammonium carboxylates is a generic chemical name for a mixture of homologs, which can be expressed by the general formula $C_nF_{2n+1}COO NH_4$. Each of these homologs was reported on the TSCA inventory.

As previously stated in our November 19 submission, our employee records and epidemiology data indicate that to date no human health problems have been observed nor disease patterns detected which are attributable or related to fluorochemical exposure. This mixture of homologous ammonium carboxylates and the corresponding homologous carboxylic acids are currently commercially available and used as follows:

3M Brand Fluorochemical Acid FC-26 Emulsifier additive in chemical specialty products
(international market only)

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APR 23 1981

HASKELL LAB.

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FLUORAD[®] Brand Fluorochemical
Surfactant FC-126
(ammonium carboxylates)

Additive used in chemical specialty
products

FLUORAD[®] Brand Fluorochemical
Surfactant FC-143
(ammonium carboxylates)

Emulsifier used in chemical
processing and as an additive in
chemical specialty products

At our Chemolite production facility, located at Highway 61 and Washington County Road 19, St. Paul, MN 55133, the subject chemicals are manufactured from _____ of locally-produced perfluoroalkane carboxylic acids and _____ of the same acid imported from our European plant in Antwerp, Belgium. Chemical reaction occurs in a closed system. Approximately 36 employees are intermittently exposed to the subject chemicals during production at the Chemolite facility. Approximately _____ of perfluoroalkane carboxylates are exported annually.

We plan to inform, by April 1, those customers and 3M employees who have, through uses and/or processing, potential significant exposure to the subject chemicals. At that time, we will summarize these findings and outline our recommendations for handling and using these products. We are by copy of this letter advising NIOSH of these new preliminary teratogenic findings. As additional information becomes available to us, we plan to advise these customers and employees accordingly.

In view of the attached preliminary findings and in line with our ongoing testing and monitoring program on fluorochemicals, the following program is planned for the ammonium carboxylate mixture:

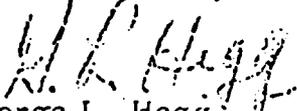
- (1) A teratogenicity study in rats.
- (2) A subsequent teratogenicity study in rabbits.
- (3) Continual industrial hygiene program to improve and refine manufacturing and packaging processes which have been developed to further reduce the exposure to plant employees.

Since certain of the information provided herein is considered confidential business information, we are providing a sanitized version of this report for the public file. In addition, we have deleted from the confidential submission inconsequential information such as the names of 3M employees for the purpose of protecting their privacy.

Should additional correspondence be necessary on this matter, please contact:

Larry Magill
Manager, Regulatory Affairs Department
Commercial Chemicals Division
3M
3M Center, 223-6S-04
Saint Paul, MN 55144
Telephone: 612/733-7062

Yours very truly,


George L. Hegg
Group Vice President
Chemicals, Film & Allied Products

GLH:sue

Attachments

cc: Acting Director, NIOSH
Park Lawn Building
5600 Fishers Lane
Rockville, MD 20855

bc: R. J. Davis/T. J. Scheuerman - 220-12E
W. G. Ewert - 220-12W
F. D. Griffith/W. C. McCormick - 220-2E
C. W. Hanson - 223-6
G. L. Hegg - 220-13C
L. C. Krogh - 223-6
J. D. LaZerte/R. A. Prokop - 236-1
L. F. Ludford - 225-5N
W. H. Pearlson - 223-6
D. R. Ricker - 53-4
P. F. Riehle - Chemolite
W. F. Scown - 223-6
S. D. Sorenson - 220-2
F. A. Ubel/D. E. Roach

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Report Number: M-601

Date: March 12, 1981

Oral Rangefinder Study of T-2998CoC in Pregnant Rats

Experiment No.:

0680RR0018

Conducted At:

St. Paul, Minnesota

Dosing Period:

January 20, 1980 to January 29, 1981

Study Director:

2/24/81
Date

2/24/81
Date

2/25/81
Date

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Introduction

This oral rangefinder study^a was conducted to determine the upper dose level of T-2998CoC^b for a subsequent oral teratology study in rats. The study was sponsored by 3M Commercial Chemical Division, St. Paul, Minnesota and was conducted by the Safety Evaluation Laboratory, St. Paul, Minnesota. The study was conducted in accordance with the Safety Evaluation Laboratory's Standard Operating Procedures for such studies. The storage location for the raw data and a copy of the final report is maintained in the Safety Evaluation Laboratory's record archives.

Methods

Thirty-six time-mated Sprague-Dawley derived female rats from Charles River Breeding Laboratory were used in the study. The animals were indiscriminately removed from the shipping boxes by Animal Care personnel and placed in the rack of cages from the left to right starting at the top and working down. Later the Study Director assigned dose groups by vertical rows. The rats were housed individually in hanging stainless steel cages with wire mesh floors and fronts in a temperature and humidity controlled room. Purina Laboratory Chow and water were available ad libitum. The lights were on a 12 hour light/dark cycle.

The animals were observed daily from day 3 through day 20 of gestation for abnormal clinical signs. Body weights were recorded on days 3, 6, 9, 12, 15 and 20 of gestation and the rats dosed accordingly using a constant dose volume of 5 ml/kg of body weight. T-2998CoC was suspended in corn oil and administered daily by oral intubation at doses of 150, 100, 75, 50 or 25 mg/kg/day to groups of 6 rats on days 6 through 15 of gestation. A control group of 6 rats received only corn oil by oral intubation on the same days. On day 20 of gestation the rats were killed by cervical dislocation and each uterus, including its contents, was examined immediately to determine if the animal was pregnant. Because two previous teratology studies (Experiment Nos: 0680TR0008 and 0680TR0010) with chemically related compounds resulted in fetuses with teratogenic changes in the lens of the eye, a few fetuses were also taken at day 20 of gestation and examined for eye abnormalities.

Blood samples from three rats in each dose group were taken before the first dose and at day 20 of gestation. Liver specimens were also taken from the same rats on day 20 of gestation. The plasma samples and liver specimens were frozen and submitted to the sponsor.

Results and Discussion

The oral administration of T-2998CoC at 150, 100, 75, 50 or 25 mg/kg/day to rats during the period of organogenesis (days 6 through 15 of gestation) did not result in any deaths. A toxic effect of reduced body weight gain occurred between days 6 and 9 of gestation in the 150 mg/kg/day dose group (Table 1).

The two nonpregnant 150 mg/kg/day rats had a more severe effect on body

weight on day 9 of the study than the pregnant high dose dams (Appendix I). They lost a considerable amount of weight and one was observed to have urinary incontinence on days 11, 12 and 13. The pregnant dams of the 100, 75, 50 and 25 mg/kg/day dose groups did not have abnormal clinical signs and gained weight at comparable levels to the 0 mg/kg/day group.

Four fetuses were examined from each of four dams in the 150 and 25 mg/kg/day dose groups for eye changes. All of the readable fetuses sectioned had eye changes consisting of one or more of the following: large lens clefts, dark streak running one-half to three-quarters of the way through the lens or disorganized lens fibers (Table 2). The lens abnormalities occurred in the same location as those observed in the two previous teratology studies (Experiment Nos: 0680TR0008 and 0680TR0010) on chemically related compounds. The abnormalities in this study appeared more pronounced than in the previous studies. In the previous studies, the teratogenic effect was a developmental eye abnormality which appeared to be an arrest in development of the primary lens fibers forming the embryonal lens nucleus, followed by secondary aberrations of the secondary lens fiber of the fetal nucleus. The same general morphological changes occurred in this rangefinder study with T-2998CoC.

Conclusion

The objective of determining an upper dose level for an oral rat teratology study was met in this study. The above results suggest that the 150 mg/kg/day dose level would be an appropriate high dose in a rat teratology study because of the toxic effect of reduced body weight gain. In addition to the toxic effect of reduced body weight gain, the teratogenic effect of lens abnormality was observed and is likely to be reproduced in a teratology study.

Table 1
 Oral Rangefinder Study of T-2998CoC in Pregnant Rats
 Mean Body Weight Gains of Pregnant Rats
 With Standard Deviations (g)

	Day				
	8	9	12	15	20
Control	20 4.2	18 7.4	21 7.5	29 1.6	76 10.7
150 mg/kg/day	21 5.5	5 17.8	30.2 ^a 8.8	12 12.8	84 12.1
100 mg/kg/day	29 4.1	15 5.1	17 4.4	19 12.6	84 12.5
75 mg/kg/day	27 6.6	11 10.6	21 2.7	19 10.5	74 12.6
50 mg/kg/day	10 6.5	16 3.7	20 5.6	27 7.3	71 10.6
25 mg/kg/day	24 2.6	16 6.4	24 6.9	29 9.3	82 5.8

^a Significantly higher than the control (Dunnett's t test $p < 0.05$)

Table 2

Oral Rangefinder Study of T-2998CoC in Pregnant Rats
Ratios of Fetuses with Eye Changes to Fetuses Examined^a

<u>High Dose Group</u> (150 mg/kg/day)	<u>Low Dose Group</u> (25 mg/kg/day)
16/16	15/15 ^b

^a Four fetuses examined from each of four dams
^b One fetus not examined because eye architecture destroyed in sectioning

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Appendix I

Oral Rangefinder Study of T-2998CoC in Pregnant Rats
 Individual Body Weights (g) and Mean Body Weights
 with Standard Deviation for Pregnant Rats

	Day						
	3	6	9	12	15	18	20
0 MG/ML/DM							
NIR	318	194	223	244	269	297	309
NIR	317	188	210	228	260	290	276
NIR	318	190	217	237	253	280	265
NIR	319	207	229	256	258	285	280
NIR	348	190	221	257	280	311	289
MEAN	190	220	243	264	297	309	
STAN. DEV	7.7	10.3	11.5	10.5	11.5	8.2	
NON PREGNANT ANIMALS							
NIR	220	184	212	221	215	222	222

	Day						
	3	6	9	12	15	18	20
150 MG/ML/DM							
OIR	301	262	222	216	257	287	267
OIR	304	182	218	217	297	261	244
OIR	300	177	191	200	244	242	314
OIR	347	206	222	226	262	278	278
MEAN	190	218	220	255	267	351	
STAN. DEV	12.9	17.5	4.6	7.7	19.4	28.3	
NON PREGNANT ANIMALS							
OIR	222	207	208	188	200	219	246
OIR	222	181	200	181	190	215	221

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Appendix I (Continued)

Oral Rangefinder Study of T-2998CoC in Pregnant Rats
 Individual Body Weights (g) and Mean Body Weights
 with Standard Deviation for Pregnant Rats

	Day						
	3	6	9	12	15	20	
100 MG/ML/DAY							
P1R	306	164	193	210	229	252	287
P1R	327	214	240	248	268	285	321
P1R	328	262	386	302	317	349	402
P1R	329	200	235	245	256	268	293
P1R	320	185	218	234	248	268	283
P1R	348	189	218	240	263	296	271
MEAN	302	212	247	264	282	288	286
STAN. DEV	33.6	21.2	20.4	29.6	34.9	40.5	

	Day						
	3	6	9	12	15	20	
75 MG/ML/DAY							
Q1R	231	193	221	243	265	268	346
Q1R	332	198	213	228	249	271	346
Q1R	333	172	203	215	235	263	346
Q1R	334	211	243	236	261	270	326
Q1R	335	197	216	225	244	268	331
Q1R	349	206	221	248	265	293	283
MEAN	194	221	233	253	272	346	
STAN. DEV	13.9	14.1	12.2	12.4	10.6	20.0	

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Appendix I (Concluded)

Oral Rangefinder Study of T-2998CoC in Pregnant Rats

Individual Body Weights (g) and Mean Body Weights
with Standard Deviation for Pregnant Rats

	Day						
	3	6	9	12	15	20	
50 MG/KG/DHY							
R1R	336	193	219	226	253	276	266
R1R	337	177	201	213	235	259	238
R1R	338	226	251	262	283	214	297
R1R	339	170	198	218	237	254	268
R1R	340	187	226	245	267	304	278
R1R	350	192	229	243	276	298	281
MEAN	191	221	236	259	286	359	
STAN. DEV	19.4	19.6	18.2	20.1	26.2	33.6	

	Day						
	3	6	9	12	15	20	
25 MG/KG/DHY							
S1R	342	216	239	266	283	304	288
S1R	343	207	234	249	279	304	283
S1R	344	185	208	227	251	292	269
S1R	345	200	219	233	249	270	248
S1R	351	205	233	238	268	307	298
MEAN	203	227	243	266	295	327	
STAN. DEV	11.4	12.8	10.4	15.2	15.3	19.4	

NON PREGNANT ANIMALS

S1R 341 187 203 219 220 228 238

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DISTRIBUTION LIST

E. G. Gortner (original + 1)

E. G. Lamprecht

R. A. Nelson → M. T. Case

W. C. McCormick → F. D. Griffith → F. A. Ubel (5)

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ATTACHMENT I

TIME LINE FOR C-8 CONTROL PROGRAM

AR 226 - 1374

- March 20, 1981 ● Informed by 3M of embryotoxic effects observed in preliminary animal studies with C-8.
- March 27, 1981 ● 3M was visited by Du Pont personnel to verify validity of test results.
- March 27-31, 1981 ● Decision made to move all females from TEFLON® area and procedures developed for handling temporary moves (Attachment II - typed April 9, 1981).
- March 31, 1981 ● Standby Media Statement and Questions and Answers received (Attachment IV).
- April 1, 1981 ● Employees informed and all females temporarily removed from exposure area (Attachment III).
- Begin blood sampling of females involved. Completed April 10, 1981.
- Begin verbal contacts with contractors as needed to assure no females of childbearing capability in exposure area.
- April 6, 1981 ● Complete Company communications package issued (Attachment IV).
- April 8, 1981 ● Work begins on dispersion modeling to determine airborne exposures in other areas of the Plant. Initial data obtained June 3, 1981. Final results completed August 7, 1981 (Attachment XIV).
- April 12, 1981 ● With medical approval, females of non-childbearing capability allowed to return to TEFLON®.
- April 14, 1981 ● Second communication to answer questions raised by females after the initial Plant announcement (Attachment V).
- Supplemental Media Standby Questions and Answers issued (Attachment VI).
- April 15, 1981 ● Communication of procedure for permanent reassignments to all wage roll (Attachment VII).

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ATTACHMENT I

(cont.)

- April 24, 1981
- Begin permanent reassignments.
 - Blood sampling begins on male employees entering TEFLON[®] Division jobs.
- May 4, 1981
- Additional toxicity testing starts at Haskell Laboratory.
 - Plant Medical Superintendent calls area obstetricians to discuss C-8 situation (Attachment VIII).
- May 6, 1981
- Initial blood sample results received and communicated to individuals (example -- Attachment IX).
- June 9, 1981
- Letters of communication issued to waste disposal vendor (Attachment X).
 - Notification letters issued to air pollution and water resources authorities (Attachments XI, XII).
- August 4, 1981
- Employee communication on blood sampling and status of program (Attachment XIII).

JFD:mah
12/14/81

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April 9, 1981

EMPLOYEE RELATIONS CONSIDERATIONS
(Ref. C-8 Communication 4-1-81)

Temporary Moves

1. Protect pay of Zone VI on loan - 2 employees.
2. All moves out of TEFLON® will be on shift announcement made.
3. All moves are temporary.
4. All TEFLON® females loaned to other divisions will be put on new division overtime roster immediately.
5. TEFLON® females loaned are to be by-passed and not charged until qualified for an OT assignment.
6. Six pool employees loaned to TEFLON® will be put on TEFLON® overtime roster immediately.
7. All male group employees loaned to TEFLON® will remain on their home roster.
8. Temporary loans from TEFLON®:
 1. All employees stay on current shift
 2. Moves made on need, work experience and seniority.
9. Male employees moved to TEFLON® were all from 2/23/81 hiring - least senior male employees.

Permanent Moves

1. Females that want and have approval will return to TEFLON® on 4/12/81.
2. Females that desire to stay in TEFLON® must talk with Dr. Power by 4/10/81.
3. Division will post on 4/13 - posting down 4/16.
4. Gate posting on 4/20 - down 4/23 - announce successful bidders 4/24/81.
5. All moves announced on 4/24 will be made immediately.
6. All TEFLON® females that do not return to TEFLON® will be required to bid on gate posting.

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Permanent Moves (Cont'd)

7. An equivalent number of junior males (minus seven pool employees) will be required to bid with TEFLON® as a choice.
8. Female employees that bid out of TEFLON® on gate posting will take their TEFLON® group service with them to new division. However, will not be used to disadvantage of employee in new division with more plant service.
9. Zone VI females that bid out of TEFLON® will have pay protected in new division until (1) they have seniority to be a successful bidder on a Zone VI job; (2) they voluntarily bid out of new division; or (3) they are involved in reduction of force to utility pool. In each case employee pay rate will be downgraded per Green Book procedure.
10. Vacation selection previously made by TEFLON® females required to bid to other division will be honored.

EMB/WAB:jsh

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CC: J. H. Todd
G. T. Rosenlund
W. A. Bower
D. D. Dalton
O. L. Darby
W. T. Darnell
H. D. Ramsey, Jr.
A. R. Stoltenberg
R. N. Taylor
E. P. Waltzer

March 31, 1981

TO: SUPERVISION THROUGH DIVISION SUPERINTENDENTS
FROM: R. J. BURGER 

C-8 COMMUNICATION

Attached information will be communicated on the following schedule.

- All Division Superintendents 9:00 a.m.,
Tuesday,
3/31/81
- All Fluoropolymer Supervision 4:00 p.m.,
Through Foremen -- Completed By: Tuesday,
3/31/81
- All Other Supervision Through 1:00 p.m.,
Supervisors -- Start At: Tuesday,
3/31/81
- All Supervision Through Foremen 9:00 a.m.,
Wednesday,
4/1/81
- All Fluoropolymers Employees 12:00 Noon,
Wednesday,
4/1/81
- All Other Employees 2:00 p.m.,
Wednesday,
4/1/81

RJB/djp

Attachment

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EMPLOYEE COMMUNICATION

We have been informed by the 3M Company about the preliminary results of a new animal study involving the fluorosurfactant, C-8, which is an essential material that has been used in excess of twenty years in fluoropolymer resins manufacture at Washington Works. 3M is our principal supplier for this chemical.

We were advised on March 20, 1981, that C-8, also known as FC-143 or ammonium perfluorooctanoate, caused birth defects in the unborn when fed by stomach tube to female rats in a laboratory experiment. This was a preliminary study designed to determine dosage limits prior to a full-scale study on C-8's potential to cause birth defects in rats.

At this time, we do not know the significance, if any, of the preliminary animal experiment as it may relate to employee exposure. Further studies are planned to define possible reproductive effects.

As a precaution based on the new study we have decided, that until further information is obtained, all female employees will be removed from areas where there is potential for exposure to C-8 and loaned immediately to other divisions. These female employees will consult with our Plant Medical Division, and those of non-childbearing capability will be given the option to return to the Fluoropolymers area. Women of childbearing capability will be allowed to bid for other plant jobs after a permanent plant posting has been made. Present pay rates will be maintained and vacation selections previously made will be honored for those females reassigned.

During the period that C-8 has been used at Washington Works, there has been no known evidence that our employees have been exposed to C-8 levels that pose adverse health effects. A preliminary acceptable exposure limit of 0.01 mg/m³ (0.56 parts per billion) was established which we believe has adequately protected our employees. At exposure levels experienced by our employees, there is no evidence to suggest there is any impairment of the male reproductive function.

3M first notified us in 1978 that exposure to C-8 could result in elevated organic fluoride levels in the blood of its employees and that these elevated levels could persist for extended periods of time. At that time, we notified employees, embarked on an extensive program to reduce exposure levels, and began blood monitoring analyses. Employees have been kept advised on new developments and of blood test results.

We ask your cooperation with job reassignments and participation in a program for additional blood sampling.

We will inform you promptly as new information is obtained.

RJB/djp

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QUESTIONS AND ANSWERS

- To Be Used As Needed To Answer Questions -

If there are any questions not answered below, they should be referred to Plant Management.

1. Q: How many female employees at your Parkersburg plant may have been exposed to C-8?

A: About sixty worked in areas where there is potential for exposure.

2. Q: Have you sampled the blood of these employees to determine if they have elevated organic fluoride levels?

A: Some but not all female employees have been sampled as part of our existing programs.

3. Q: Do they have levels of C-8 above normal?

A: Yes, some do.

4. Q: Are any of the sixty female employees pregnant?

A: Yes, two that we know of.

5. Q: Are there any former employees you know of who may have been exposed to C-8 and who are now pregnant?

A: Yes, one that we know of.

6. Q: What have you advised these pregnant women to do?

A: We have advised these employees to consult the plant physician for an explanation of the potential risks and will have them consult also with their personal physician. The exact significance of the animal test results to the human offspring is yet unknown. However, we believe it prudent to eliminate any further exposure that results in blood levels greater than background until additional data are obtained.

7. Q: Have you attempted to locate former female employees to advise them of the 3M Company's animal study which indicated that C-8 may be teratogenic?

A: We are in the process of reviewing our employment records and where appropriate, former employees will be notified.

8. Q: Do you have any knowledge of Du Pont employees or former employees who have been exposed to C-8 whose children suffered birth defects?

A: No. There is no evidence of birth defects among children born of mothers who have been exposed to C-8 compounds at Du Pont.

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9. Q: Do you have any knowledge of 3M Company employees or former employees who have been exposed to C-8 whose children suffered birth defects?
- A: No. We are not knowledgeable of the pregnancy outcome of any 3M employees or former employees who were exposed to C-8.
10. Q: What is the possibility that employees or former employees of childbearing age with elevated organic fluoride levels may give birth to children with defects.
- A: We do not know, but we are taking appropriate steps to avoid further exposure.
11. Q: Is there any indication that male employees or former male employees exposed to C-8 may have suffered loss of reproductive function?
- A: We have no indication that C-8 has an effect on the male reproductive system or its function. The reproductive organs of the male laboratory animals exposed to C-8 were closely examined and were normal, with no evidence of abnormalities attributable to C-8 exposure.
12. Q: Are there any tests that can assure the fetus is all right?
- A: There are no tests which can assure that the fetus is all right. There are tests which can detect fetal abnormalities in some cases. If these tests are done and are normal, there is a good likelihood that the fetus is all right.
13. Q: What advice do we have for women of childbearing capability who have been exposed, about becoming pregnant?
- A: This is a personal subject between the woman and her physician.
14. Q: Will elevated organic fluoride levels in the blood decrease in time?
- A: Yes.
15. Q: How long does it take for these levels to fall to background levels?
- A: It is not known at this time. Blood samplings is continuing.

15. Q: Can employees and former employees with elevated organic fluoride levels donate blood safely?
- A: Blood donating is a deferrable option. Persons who have elevated blood levels of C-8 or who have worked in areas of potential exposure to C-8 and the blood level has not been determined should not donate blood until the blood level of C-8 returns to background levels.
17. Q: What is the background level?
- A: In our experience in blood tests conducted among employees with little chance for potential exposure, organic fluoride blood levels ranged up to 0.4 ppm
18. Q: Have you resampled employees' blood recently?
- A: Yes, and we are taking additional samples in an ongoing program.
19. Q: Were the levels lower in the recent blood samples?
- A: So far there is no obvious trend with the data available.
20. Q: Is there danger to the families of employees who work in the area?
- A: By following the established practices and procedures, use of personal protective equipment and following good personal hygiene practices, there should be no hazard to the employee's family.
21. Q: What operating procedures were instituted by Du Pont after the first 3M report in 1978?
- A: Extensive engineering programs were developed which included equipment modifications and increased use of personal protective equipment. In addition, we instituted blood monitoring and air sampling programs as well as more stringent housekeeping standards.
22. Q: What additional changes in operating procedures do you plan now?
- A: This has not been determined. We are reviewing the situation.
23. Q: Are you looking for a substitute for C-8?
- A: Yes, we have been for some time.
24. Q: What are the possible substitutes?
- A: We have not identified one at present.

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25. Q: Why did the 3M Company test C-8 for teratogenicity?
A: We understand that C-8 is chemically similar to other compounds made by 3M and that in earlier testing were found to be teratogenic.
26. Q: When did Du Pont learn of the latest study results?
A: March 20, 1981.
27. Q: Has the appropriate Federal regulatory agencies been notified?
A: Yes. 3M, our supplier, has notified EPA of the study and its results.
28. Q: What were the birth defects noted by 3M in the unborn fetus?
A: Eye defects are reported but complete testing will be required.
29. Q: What additional animal testing is planned?
A: Elaborate C-8 teratology evaluations of laboratory results to confirm 3M preliminary results and to identify safe exposure level for females.
30. Q: What is Du Pont's policy on employing women around embryotoxins?
A: Women of childbearing capability are allowed to work in areas of potential exposure to teratogens where a safe exposure level is known and the exposures can be maintained below these levels. Women of childbearing capability are not allowed to work in areas where safe levels are not known or where the potential exposures are above safe levels. Women who are not of childbearing capability can work in areas of potential exposure to teratogens.
31. Q: Has Du Pont ever required or suggested that an employee be sterilized?
A: No.
32. Q: Are there any other chemicals used at your Parkersburg plant that are embryotoxic?
A: Yes, DMF (dimethyl formamide) and HFA (hexafluoroacetone).

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33. Q: What products are sold by Du Pont using C-8 (ammonium perfluorooctanoate)?

A: Various fluorocarbon resin and dispersion products.

34. Q: Is there any problem involved with cookware which has been coated with fluorocarbon resin?

A: No

35. Q: Will Du Pont be notifying its customers of the most recent findings reported by 3M?

A: Yes.

36. Q: Have women been removed from exposure at all Du Pont locations?

A: No, not at those locations where blood levels are at background.

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E. I. DU PONT DE NEMOURS & COMPANY
INCORPORATED

WILMINGTON, DELAWARE 19898

POLYMER PRODUCTS DEPARTMENT

April 6, 1981

PERSONAL AND CONFIDENTIAL

R. E. DREXEL	J. R. GIBSON - ADMIN
E. D. BOELTER	W. E. TATUM - ADMIN
I. A. LUNDGAARD	J. F. SCHMUTZ - LEGAL
R. L. RICHARDS, JR.	G. A. HAPKA - LEGAL
J. C. BESPERRA	C. D. DE MARTINO - ER
J. T. SMITH	B. W. KARRH - ER
W. R. DE GRAW/M. ROCCONI	R. P. MC CUEN - PA
N. J. IRSCH	J. L. STOWELL - PA
P. J. MEYERS	B. C. MC KUSICK - CR&D
H. E. SERENBETZ	A. L. DADE - F&F
J. W. RAINES	W. R. HENDRIX - F&F
F. N. ARONHALT	F. E. FRENCH - C&P
E. D. CHAMPNEY	R. L. RHODES - FIBR
J. A. BLUMBERG	A. A. WRIGHT - FIBR
H. A. SMITH	A. C. HAVEN - INTL
L. F. PERCIVAL	*W. G. MIKELL - EXP. STATION
D. C. SANDERS	A. B. PALMER - C&P
M. A. SMOOK - CHS-314	C. C. GRIFFITH - PHOTO
*J. H. TODD - WASH. WKS.	*W. C. EVANS - DORDRECHT
*H. F. CANFIELD - CIRCLEVILLE	H. G. DRINKWATER - GENEVA
*J. F. GLEITZ - GERMAY PARK	C. D. ROBINSON - GENEVA
*B. W. MELVIN - CHESTNUT RUN	J. B. SHAFER - SPRUANCE

C-8 PERFLUOROCTANOATE

Attached is the final employee communications package that is being used to implement corporate actions relative to recent findings by 3M on the teratogenic potential of ammonium perfluorooctanoate.

It contains the communications schedule, appropriate employee communications, questions and answers, media standby-statement, a letter outlining activities of the FC-143 Communications and Coordination Committee, and letters to customers.

Please destroy all previous drafts.

R. D. INGALLS
ENERGY & ENVIRONMENTAL AFFAIRS
MANUFACTURING DIVISION

RDI/is
Attachments

*Employee Communication for individual site only.

There's a world of things we're doing something about

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*Refers to number in upper right hand corner of page.

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PERSONAL & CONFIDENTIAL

C-8 - EMPLOYEE COMMUNICATION

Timetable:

	<u>Initial</u>	<u>Communication E.S.T.</u>
<u>Washington Works</u>		
• Line Supervision through 2nd Line	3/31	09:00
• First Line Supervision	4/1	09:00
• Wage Roll	4/1	12:00
 <u>Other Domestic Locations</u>		
• Supervision - Same as above		
• Wage Roll - Same as above		
 <u>Foreign Locations</u>		
• Europe	4/2	A.M. (local)
• Japan	4/2	A.M. (local)

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EMPLOYEE COMMUNICATION

We have been informed by the 3M Company about the preliminary results of a new animal study involving the fluorosurfactant, C-8, which is an essential material that has been used for more than 20 years in fluoropolymer resins manufacture at Washington Works. 3M is our principal supplier for this chemical.

We were advised on March 20, 1981 that C-8, also known as FC-143 or ammonium perfluorooctanoate, caused birth defects in the unborn when fed by stomach tube to female rats in a laboratory experiment. This was a preliminary study designed to determine dosage limits prior to a full-scale study on C-8's potential to cause birth defects in rats.

At this time, we do not know the significance, if any, of the preliminary animal experiment as it may relate to employee exposure. Further studies are planned to define possible reproductive effects.

As a precaution, based on the new study we have decided that until further information is obtained, all female employees will be removed from areas where there is potential for exposure to C-8 and loaned immediately to other divisions. These female employees will consult with our Plant Medical Division, and those of non childbearing capability will be given the option to return to the fluoropolymer area. Women of childbearing capability will be allowed to bid for other plant jobs after a permanent plant

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posting has been made. Present pay rates will be maintained and vacation selections previously made will be honored for those females reassigned.

During the period that C-8 has been used at Washington Works, there has been no known evidence that our employees have been exposed to C-8 levels that pose adverse health effects. A preliminary acceptable exposure limit of 0.01 mg/m³ (0.56 parts per billion) was established which we believe has adequately protected our employees. There is no evidence to suggest there is any impairment of the male reproductive function.

3M first notified us in 1978 that exposure to C-8 could result in elevated organic fluoride levels in the blood of its employees and that these elevated levels could persist for extended periods of time. At that time, we notified employees, embarked on an extensive program to reduce exposure levels, and began blood monitoring analyses. Employees have been kept advised on new developments and of blood test results.

We ask your cooperation with job reassignments and participation in a program for additional blood sampling.

We will inform you promptly as new information is obtained.

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QUESTIONS AND ANSWERS

(To be used as needed to answer questions)

If there are any questions not answered below they should be referred to plant management.

- Q01. How many female employees at your Parkersburg* plant may have been exposed to C-8?
- A01. About (50)* worked in areas where there is potential for exposure.
- Q02. Have you sampled the blood of these employees to determine if they have elevated organic fluoride levels?
- A02. Some but not all employees have been sampled as part of our existing programs.
- Q03. Do they have levels of C-8 above normal?
- A03. Yes, some do.*
- Q04. Are any of the fifty female employees pregnant?
- A04. Yes, two that we know of.*
- Q05. Are there any former employees you know of who may have been exposed to C-8 and who are now pregnant?
- A05. Yes, one that we know of.*
- Q06. What have you advised these pregnant women to do?
- A06. We have advised these employees to consult the plant physician for an explanation of the potential risks and will have them consult also with their personal physician. The exact significance of the animal test results to the human offspring is yet unknown. However, we believe it prudent to eliminate any further exposure that results in blood levels greater than background until additional data are obtained.

*Adjust for other sites.

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Q07. What is the background level?

A07. In our experience with blood tests conducted among employees with little chance for potential exposure, organic fluoride blood levels ranged up to 0.4 PPM.

Q08. Have you attempted to locate former female employees to advise them of the 3M Company's animal study which indicated that C-8 may be teratogenic?

A08. We are in the process of reviewing our employment records and where appropriate, former employees will be notified.

Q09. Do you have any knowledge of Du Pont employees or former employees who have been exposed to C-8 whose children suffered birth defects?

A09. We know of no evidence of birth defects caused by C-8 at Du Pont. In light of 3M results, we will investigate further.

Q10. Do you have any knowledge of 3M Company employees or former employees who have been exposed to C-8 whose children suffered birth defects?

A10. No. We are not knowledgeable of the pregnancy outcome of any 3M employees or former employees who were exposed to C-8.

Q11. What is the possibility that employees or former employees of childbearing age with elevated organic fluoride levels may give birth to children with defects?

A11. We do not know, but we are taking appropriate steps to avoid further exposure.

Q12. Is there any indication that male employees or former male employees exposed to C-8 may have suffered loss of reproductive function?

A12. We have no indication that C-8 has an effect on the male reproductive system or its function. The reproductive organs of the male laboratory animals exposed to C-8 were closely examined and were normal, with no evidence of abnormalities attributable to C-8 exposure.

Q13. Are there any tests that can assure the fetus is all right?

A13. There are no tests which can assure that the fetus is all right. There are tests which can detect fetal abnormalities in some cases.

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- Q14. What advice do we have for women of childbearing capability, who have been exposed, about becoming pregnant?
- A14. This is a personal subject between the woman and her physician. Any questions of a personal nature will be handled on an individual basis.
- Q15. Will elevated organic fluoride levels in the blood decrease in time?
- A15. Yes.
- Q16. How long does it take for these levels to fall to background levels?
- A16. It is not known at this time. Blood sampling is continuing.
- Q17. Can employees and former employees with elevated organic fluoride levels donate blood safely?
- A17. Blood donating is a deferrable option. Persons who have elevated blood levels of C-8 or who have worked in areas of potential exposure to C-8 and the blood level has not been determined should not donate blood until the blood level of C-8 returns to background levels.
- Q18. Have you resampled employees' blood recently? *
- A18. Yes, and we are taking additional samples in an ongoing program.
- Q19. Were the levels lower in the recent blood samples? *
- A19. So far there is no obvious trend with the data available.
- Q20. Is there danger to the families of employees who work in the area?
- A20. By following the established practices and procedures, use of personal protection equipment and following good personal hygiene practices, there should be no hazard to the employee's family.

*Adjust for other sites.

Q21. What operating procedures were instituted by Du Pont after the first 3M report in 1978?

A21. We increased use of personal protective equipment, instituted blood monitoring and air sampling programs, improved housekeeping and made certain equipment modifications. Additional engineering programs are under way.

Q22. What additional changes in operations procedures do you plan now?

A22. This has not been determined. We are reviewing the situation.

Q23. Are you looking for a substitute for C-8?

A23. Yes, we have been for some time.

Q24. What are the possible substitutes?

A24. We have not identified one at present.

Q25. Why did the 3M Company test C-8 for teratogenicity?

A25. We understand that C-8 is chemically similar to other compounds made by 3M and that in earlier testing were found to be teratogenic.

Q26. When did Du Pont learn of the latest study results?

A26. March 20, 1981.

Q27. Has the appropriate Federal regulatory agencies been notified?

A27. Yes. It is our understanding that 3M, our supplier, has notified EPA of the study and its results.

Q28. What were the birth defects noted by 3M in the unborn fetus?

A28. Eye defects are reported but complete testing will be required.

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- Q29. What additional animal testing is planned?
- A29. C-8 teratology evaluations of laboratory animals to confirm 3M preliminary results will be conducted to identify a safe exposure level for females.
- Q30. What is Du Pont's policy on employing women around embryo-toxins?
- A30. Women of childbearing capability are allowed to work in areas of potential exposure to teratogens where a safe exposure level is known and the exposures can be maintained below these levels. Women of childbearing capability are not allowed to work in areas where safe levels are not known or where the potential exposures are above safe levels. Women who are not of childbearing capability can work in areas of potential exposure to teratogens.
- Q31. Has Du Pont ever required or suggested that an employee be sterilized?
- A31. No.
- Q32. Are there any other chemicals used at your Parkersburg plant that are embryotoxic?
- A32. Yes. DMF (dimethyl formamide) and HFA (hexafluoroacetone).
- Q33. Is there any problem involved with cookware which has been coated with fluorocarbon resin?
- A33. No.
- Q34. Will Du Pont be notifying its customers of the most recent findings reported by 3M?
- A34. Yes.
- Q35. Does Du Pont manufacture fluorinated surfactants at its Deepwater, New Jersey plant?
- A35. Yes, but these are manufactured by different technology and are chemically different from C-8 (FC-143).

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- Q36. Is it possible that people working with fluoropolymer dispersions may be exposed to fluorinated surfactants and develop high blood fluoride levels?
- A36. Du Pont employees working with fluoropolymer dispersion products have been tested and show normal background level of blood fluoride.
- Q37. If sintered fluorocarbon products do not contain C-8, what happens to the C-8 during sintering or other heating operations?
- A37. It is removed in processing.
- Q38. Does Du Pont monitor airborne exposure levels?
- A38. Yes.
- Q39. Have women been removed from areas with potential for exposure at all Du Pont locations?
- A39. Each site is taking appropriate action.

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STANDBY STATEMENT
FC-143 EXPOSURE

We have been informed by the 3M Company about the results of a preliminary animal study involving the fluorosurfactant, ammonium perfluorooctanoate, also known as FC-143.

3M is our principal supplier for this chemical, which Du Pont uses in certain manufacturing processes.

We were advised that FC-143 caused defects in unborn rats when fed by stomach tube to female rats in a laboratory experiment. This was a preliminary study designed to determine dosage limits prior to a full-scale study on FC-143's potential to cause birth defects in rats.

We are considering all implications of the results of the preliminary 3M study. Additional test work is planned by 3M and Du Pont.

At this time we do not know the significance, if any, of this experiment as it relates to employees with potential for exposure. During the many years we have used FC-143, there has been no known evidence of adverse health effects from employee exposure.

As a safeguard, however, where appropriate, Du Pont has reassigned female employees of childbearing potential. Female employees of childbearing potential are not being reassigned at other locations where blood sampling and air monitoring indicate there is no cause for concern.

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NOTE: Dr. Bruce W. Karrh, of the Medical Division, will respond to media inquiries of a corporate medical nature. For inquiries to be addressed by Dr. Karrh, contact Roger R. Morris, Public Affairs (774-9561). For nonmedical inquiries of a corporate nature, contact John L. Stowell, Public Affairs (774-1843).

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Q01. At which Du Pont plants have you reassigned female employees to avoid potential exposure to FC-143?

A01. At Parkersburg, West Virginia, and Circleville, Ohio.

Q02. How many female employees have been reassigned at each plant?

A02. About 50 at Parkersburg and 1 at Circleville.

Q03. Are any of these employees pregnant?

A03. Yes, two that we know of at Parkersburg.

Q04. Are there any former employees you know of who may have been exposed to FC-143 and who are now pregnant?

A04. Yes, one that we know of at Parkersburg.

Q05. What have you advised these pregnant women to do?

A05. We have advised these employees at Parkersburg to consult the plant physician for an explanation of the potential risks and, if they wish, to consult also with their personal physician. The exact significance of the animal test results to human offspring is yet unknown, but we believe the likelihood of risk is small. However, we believe it is prudent to eliminate any further exposure until additional data are obtained.

Q06. Have you sampled the blood of these employees to determine if they have elevated organic fluorine levels?

A06. Some but not all female employees have had blood samples taken and analyzed as part of our existing program.

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Q07. Do they have above-normal organic fluorine blood levels?

A07. Yes, some have above-background levels.

Q08. Have you attempted to locate former female employees to advise them of the 3M Company's animal study which indicated that FC-143 may be teratogenic?

A08. We are reviewing our employment records and, where appropriate, former employees will be notified.

Q09. Do you have any evidence that Du Pont employees or former employees who have been exposed to FC-143 have had children who suffered birth defects?

A09. We have no evidence of birth defects caused by FC-143 at Du Pont. In the light of the 3M study, we will investigate further.

Q10. Do you have any knowledge that 3M employees or former employees who have been exposed to FC-143 have had children who suffered birth defects?

A10. We are not aware of any adverse pregnancy outcomes among 3M employees or former employees with potential for exposure to FC-143.

Q11. What is the possibility that employees of childbearing potential with elevated organic fluorine levels may give birth to children with defects?

A11. There is very little likelihood that employees would bear children with defects due to exposure to FC-143, even if it

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is a teratogen, because their exposure was at relatively low levels. However, until more facts are known about FC-143 and higher-than-background organic fluorine blood levels, we believe it is prudent to remove females of childbearing potential from the risk of potential exposure.

Q12. Is there any indication that male employees or former employees exposed to FC-143 may have suffered loss of reproductive function?

A12. We have no indication that FC-143 has an effect on the male reproductive system or its function. The reproductive organs of male laboratory animals exposed to FC-143 were examined and were normal, with no evidence of abnormalities attributable to FC-143 exposure.

Q13. Are there any tests that can assure the fetus is all right in the case of an expectant mother who was exposed to FC-143?

A13. There are no tests which can assure the fetus is all right. There are some tests which can detect fetal abnormalities in some cases.

Q14. What will you advise females of childbearing potential who have been exposed about becoming pregnant?

A14. This is a personal matter between the woman and her personal physician. Du Pont physicians will give full cooperation to employees' personal physicians. Any other matters of a personal nature will be handled on an individual, confidential basis.

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Q15. What is the background level?

A15. In our experience with blood tests conducted among employees with little chance for potential exposure, organic fluorine blood levels have ranged from 0.0 parts per million to 0.4 ppm.

Q16. Will elevated organic fluorine levels in the blood decrease in time?

A16. Yes.

Q17. How long does it take for these blood levels to fall to background levels?

A17. We do not know at this time, but we believe the rate of decline is relatively slow.

Q18. Can employees and former employees with elevated organic fluorine blood levels donate blood safely?

A18. A person who has elevated organic fluorine blood level should not donate blood until the organic fluorine blood level returns to background levels. A person who has worked in an area of potential exposure to FC-143 and whose blood level has not been determined should not donate blood until the organic fluorine level has been determined to be no higher than background.

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Q19. I understand an employee at the Parkersburg plant suffered a miscarriage. Was this related to FC-143 exposure?

A19. We have no information that indicates a higher risk of miscarriage due to exposure to FC-143.

Q20. Have you resampled employees' blood recently?

A20. Yes, we have and are taking additional samples in an ongoing program.

Q21. Were the levels lower in the recent blood samples?

A21. So far, there is no obvious trend, with the data available.

Q22. What operations procedures were changed by Du Pont after you first learned that exposed employees may have elevated organic fluorine blood levels?

A22. We increased the use of personal protective equipment, instituted blood monitoring and air sampling programs, improved housekeeping, and made certain equipment improvements. Additional engineering programs are under way.

Q23. What additional changes in operations procedures do you plan now?

A23. This has not been determined. We are reviewing the situation.

Q24. Are you looking for a substitute for FC-143?

A24. Yes.

Q25. What are the possible substitutes?

A25. We have not identified one at present.

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Q26. Why did the 3M Company test FC-143 for teratogenicity?

A26. We understand FC-143 is chemically similar to other compounds made by 3M and that in earlier testing these other compounds (a perfluorosulfonic acid and a perfluoroalcohol) were found to be teratogenic.

Q27. What were the birth defects noted by 3M in the unborn fetus?

A27. Eye defects were noted, but complete testing will be required.

Q28. What additional animal testing is planned?

A28. FC-143 teratology evaluations of laboratory animals will be conducted to confirm results of the preliminary 3M study and to identify a safe exposure level for female employees of childbearing potential.

Q29. When did Du Pont learn of the preliminary teratology study results on FC-143?

A29. March 20, 1981.

Q30. Has the appropriate Federal regulatory agency been notified?

A30. It is our understanding that 3M, our supplier, has notified the Environmental Protection Agency of the study and its results.

Q31. What is Du Pont's policy on employing females around teratogens?

A31. Women of childbearing potential are allowed to work in areas of potential exposure to teratogens where a safe exposure level is known and the exposure can be maintained below these levels. Women of childbearing potential are not allowed to work in areas where safe levels are not known or where the

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potential exposures are above safe levels. Women who are not of childbearing potential can work in areas of potential exposure to teratogens.

Q32. Has Du Pont ever required or suggested that an employee be sterilized?

A32. No.

Q33. Are there any other embryotoxic chemicals used at your Parkersburg plant?

A33. Yes. DMF (dimethyl formamide) and HFA (hexafluoroacetone).

Q34. How is FC-143 used at Du Pont?

A34. This is a water soluble compound used for its ability to modify the wettability of materials.

Q35. What products are made by Du Pont using FC-143?

A35. Various fluoropolymer resins, perfluoroelastomers, and polyimide films.

Q36. Is FC-143 found in any of these products as supplied to the marketplace?

A36. Yes, fluoropolymer dispersions contain up to one-half percent of FC-143.

Q37. What are uses for the dispersion?

A37. Fluoropolymer dispersions are used to coat various fibers and metals. In most but not all of the coating operations, the FC-143 is destroyed by a sintering process. Sintering is a

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high-temperature curing process used in all fluoropolymer coating processes except in the manufacture of some fiber and fluoropolymer resin combinations.

- Q38. Are there any applications where FC-143 is not destroyed?
- A38. Yes, in packings, gaskets, and industrial filtration products.
- Q39. Where are gaskets and packings used?
- A39. We don't know all the places. However, we can assume that any operations where liquids are being transported might use pump packings, valve stem packings, and gaskets.
- Q40. What industrial filtration products use dispersions?
- A40. Some industrial power plants use filter bags to collect finely divided coal ash. Many filter bags are made of woven glass fibers coated with dispersions which are not sintered.
- Q41. If packings and gaskets are used in systems to transport liquids, could they come into contact with liquids intended for human consumption?
- A41. We believe most of the applications involving our dispersions in packings and gaskets are industrial operations. Du Pont does not recommend the use of unsintered dispersions in applications where the material would come into contact with food, beverages, or potable water.

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Q42. You said Du Pont does not recommend such uses, but has the Company ever communicated this caution to customers?

A42. Yes. We advise customers orally and in writing that articles coated with fluoropolymer dispersions which are sintered should be in compliance with the Food and Drug Administration regulation (21 CFR 177.1550) for food contact. We advise customers that coatings that are not sintered will not comply with the FDA regulation.

Q43. Are any consumer products made and sold by Du Pont involved in this concern?

A43. No. Based upon our experience in monitoring the blood levels of our employees who work in areas where formulated products containing FC-143 are used, we do not believe there is cause for concern. For our industrial customers for fluoropolymer dispersions, we have communicated safe handling procedures for these materials. We will, of course, review this subject in greater depth and update our advice if further study warrants any changes in recommended procedures.

Q44. Is there any problem involved with cookware which has been coated with nonstick finish?

A44. No, since cookware coatings are sintered, thereby destroying the FC-143.

Q45. Will Du Pont be notifying its customers of the most recent findings reported by 3M?

A45. Yes.

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Q46. Does Du Pont manufacture fluorinated surfactants at its Deepwater, New Jersey, plant?

A46. Yes, but these are manufactured by different technology and are chemically different from FC-143.

Q47. Is it possible that people using fluoropolymer dispersions may be exposed to FC-143 and develop elevated organic fluorine blood levels?

A47. Du Pont employees using fluoropolymer dispersion products who have been tested show no elevation over background levels.

Q48. Are there other manufacturers of products competing with and similar to fluoropolymer dispersions?

A48. Yes, both in the United States and in other countries.

Q49. Are they aware of the 3M study of FC-143?

A49. We have suggested to 3M that it advise all of its FC-143 customers.

Q50. Is FC-143 used in the manufacture of fluoropolymer resins at any Du Pont plants other than Parkersburg?

A50. Yes, at Dordrecht, The Netherlands, and at a joint venture, Mitsui Fluorochemicals Company, Ltd., in Japan, which is managed by our Japanese partner.

Q51. Are female employees at Dordrecht and in Japan being reassigned or relocated?

A51. There are no female employees at Dordrecht who have the potential for exposure to FC-143. We are advising our Japanese partner for appropriate action.

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Q52. Are there other Du Pont plants where FC-143 is used?

A52. (NOTE: Plant managers should mention only their sites and refer media inquiries of a corporate nature involving other sites to Public Affairs.)

Small quantities of FC-143 or FC-143-containing materials are used at the Chambers Works in Deepwater; Germay Park, Chestnut Run, and the Experimental Station in Wilmington, Delaware; Philadelphia; Toledo, Ohio; Parlin, New Jersey; Fairfield, Connecticut; Richmond, Virginia; Brevard, North Carolina; Rochester, New York; Mechelen, Belgium; and Ajax, Canada.

Q53. Why haven't you reassigned female employees of childbearing potential at these sites?

A53. Some of these sites do not employ females in areas of potential exposure to FC-143. In other instances, Du Pont employees using fluoropolymer dispersion products who have been tested show no elevation of organic fluorine blood levels above background.

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ESTABLISHED 1902

E. I. DU PONT DE NEMOURS & COMPANY
INCORPORATED

WILMINGTON, DELAWARE 19898

POLYMER PRODUCTS DEPARTMENT

CC. A. L. RICHARDS, JR.
J. C. BESPERRA
J. R. GIBSON - ADMIN.

March 31, 1981

J. T. SMITH/N. J. IRSCH	R. L. RHODES/A. A. WRIGHT - TF
W. R. DE GRAW/M. ROCCONI	A. C. HAVEN - INTL
H. E. SERENBETZ/J. W. RAINES	G. A. HAPKA - LEGAL
F. N. ARONHALT/E. D. CHAMPNEY	B. C. MC KUSICK - CR&D
F. E. FRENCH/A. B. PALMER - C&P	B. W. KARRH - ER
A. L. DADE/W. R. HENDRIX - F&F	J. L. STOWELL - PA

FC-143 COMMUNICATIONS & COORDINATION COMMITTEE

Following are the committee members:

<u>DEPT.</u>	<u>NAME</u>
PPD	J. T. Smith
	N. J. Irsch
	W. R. DeGraw
	W. K. Nace
	H. E. Serenbetz
	J. W. Raines
C&P	F. N. Aronhalt
	E. D. Champney
F&F	F. E. French
	A. B. Palmer
FIBR	A. L. Dade
	W. C. Haaf
INTL	R. L. Rhodes
	A. A. Wright
LEGAL	A. C. Haven
CR&D	G. A. Hapka
ER	B. C. McKusick
PA	B. W. Karrh
	J. L. Stowell

This committee will meet each day at 10:00 a.m. in D-12015 to review status.

Industrial Department Committee members will direct all questions to Walt Raines (in his absence, H. E. Serenbetz) for documentation and development of consistent answers. He will keep all committee members informed.

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There's a world of things we're doing something about

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March 31, 1981

J. L. Stowell will be prime advisor on media related questions. However, such questions and answers should also be communicated to J. W. Raines.

Dr. B. W. Karrh will serve as the corporate spokesperson for all medical questions.

Each site should designate a principal spokesperson to avoid conflicting comments.



J. W. RAINES
ENERGY & ENVIRONMENTAL AFFAIRS
MANUFACTURING DIVISION

JWR:ldr

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CC: W. VAN HOEVEN - F&F
J. B. RHODES - TFD

E. I. DU PONT DE NEMOURS & COMPANY

INCORPORATED

WILMINGTON, DELAWARE 19898

POLYMER PRODUCTS DEPARTMENT
PERSONAL & CONFIDENTIAL

April 1, 1981

FPD PERSONNEL

CUSTOMER ADVISORY LETTER -
AMMONIUM PERFLUOROCTANOATE

The enclosed letter is being mailed to all domestic customers (List 5062) on Thursday, April 2.

The purpose is to advise our customers of experimental findings obtained by the 3M Company on the surfactant used in the manufacture of our fluoropolymer resins and dispersions. The information supplied by 3M has resulted in the reassignment of female personnel located in our direct resin manufacturing areas.

The information obtained to date indicates that our customers who use resins and dispersions in subsequent processing steps should continue to follow their existing good manufacturing procedures.

All questions or inquiries which may be generated as a result of this advisory letter should be referred to:

F. N. Aronhalt (774-6349)

or in my absence:

R. W. Moore (774-7387)

R. H. Geuder (774-1288)

F. N. ARONHALT
NATIONAL SALES MANAGER
FLUOROPOLYMERS DIVISION

FNA:dfa
Enclosure

EID079464

000064

AJP002634



E. I. DU PONT DE NEMOURS & COMPANY

INCORPORATED

WILMINGTON, DELAWARE 19898

April 2, 1981

POLYMER PRODUCTS DEPARTMENT

Dear Customer:

On March 20, 1981, the 3M Company, our supplier of the surfactant ammonium perfluorooctanoate, also known as FC-143, advised us that this material has been found to cause birth defects in the unborn when fed by stomach tubes to female rats in a laboratory experiment. Du Pont uses FC-143 in the manufacture of most of its fluoropolymer resins.

Much more testing must be conducted to determine the significance of the 3M experiment. As part of the ongoing program to determine the safety of our materials, both Du Pont's Haskell Laboratory and 3M are now planning more detailed experiments.

With the exception of aqueous dispersions, there is no significant residual FC-143 in any of the fluoropolymer resins which we sell. Aqueous dispersions may contain up to 0.45% by weight FC-143. Analysis of the organic fluorine content in the blood of Du Pont personnel who use aqueous dispersions in fabricating finished products shows no elevation over typical levels measured in non-exposed employees. Female personnel in these areas are not being reassigned. However, we have taken the precaution of reassigning female personnel in the areas where our resins are manufactured and FC-143 itself is handled.

At this time, if you are following the Safe Handling Procedures previously given to you, it does not appear that changes in your processing operations are warranted. We do recommend that you continue to follow the Safe Handling Procedures (attached). Further studies are being conducted and we will advise you if there are any changes in our recommendations.

Should you have any questions, please contact us at your convenience.

Yours very truly,

Frank N. Aronhalt
National Sales Manager
Fluoropolymers Division

FNA:dfa

EID079465

DRAFT OF LETTER TO CUSTOMERS OF:

Textile Fibers - Products containing Teflon® dispersions in an unsintered state.

April 2, 1981

Dear

On March 20, 1981, the 3M Company, our supplier of the surfactant ammonium perfluorooctanoate (FC-143), advised us the material has been found to cause birth defects when fed by stomach tube to female rats in a laboratory experiment. Du Pont has used FC-143 in the manufacture of its fluoropolymer resins for many years and has not experienced any known human-related problems. Our manufacturing process is such that only the fluoropolymer dispersions contain any residual FC-143, ~ 0.45% by weight.

These dispersions are used as impregnants in the family of Teflon® and Kevlar® packing yarns sold by Du Pont. Residual levels of FC-143 are present in these packing yarns. Other forms of Teflon® fiber are not known to contain residual FC-143.

As part of Du Pont's ongoing program for determining the safety of the materials used in the manufacture of or contained in the products we sell, we have been monitoring the organic fluorine content of the blood of the personnel involved with producing fibers. Our findings are:

At Du Pont's facilities which use fluoropolymer dispersions containing FC-143 in a manner similar to yours, we have found no elevation of the organic fluorine content over that of unexposed people.

EID079466

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ALP002636

We intend to conduct more testing to determine the significance of the 3M experiment as it relates to our employee exposure and the products we sell. We have reviewed our procedures for handling fluoropolymer dispersions in our plants and plan no changes.

At this point in time, it does not appear to us that changes in your operations are warranted when handling impregnated packings. We will keep you informed of any further developments.

EID079467

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AJP002637



E. I. DU PONT DE NEMOURS & COMPANY
INCORPORATED
WILMINGTON, DELAWARE 19898

FABRICS & FINISHES DEPARTMENT

April 1, 1981

Dear Sir:

As part of Du Pont's ongoing program to survey the safety of all our materials, we think you should be advised of a March 20, 1981 announcement from the 3M Company, our surfactant supplier. 3M informed us that based on preliminary laboratory experiments involving a pure surfactant, birth defects resulted when fed to female rats. This surfactant is used at low concentrations by Du Pont to manufacture fluoropolymers which, in turn, are one of the components in our non-stick finishes.

In-depth investigation of the presence of this surfactant in coatings determined that the 3M surfactant was destroyed at normal curing temperatures and no detectable residue remained. As such, your coated products pose no health hazards to your customers.

If you are following our recommended "Safe Handling Practices" guide, changes in your manufacturing operations are not required. A copy of the guide is attached. Changes may be advisable if you are not following these recommended practices and our representatives will be available to discuss them with you.

Should you have any questions, please contact us at your convenience.

Very truly yours,

Richard M. Gray
Sales Manager
TEFLON® FINISHES

RMG:crj

© TEFLON is Du Pont's registered trademark.

EID079468

AJP002638



E. I. DU PONT DE NEMOURS & COMPANY
INCORPORATED
WILMINGTON, DELAWARE 19898

FABRICS & FINISHES DEPARTMENT

April 3, 1981

Dear Mr. President:

The 3M Company recently told us that a fluorosurfactant (FC-143) we buy from 3M has caused birth defects in rats in a laboratory test. This product is a minor (less than 0.5 percent) ingredient in dispersions used to make our impregnated fluorocarbon felt.

It is our belief that the FC-143 is destroyed in the normal heat treatment of our impregnated felts. We are now testing to see if any residue of the compound can be detected in our finished product. We will let you know as soon as we get definitive results.

Sincerely,

MIKE COCO
SALES MANAGER - INDUSTRIAL
ELECTRONIC/INDUSTRIAL
COMPOSITES & COATINGS
SPECIALTY PRODUCTS DIVISION

MC/sew

EID079469

AP002639

WASHINGTON WORKS
PROPOSED COMMUNICATION TO FEMALES
WHO HAD WORKED IN FLUOROPOLYMERS AREA

As follow-up to our original communication on C-8 (FC-143) we have some additional information pertaining to questions that have been asked. This is in accord with our practice of keeping you informed in such matters as new information is obtained.

There have been rumors that two women who worked in Fluoropolymers have had children with birth defects. We are not aware of any human birth defects attributable to FC-143. We do know of two women who worked in this area before or during pregnancy whose children reportedly had defects detected at birth. We became aware of this information after 3M notified us of the animal study. We do not know whether there is a relationship. We are investigating this matter further, and we are considering additional studies.

Some employees have asked what advice we have for female employees of childbearing potential who have been exposed to FC-143 about becoming pregnant. Until we have additional information about the potential effects of FC-143 on the human fetus, we think this is a matter of sufficient concern that, as a precaution, a female who has an organic fluorine blood level above background level should consult with her personal physician prior to contemplating pregnancy. We will provide all information we have on FC-143 to employees' personal physicians.

Another question is what we have told female employees who have mentioned they are considering voluntary sterilization. The plant physician and area supervision have told them that we strongly recommend against sterilization for job-related reasons. Each woman who raised this subject has been told that her employment, her seniority, her pay, and her benefits are fully protected and that there was no need to even consider a surgical procedure. The women were told that whether or not they elected such surgery was a personal matter that would have to be decided by them in consultation with their husbands and their personal physicians.

/djp
4/9/81..

EID079470

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AJP002640



E. I. DU PONT DE NEMOURS & COMPANY
INCORPORATED
WILMINGTON, DELAWARE 19898

POLYMER PRODUCTS DEPARTMENT

April 14, 1981

PERSONAL & CONFIDENTIAL

R. E. DREXEL	J. R. GIBSON - ADMIN
E. D. BOELTER	W. E. TATUM - ADMIN
I. A. LUNDGAARD	J. F. SCHMUTZ - LEGAL
R. L. RICHARDS, JR.	G. A. HAPKA - LEGAL
J. C. BESPERRA	C. D. DE MARTINO - ER
J. T. SMITH	B. W. KARRH - ER
W. R. DE GRAW/M. ROCCONI	R. P. MC CUEN - PA
P. J. MEYERS	J. L. STOWELL - PA
H. E. SERENBETZ	B. C. MC KUSICK - CR&D
J. W. RAINES	A. L. DADE - F&F
R. D. INGALLS	W. R. HENDRIX - F&F
F. N. ARONHALT	F. E. FRENCH - C&P
E. D. CHAMPNEY	R. H. RHODES - FIBR
J. A. BLUMBERG	A. A. WRIGHT - FIBR
H. A. SMITH	A. C. HAVEN - INTL
L. F. PERCIVAL	W. G. MIKELL - EXP. STATION
D. C. SANDERS	A. B. PALMER - C&P
M. A. SMOOK - CHS-314	C. C. GRIFFITH - PHOTO
J. H. TODD - WASH. WKS.	W. C. EVANS - DORDRECHT
H. F. CANFIELD - CIRCLEVILLE	H. G. DRINKWATER - GENEVA
J. F. GLEITZ - GERMAY PARK	C. D. ROBINSON - GENEVA
B. W. MELVIN - CHESTNUT RUN	

C-8 PERFLUOROCTANOATE

Attached are; (1) the final Supplemental Standby Questions and Answers prepared to address additional media questions that may arise from (2) the Supplemental Employee Communication currently underway at Washington Works.

N. J. Irsch
Manufacturing Division

NJI:adw
Attachment

EID079471

AP002641

000071

Final Draft - 4/13/81

*Approved for use
4/14*

SUPPLEMENTAL STANDBY Q&As

FC-143 EXPOSURE

(NOTE: These Q&As are supplemental to the final standby of 4/3/81. They address additional questions that may arise from a supplemental communication to Washington Works employees.)

Q01. Is it true that two women who worked in the FC-143 area at your Parkersburg plant have had children with birth defects?

A01. We are not aware of any human birth defects attributable to ammonium perfluorooctanoate, also known as FC-143. We do know of two women who worked in this area before or during pregnancy whose children reportedly had defects detected at birth. We do not know whether there is a relationship. We are investigating this matter further, and we are considering additional studies.

Q02. Can you be more specific about these two defects?

A02. (Refer question to Dr. Bruce W. Karrh of the Medical Division.)

EID079472

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AJP002642

Q03. What have you told female employees who have mentioned they were considering sterilization?

A03. The plant physician has told them that we strongly recommend against sterilization for job-related reasons. Each woman who raised this subject was told that her employment, her pay rate, her seniority, and her benefits would be fully protected and there was no need even to consider a surgical procedure. The women were told that whether or not they elected such surgery was a personal matter that would have to be decided by them in consultation with their husbands and their personal physicians.

Q04. Despite these assurances, did any of the female employees who were reassigned from the FC-143 area subsequently decide to be sterilized?

A04. Yes, a few did at Parkersburg. This was their personal decision. I emphasize that each had been told individually that we strongly recommend against sterilization for job-related reasons because it was not necessary.

Q05. How many exactly?

A05. Four.

Q06. What happened to the women who decided to be sterilized?

A06. Each of them had the option of either accepting reassignment to another job with the same pay at the plant or returning to her previous work assignment.

EID079473

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AJP002643

Q07. Are there any other female employees who were reassigned from the FC-143 area who in retrospect were not of child-bearing potential?

A07. Yes, we have been told by our plant physician that some women in this area later presented evidence that they were not of childbearing potential at the time of the reassignment. They also had the option of accepting reassignment or returning to their previous jobs.

Q08. How many exactly?

A08. Nine.

Q09. Will you give me the names of the women who chose sterilization?

A09. No. To do so would be an invasion of their privacy.

Q10. What will you advise female employees of childbearing potential about becoming pregnant if they potentially were exposed to FC-143?

A10. As a precaution, a female who has an organic fluorine blood level above the background level should consult with her personal physician prior to contemplating pregnancy. Until we have additional information about the potential effects of FC-143 on the human fetus, we think this is a necessary precaution. We will provide all information we possess about FC-143 to employees' personal physicians to aid in this decision.

EID079474

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AJP002644

Q11. What products are involved with FC-143?

A11. (NOTE: This response should be used only in response to a question that mentions the trademark, "Teflon". A general question can be answered by A35 through A44 of the 4/3/81 standby.)

FC-143 is made by several different companies in the manufacture of a variety of fluoropolymer dispersions, including some of Du Pont's "Teflon" products. Any Du Pont fluoropolymer dispersion used in consumer products goes through a process that destroys FC-143, with the possible exception of some plumbing packing materials.

#

EID079475

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ALP002645

O: J. T. SMITH) - VIA TELETYPE
PPD)
D12008 - WILM.)

WASHINGTON WORKS
PROPOSED COMMUNICATION TO FEMALES
WHO HAD WORKED IN FLUOROPOLYMERS AREA

As follow-up to our original communication on C-8 (FC-143) we have some additional information pertaining to questions that have been asked. This is in accord with our practice of keeping you informed in such matters as new information is obtained.

There have been rumors that two women who worked in Fluoropolymers have had children with birth defects. We are not aware of any human birth defects attributable to FC-143. We do know of two women who worked in this area before or during pregnancy whose children reportedly had defects detected at birth. We became aware of this information after 3M notified us of the animal study. We do not know whether there is a relationship. We are investigating this matter further, and we are considering additional studies.

Some employees have asked what advice we have for female employees of childbearing potential who have been exposed to FC-143 about becoming pregnant. Until we have additional information about the potential effects of FC-143 on the human fetus, we think this is a matter of sufficient concern that, as a precaution, a female who has an organic fluorine blood level above background level should consult with her personal physician prior to contemplating pregnancy. We will provide all information we have on FC-143 to employees' personal physicians.

Another question is what we have told female employees who have mentioned they are considering voluntary sterilization. The plant physician and area supervision have told them that we strongly recommend against sterilization for job-related reasons. Each woman who raised this subject has been told that her employment, her seniority, her pay, and her benefits are fully protected and that there was no need to even consider a surgical procedure. The women were told that whether or not they elected such surgery was a personal matter that would have to be decided by them in consultation with their husbands and their personal physicians.

/dip
4/9/81

EID079476

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AFD002646

ATTACHMENT VII

SUPERVISORY INFORMATION MANUAL
INDEX 2

April 15, 1981

TO: ALL SUPERVISION

PERSONNEL MOVEMENT

As a result of the need to move some TEFLON® females to other divisions, the following guidelines have been developed.

Please communicate the guidelines to all wage roll employees reporting to you.

I. Required Moves From TEFLON®

- Females who do not have Medical approval to stay will be required to bid on Gatehouse Posting as though they were demoted from their Group.
- These employees are to fill out the following on the Gatehouse Bid Card:
 1. Mark block "I am required to bid"
 2. Number all Groups except TEFLON®
 3. Number all shifts

II. Who May Bid To TEFLON®

- Only male employees or female employees of non-childbearing capability will be allowed to move to TEFLON®.
- Female employees must have approval from the Medical Division by end of Gatehouse posting period to be considered.

III. Vacancies To Be Posted At Gatehouse 4/20/81

- TEFLON® - 16 Replacements
- Filaments - 8 New vacancies
- LUCITE® - 4 New vacancies
- Power & Services - 1 New vacancy

BUTACITE® and C&P will be taking a reduction of force of one each.

EID079477

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AJP002647

IV. Gatehouse Bidding Procedures

A. General

- Sixteen TEFLON® females will be required to bid from TEFLON®.
- One BUTACITE® and one C&P employee will be required to bid because of a reduction of force.
- Normal Gatehouse bidding procedures will be followed except in the case not enough qualified employees bid voluntarily to TEFLON® to fill vacancies.

B. Moves Required To Fill Remaining TEFLON® Vacancies

- If TEFLON® vacancies are not filled voluntarily by qualified bidders or qualified Utility Pool employees, least senior Plant Service male Group employees will be required to move to TEFLON®.
- If Gatehouse Bid Cards have not been entered by least senior male Group employees required to move to TEFLON®, shift preferences will be taken from their Group Job Request cards based on most desired shift Job indicated.
- Least senior male Group employees who may be required to move to TEFLON® should enter a Gatehouse Bid Card listing shift preferences if different than ones listed on their Group Job Request Cards.

V. Group Service For TEFLON® Females Required To Move From TEFLON®

- TEFLON® females required to move to other divisions will use either their TEFLON® Group Service or prior Group Service in their new division within last three years, whichever is greater, as their Group Service in new division for Group bidding purposes.
- Actual Group Service will start at "zero" unless prior Group Service in new division. Actual Group Service will be used if she bids out of her new division and later bids back per "Green Book" procedure.

VI. Scheduled Vacations For TEFLON® Females

- Vacation selections previously made by TEFLON® females required to move to other divisions will be honored.
- If TEFLON® females change shifts in moving to other divisions, they will be allowed to take a "first choice" vacation period (any number of consecutive workdays). Any other vacation days rescheduled must follow division procedures.

EID079478

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AJP002648

VII. Pay Protection For TEFLON® Females

- TEFLON® females currently above Zone IV who are required to move to other divisions will have their rate of pay protected in their new division until:

1. They have seniority to be a successful bidder on an equivalent Zone Job.
2. They voluntarily bid out of new division, or
3. They are involved in a reduction of force to the Utility Pool.

In each case, employee pay rate will be downgraded per "Green Book" procedure.

VIII. Timing Of Personnel Moves

- All moves resulting from Gatehouse Posting will be made immediately.

If you have any questions about the above guidelines, please call C. E. Allman (4258) or E. M. Bond (4304).

EMPLOYEE RELATIONS DEPARTMENT

O.T.

EMB:jsh

EID079479

AJP002649

000079



E. I. DU PONT DE NEMOURS & COMPANY
INCORPORATED

WILMINGTON, DELAWARE 19898

POLYMER PRODUCTS DEPARTMENT

cc: J. T. Smith/N. J. Irsch
W. R. DeGraw/M. Rocconi
H. E. Serenbetz/J. W. Raines
F. N. Aronhalt/E. D. Champney
F. E. French/A. B. Palmer, C&P
A. L. Dade/W. R. Hendrix, F&F
R. L. Rhodes/A. A. Wright, TF
A. C. Haven, Intl
G. A. Hapka, Legal
B. C. McKusick, CR&D
B. W. Karrh, ER
J. L. Stowell, PA

May 4, 1981

PERSONAL AND CONFIDENTIAL

J. H. TODD
WASHINGTON WORKS

BLOOD SAMPLING RESULTS
COMMUNICATIONS

Results are available from blood sampling of Washington Works personnel. As you have indicated, employees should be informed of the results promptly.

Outlined below is the recommended method and content of the communication:

Supervision will pass out envelopes from Plant Medical containing a card with the results.

When the results are given to females of childbearing capability who were reassigned or relocated from the fluoro-carbons area, they will be encouraged to talk with the plant physician who will be available to consult with them. It is anticipated that this would begin Wednesday. The plant physician will advise them again that we do not know the significance of the preliminary animal exposure as it relates to human exposure, but that a program has been started at Haskell Laboratory. Results will be available in several months. He will advise them that if they are contemplating pregnancy, they should consult with their own physician, and that they ask their physician to contact the Du Pont plant physician.

The plant physician will contact selected physicians in the community using the attached communication as a guide. Essentially, this communication advises that as a precaution, pregnancy be deferred until there is additional information.

EID079480

J. H. Todd

- 2 -

May 4, 1981

For males and females of non-childbearing potential, their supervision will pass along the envelopes with the blood analyses as in the past, with the offer that consultation with the plant physician will be arranged if the employee desires it.

We understand that the plant feels that no further advice need be given relative to donating blood. Previous communications with employees have covered this subject satisfactorily.



R. D. INGALLS
ENERGY & ENVIRONMENTAL AFFAIRS
MANUFACTURING DIVISION

RDI/is
Attachment

AJP002651

EID079481

000081

WASHINGTON WORKS

PLANT PHYSICIANS' COMMUNICATION TO COMMUNITY PHYSICIANS

On March 20, 1981, we were advised by the 3M Company that FC-143, or Ammonium Perfluorooctanoate, caused birth defects in the unborn when fed by stomach tubes to female rats in a laboratory experiment. The defects noted were lenticular opacities in fetuses of the exposed animals. 3M is our prime supplier for this chemical. This was a preliminary study designed to determine dosage limits prior to a full-scale study on FC-143's potential to cause birth defects in rats.

At this time, we do not know the significance, if any, of the preliminary animal exposure as it may relate to employee exposure. Further studies are planned to define possible reproductive effects.

As a precaution, we removed all female employees of childbearing capability from areas where there was a potential for significant exposure to FC-143.

During the period that FC-143 has been used at Washington Works, there has been no known evidence that our employees have been exposed to levels posing an adverse health effect. At exposure levels experienced by our employees, there is no evidence to suggest there is any impairment to the male reproductive functions.

AJP002652

EID079482

000082

Some of our employees have asked what advice we have for female employees of childbearing capability who have been exposed to FC-143 about becoming pregnant. Until we have additional information about the effects of FC-143 on the human fetus, we think that under some conditions, it may be prudent for a female employee who has had jobs in which there was significant potential for exposure to FC-143 (those that have just been reassigned) to defer pregnancy. However, there are many factors to be considered in such a decision. We would be glad to discuss each individual case with you if you desire.

We believe levels of exposure have been safe, but we want to confirm that. We do know that FC-143 can be detected at low levels in the blood of our employees who have exposure potential to this material, and that these elevated blood levels decrease with time.

Since this information may change as test results are obtained, please call me so you can obtain the latest information before you advise patients.

RDI:tps
5/4/81

EID079483 .

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AJP002653

G-428 REV. 6/78



EXAMPLE

PERSONAL AND CONFIDENTIAL
EMPLOYEE/APPLICANT COPY

PHYSICAL EXAMINATION

TO: NAME (P.R. #)

ADDRESS: _____

DATE	TIME
5/6/81	
MEDICAL EXAMINER	

A report of your examination will be sent to your personal physician if you request.

(Authorized By)

PHYSICAL EXAMINATION REPORT

We have no recommendations to make at this time, other than any made at the time of the examination.

Please note the following. April 1981 blood sample had () ppm organic fluorine (measured as C-8).

If you have any questions, please have your supervision make an appointment for you to see Y. L. Power, M.D.

We will be glad to discuss this subject with you.

EXAMINER M.D.

ALP002654

EID079484

000084

ATTACHMENT X

(Supernate letter to Chemical Waste Management, 6/9/81)

BCC: D. K. Duncan, Wilmington
C. L. Hoover, E&M
B. J. Reilly, Legal
P. A. Palmer, Louviers
J. H. Todd/G. T. Rosenlund
R. J. Burger/C. R. Campbell
W. T. Darnell/T. L. Schrenk
R. N. Taylor
J. F. Doughty
P. Thistleton

In Turn:

W. A. Bower
D. D. Dalton
A. R. Stoltenberg
H. D. Ramsey
R. E. Hansel
J. J. DiNicola

/hcw
1301A

EID079485

000085

AJP002655



E. I. DU PONT DE NEMOURS & COMPANY

INCORPORATED

P. O. Box 1217
PARKERSBURG, W. VA. 26101

POLYMER PRODUCTS DEPARTMENT

June 9, 1981

Chemical Waste Management
c/o Ohio Liquid Disposal, Inc.
504 Liberty Street
Fremont, Ohio 43420

Gentlemen:

The purpose of this letter is to provide toxicity information on one of the ingredients contained in the supernate liquid waste which you handle for this plant.

The 3M Company, supplier of the surfactant ammonium perfluoro-octanoate, also known as FC-143, has advised us that this material has been found to cause defects in the unborn when fed by stomach tubes to female rats in a laboratory experiment. This surfactant is used in the manufacture of fluoropolymer resins and is present at a concentration of approximately 0.1 to 0.3% in the supernate waste which you handle. Much more testing must be conducted to determine the significance of the 3M experiment. As part of the ongoing program to determine the safety of our materials, both Du Pont's Haskell Laboratory and 3M are now planning detailed experiments. Analysis of the organic fluorine content in the blood of Du Pont personnel who fabricate finished products using the dispersions which contain this ingredient show no elevation over typical levels measured in non-exposed employees. Female personnel of *childbearing capability who worked in areas where the resins containing the ingredient are manufactured or the ingredient is handled* have been reassigned to other work areas.

Our product bulletins caution that skin contact should be avoided with dispersion containing the surfactant and the material should be washed off with water if splashed on the skin. Eye protection should be used and if splashed in the eyes should be flushed out with water and medical attention sought to insure that the material has been removed. These precautions are advised in handling the waste.

Since the supernate is loaded and unloaded outdoors, no special ventilation should be required. Breathing waste vapors when opening the loading hatch, inspecting the liquid level, etc., should be avoided.

AP002656

EID079486

There's a world of things we're doing something about

000086

The Waste Characterization Forms outlining the properties of this waste have been changed to include these cautions and are attached. Please sign and return two copies of this letter where indicated under accepted.

If you have any questions concerning this information or need additional information, please call me at 863-4271.

Very truly yours,



A. C. Huston
Environmental Control Consultant
Washington Works

Accepted: Chemical Waste Management
c/o Ohio Liquid Disposal, Inc.
504 Liberty Street
Fremont, Ohio 43420

ACH:hcw
Attachment
1301A

EID079487

000087

AJP002657

WASTE CHARACTERIZATION

DuPont - Washington Works

DU POINT CODE DUP 10T

I. LOCATION Washington Works APPROVED Date 6/10/81
 EPA I.D.# WVD045875291

CONTRACTOR'S CODE _____
 EPA CODES None
 OTHER CODES _____

II. NAME OF WASTE Supernate

III. COMPOSITION

A. MAJOR COMPONENTS	C. ONE TIME OR TYPICAL ANALYSIS	D. CONCENTRATION RANGE %		E. EXPOSURE LIMITS	
		UPPER	LOWER	+ACGIH	+OSHA
1. <u>Water</u>	<u>94.3</u>	<u>98.0</u>	<u>90.0</u>	_____	_____
2. <u>TRITON®</u>	<u>4.7</u>	<u>6.0</u>	<u>1.5</u>	_____	_____
3. <u>TEFLON®</u>	<u>1.0</u>	<u>4.0</u>	<u>0.5</u>	_____	_____
4. _____	_____	_____	_____	_____	_____
5. _____	_____	_____	_____	_____	_____

B. TRACE COMPONENTS NOT LISTED ABOVE (PPM) CN _____ Ag _____ As _____ Ba X
Cd _____ Cr _____ Cu _____ Hg _____ Ni _____ Pb _____ Se _____
Zn X S* _____ Cl* _____ N* _____ P* _____ F* X I* _____
 OTHER Ammonium Hydroxide, Citric Acid, Duponol, C-8 (ammonium perfluorooctanoate)**,
Glass Beads, Sodium Hydroxide

IV. PHYSICAL STATE @ 25°C (CIRCLE): SOLID LIQUID SLUDGE LIQUID/SOLID PHASES GAS
 OTHER TEFLON® sludge formation is time dependent and redispersible.
 SOLIDS : IS THERE A DUSTING HAZARD IF CONTAINERS ARE OPENED? No
 LIQUIDS : MULTIPLE PHASES? No VOL% OF EACH PHASE _____
 LIQUIDS & SLUDGES : CAN THE WASTE BE PUMPED? Yes FOURED? Yes
 LIQUID/SOLID PHASES: % FREE FLOWING LIQUID LAYER _____ (VOLUME %) _____
 GASES : PRESSURE OF CONTAINER _____ PSIG

V. CONTAINMENT (CIRCLE)
BULK MC 304, MC 307 (MC 312) _____
 55-GAL. STEEL DRUMS (DOT _____)
 30-GAL. FIBER DRUMS (DOT _____)
 5-GAL. PAILS _____
 OTHER _____
 APPROX. WT. PER CONTAINER 45,000 LBS.

VI. PROPERTIES (CIRCLE)
 COMBUSTIBLE (FF _____ °F) IGNITABLE (FF _____ °F)
 (CLOSED CUP) (CLOSED CUP)
 CORROSIVE _____ OSHA CARCINOGEN _____
 pH 10 ODOR (YES) NO Ammonia
 Btu/LB. _____ COLOR _____
 REACTIVE _____
 TOXIC See remarks below
 OTHER _____

VII. D.O.T. SHIPPING NAME Process Water (Spent)
 D.O.T. HAZARD CLASSIFICATION Not Regulated
 U.M. NO. _____ N.A. NO. _____

VIII. VOLUME (FOR PLANNING PURPOSES ONLY)
 THIS REQUEST _____
 ANNUAL _____
 IX. REMARKS **Special health considerations are noted on attached sheet.

*Organically bound only

AJP002658

ATTACHMENT TO WCF DUP 10T

SUPERNATE - DUP-10T WASTE

The 3M Company, supplier of the surfactant ammonium perfluorooctanoate, also known as FC-143, has advised us that this material has been found to cause defects in the unborn when fed by stomach tubes to female rats in a laboratory experiment. This surfactant is used in the manufacture of fluoropolymer resins and is present at a concentration of approximately 0.1 to 0.3% in the supernate waste which you handle. Much more testing must be conducted to determine the significance of the 3M experiment. As part of the ongoing program to determine the safety of our materials, both Du Pont's Haskell Laboratory and 3M are now planning detailed experiments. Analysis of the organic fluorine content in the blood of Du Pont personnel who fabricate finished products using the dispersions which contain this ingredient show no elevation over typical levels measured in non-exposed employees. Female personnel of childbearing capability who worked in areas where the resins containing the ingredient are manufactured or the ingredient is handled have been reassigned to other work areas.

Our product bulletins caution that skin contact should be avoided with dispersion containing the surfactant and the material should be washed off with water if splashed on the skin. Eye protection should be used and if splashed in the eyes should be flushed out with water and medical attention sought to insure that the material has been removed. These precautions are advised in handling the waste.

Since the supernate is loaded and unloaded outdoors, no special ventilation should be required. Breathing waste vapors when opening the loading hatch, inspecting the liquid level, etc., should be avoided.

/hcw
1313A

AJP002659

EID079489

000089

ATTACHMENT XI

(Letter, A. C. Huston to Carl G. Beard II, June 9, 1981)

BCC: D. K. Duncan, Wilmington
B. J. Reilly, Legal
R. I. Wevodau, Louviers
J. H. Todd/G. T. Rosenlund
R. J. Burger/C. R. Campbell
W. T. Darnell/T. L. Schrenk
R. N. Taylor
J. F. Doughty
P. Thistleton
In Turn:

W. A. Bower
D. D. Dalton
A. R. Stoltenberg
H. D. Ramsey
R. E. Hansel
J. J. DiNicola

/hcw
1303A

EID079490

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AJP002660



E. I. DU PONT DE NEMOURS & COMPANY
INCORPORATED

P. O. Box 1217
PARKERSBURG, W. VA. 26101

POLYMER PRODUCTS DEPARTMENT

June 9, 1981

CERTIFIED MAIL -
RETURN RECEIPT REQUESTED

Mr. Carl G. Beard II, Director
W. Va. Air Pollution Control Commission
1558 Washington Street, East
Charleston, West Virginia 25311

Dear Mr. Beard:

This letter is to inform you of toxicity information we have received from our supplier of the surfactant ammonium perfluorooctanoate, also known as FC-143, which is present in small quantities in eight vents from our fluoropolymers processes. The total venting of this material is about 1½ pounds per hour. The 3M Company has advised us that this material has been found to cause defects in the unborn when fed by stomach tubes to female rats in a preliminary laboratory experiment.

Much more testing must be conducted to determine the significance of the 3M experiment. As part of the ongoing program to determine the safety of our materials, both Du Pont's Haskell Laboratory and 3M are now planning more detailed experiments. However, we have taken the precaution of reassigning female personnel of childbearing capability to areas outside those in which fluoropolymer resins are manufactured or FC-143 is handled.

At this time, we do not know the significance, if any, of the preliminary animal experiment. FC-143 has been in use for decades without apparent adverse affects in humans.

If you need any additional information, please let me know.

Very truly yours,

A. C. Huston
Environmental Control Consultant
Washington Works

ACH:hcw
1303A (N)

EID079491

000091

ATTACHMENT XII

(C-8 Letter to David W. Robinson from A. C. Huston, June 9, 1981)

BCC: D. K. Duncan, Wilmington
B. J. Reilly, Legal
R. F. Rocheleau, Louviers
J. H. Todd/G. T. Rosenlund
R. J. Burger/C. R. Campbell
W. T. Darnell/T. L. Schrenk
R. N. Taylor
J. F. Doughty
P. Thistleton
In Turn:
W. A. Bower
D. D. Dalton
A. R. Stoltenberg
H. D. Ramsey
J. J. DiNicola
R. E. Hansel

/hcw
1306A

EID079492

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AJP002662



E. I. DU PONT DE NEMOURS & COMPANY

INCORPORATED

P. O. BOX 1217

PARKERSBURG, W. VA. 26101

POLYMER PRODUCTS DEPARTMENT

CC: Jack J. Schramm, Regional Adm.,
EPA, Region III
Permit Programs Monitoring Unit,
3EN43MI
6th and Walnut Streets
Philadelphia, Pennsylvania 19106

C. Ronald Sandy, Supervisor
W. Va. Div. of Water Resources
6321 Emerson Avenue
Parkersburg, WV 26101

June 9, 1981

CERTIFIED MAIL -
RETURN RECEIPT REQUESTED

David W. Robinson, Chief
W. Va. Division of Water Resources
1201 Greenbrier Street
Charleston, WV 25311

Dear Sir:

This letter is to inform you of toxicity information we have received from our supplier of the surfactant ammonium perfluorooctanoate, also known as FC-143, which is present in our outfall 005 (permit (WV0001279) in a concentration of about 0.1 mg/L. The 3M Company has advised us that this material has been found to cause defects in the unborn when fed by stomach tubes to female rats in a preliminary laboratory experiment. Du Pont uses FC-143 in the manufacture of fluoropolymer resins.

Much more testing must be conducted to determine the significance of the 3M experiment. As part of the ongoing program to determine the safety of our materials, both Du Pont's Haskell Laboratory and 3M are now planning more detailed experiments. However, we have taken the precaution of reassigning female personnel of childbearing capability to areas outside those in which fluoropolymer resins are manufactured or FC-143 is handled.

At this time, we do not know the significance, if any, of the preliminary animal experiment. FC-143 has been in use for decades without apparent adverse affects in humans.

If you need additional information, please let me know.

Very truly yours,

A. C. Huston
Environmental Control Consultant
Washington Works

ACH:hcw
1306A

EID079493

AJP002663

ATTACHMENT XIII

CC: Plant Staff
Manufacturing Supts
Maintenance Supts
Power & Services Supt
Research Supts

August 4, 1981

TO: H. T. BEGG
D. A. ERDMAN
L. W. GOIN
M. E. MAYBERRY
T. L. SCHRENK
S. J. WATSON
R. J. ZIFFEL

FROM: R. J. BURGER

C-8 PROGRAM
REVISION 1

The attached memo is to be communicated to your employees on the following schedule:

All Supervision after 8:00 AM - August 4

All Employees after 11:00 AM - August 5

Other Divisions may have employees who formerly worked in Fluoropolymers and participated in the blood sampling program. Where appropriate, please communicate with those employees on the same schedule.

RJB/sbr
Attachment
0224R

AJP002664

EID079494

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July 31, 1981

TO: FLUOROPOLYMERS PRODUCTION, TECHNICAL AND MECHANICAL SUPERVISION

FROM: R. J. BURGER

C-8 PROGRAM

As followup to previous communications, this information is to be used to communicate to employees. As additional information is available, we will inform you.

Blood Sampling

The blood sampling program for C-8 has been expanded. The program is voluntary.

- Production, Maintenance and Technical personnel, including supervision assigned to the Fluoropolymers Divisions, will be sampled annually during normal physicals.
- New permanent Production wage roll employees in the Fluoropolymers Divisions will be sampled as soon as practical upon entering the job and during the first quarter, second quarter, and at 12 months, then annually during physicals.
- Women who have left TEFLON® or who were sampled in April and May, 1981, will be resampled in four months and annually during physicals.
- Other selected individuals who have left TEFLON®, including some former employees, will be sampled annually.

C-8 blood results will be provided to individuals as results are available.

Thus far, we have seen no obvious trend of C-8 levels in blood with time. A better comparison will be possible with the above sampling program.

EID079495

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AJP002665

JULY 31, 1981

Toxicity Studies

Additional embryotoxic testing, including inhalation studies, is being conducted at Haskell Laboratories (the 3M Company data was based only on ingestion of C-8 by the test animals).

C-8 Replacement

An aggressive program is underway by Research and Technical to develop and test replacement materials for C-8. This includes toxicity studies at Haskell Laboratories.

Air Monitoring

The air monitoring program in Fluoropolymers is being expanded. Both personal and area samples will be collected at increased frequencies. The personal samples will determine the exposure level of various job tours, while the area samples will determine average C-8 concentrations in various locations.

The specific GC test for C-8 in air, developed at the Experimental Station, has been set up in the TEFLON® Lab. This will provide more accurate and timely results.

RJB/sbr
0211R

EID079496

000096

AJP002666

April 6, 1981

PERSONAL & CONFIDENTIAL

TO: W. A. BOWER

FROM: Y. L. POWER, M.D.

The following is what I basically discussed with each female employee working in TEFLON® who expressed a desire to undergo a tubal ligation:

1. I strongly advised them that to undergo a tubal ligation just to maintain a position in a particular area of the Plant is not medically justifiable.
2. I saw the women who were considering tubal ligation very shortly after they were notified concerning C-8 and believe that they were reacting emotionally without thinking carefully about the consequences of this procedure. I urged them not to make any rash decisions and to consider very carefully what they were considering.
3. If they insisted upon tubal ligation, we couldn't prevent them from having it done.
4. Several of the women stated that they were considering having this procedure done anyway - most stated that they had no desire to have additional children.
5. I did not discuss or mention disability benefits.

YLP:mah

EID079497

000097

AJP002667

UNIT 10

CC: H. G. Smyth - ERD, N-13514
B. W. Culpepper, M.D.
J. C. Bonnett, M.D.

PERSONAL & CONFIDENTIAL

AR 226 - 1375

TO: C. DE MARTINO

FROM: BRUCE W. KARRH, M.D. *BWK*

March 25, 1981

AMMONIUM PERFLUOROCTANOATE (FC-143)
C-8 COMPOUNDS

The fluorinated surfactant C-8 compound, which is used in Teflon® manufacture at Parkersburg and in other applications at Chambers Works, has been found to cause scarring of the eyes of rat fetuses following maternal exposures during pregnancy. The study was done by 3-M, the supplier of the material, and was reported by 3-M to EPA under Section 8e of TSCA on Monday, March 23. 3-M does not plan to inform its employees until the second week of April.

Effects were found in the fetuses of mothers exposed at feeding concentrations ranging from 25-150 mg/Kg body weight. A no-effect level has not been determined. Somewhat similar fluorinated alcohol compounds were found by 3-M to have similar teratogenic effects in studies reported to EPA in November 1980. The current study was done for a different reason and the teratogenic effect was an incidental finding. There is reason to question the validity of the study and Dr. R. E. Staples, Teratologist at Haskell Laboratory, is to meet with 3-M this week and review the study and its results. However, the study is probably valid.

At present, about 50 women employees have potential for exposure to C-8 compounds at Parkersburg and an undetermined number at Dordrecht, Chambers Works, and Japan. Of the 50 female employees at Parkersburg, three are pregnant now and 2 probably pregnant. The reproductive capability of the others is unknown at present. One employee who worked in the area had a miscarriage followed immediately by a normal pregnancy with a recent normal outcome. Her potential C-8 exposure throughout both pregnancies was described as "heavy." There was one recent abnormal pregnancy outcome with one female employee at the Plant, but she did not work where there was any possibility of exposure to C-8.

Of the employees presently pregnant, one is in her 7th month, one in her 5th month, one in her 3rd month, and 2 probably just pregnant. One complicating factor is that C-8 is retained in the body for a very long time after exposure ceases.

The plan at present is to convene a meeting after Dr. Staples reviews 3-M's work, probably by March 27. PPD, C&P, Haskell Laboratory, EEO Section, Labor Law Division, Medical Division, Textile Fibers, F&F, and General Legal will participate. If the 3-M study is valid, women of child-bearing potential will probably be excluded from jobs where there is potential for exposure to C-8 compounds, at least until a no-effect level is determined. Present plans are to communicate to employees no later than April 3 and an appropriate package is being prepared now. Haskell Laboratory will determine what additional testing needs to be done.

Please let me know if you need additional information.

BWK:ceb

EID096503

000098

DWNU00146

D

AMERICAN UNIVERSITY

Medicine
Health Physics
Industrial Hygiene
Toxicology
Medical Department/3M

AR 226 - 1376
Reserved and Confidential

3M Center
St. Paul, Minnesota 55101
612/733 1110

March 27, 1981



Blaine C. McKusick, Ph.D.
Haskell Laboratory
Elkton Road
Newark, Delaware 19711

Dear Blaine:

A copy of the TSCA Section 8(e) notification regarding perfluoroalkane carboxylic acids and corresponding ammonium carboxylates is enclosed. Please contact us if you have further questions.

Sincerely,

Frank

F. D. Griffith, Ph.D.
Manager, Toxicology Services

FDG:klh

Enclosure

RECEIVED

MAR 27 1981

HASKELL LABORATORY

AIP002950

EID079613

000099

Frank A. Ubel, M. D.
Medical Director

March 20, 1981

3M

Acting Director, NIOSH
Park Lawn Building
5600 Fishers Lane
Rockville, MD 20855

Dear Sir:

Subject: Notice to EPA Regarding Section 8(e)
of the Toxic Substances Control Act

Please find enclosed for your information a copy of the subject notice submitted to EPA on this date. You will note from our letter to EPA that we regard certain parts of this notice as trade secret or confidential business information. Therefore, this information should be handled according to Section 15 of the Occupational Safety and Health Act (29 USC 664). In the event you determine that it may be necessary to disclose certain of this information to the general public, we request that you contact 3M prior to such disclosure.

Very truly yours,



Frank A. Ubel, M.D.

ss

Enclosure

General Counsel/3M
720 ZL 3M Center
Saint Paul, Minnesota 55101
612/733 5181

AJP002951

EID079614

000100

3M Center
 St. Paul, Minnesota 55144
 612/733 1110

March 20, 1981



Document Control Officer
 Chemical Information Division
 Office of Toxic Substances (WH-557)
 Environmental Protection Agency
 401 M Street, S.W.
 Washington, D.C. 20460

Gentlemen:

Subject: Section 8(e) Toxic Substances Control Act (TSCA)
 Perfluoroalkane Carboxylic Acids and Corresponding
 Ammonium Carboxylates

Please find attached 3M Report entitled "Oral Rangefinder Study of T-2998CoC in Pregnant Rats", dated March 12, 1981. Preliminary information from this study has indicated that oral dosing of the subject ammonium carboxylate mixture produces the described teratogenic effects. This Report and the findings described in the article published in the August 1980 American Industrial Hygiene Journal and referenced as part of BEHQ-1180-07760, request us to submit this information pursuant to Section 8(e) of TSCA and EPA's statement of interpretation published in the FEDERAL REGISTER, March 16, 1978.

Perfluoroalkane ammonium carboxylates is a generic chemical name for a mixture of homologs, which can be expressed by the general formula $C_nF_{2n+1}COO NH_4$. Each of these homologs was reported on the TSCA Inventory.

As previously stated in our November 19 submission, our employee records and epidemiology data indicate that to date no human health problems have been observed nor disease patterns detected which are attributable or related to fluorochemical exposure. This mixture of homologous ammonium carboxylates and the corresponding homologous carboxylic acids are currently commercially available and used as follows:

3M Brand Fluorochemical Acid FC-26 Emulsifier additive in chemical specialty products
 (international market only)

AP002952

EID079615

000101

FLUORAD® Brand Fluorochemical
Surfactant FC-126
(ammonium carboxylates)

Additive used in chemical specialty
products

FLUORAD® Brand Fluorochemical
Surfactant FC-143
(ammonium carboxylates)

Emulsifier used in chemical
processing and as an additive in
chemical specialty products

At our Chemolite production facility, located at Highway 61 and Washington County Road 19, St. Paul, MN 55133, the subject chemicals are manufactured from of locally-produced perfluoroalkane carboxylic acids and of the same acid imported from our European plant in Antwerp, Belgium. Chemical reaction occurs in a closed system. Approximately 36 employees are intermittently exposed to the subject chemicals during production at the Chemolite facility. Approximately of perfluoroalkane carboxylates are exported annually.

We plan to inform, by April 1, those customers and 3M employees who have, through uses and/or processing, potential significant exposure to the subject chemicals. At that time, we will summarize these findings and outline our recommendations for handling and using these products. We are by copy of this letter advising NIOSH of these new preliminary teratogenic findings. As additional information becomes available to us, we plan to advise these customers and employees accordingly.

In view of the attached preliminary findings and in line with our ongoing testing and monitoring program on fluorochemicals, the following program is planned for the ammonium carboxylate mixture:

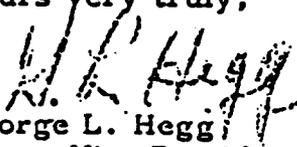
- (1) A teratogenicity study in rats.
- (2) A subsequent teratogenicity study in rabbits.
- (3) Continual industrial hygiene program to improve and refine manufacturing and packaging processes which have been developed to further reduce the exposure to plant employees.

Since certain of the information provided herein is considered confidential business information, we are providing a sanitized version of this report for the public file. In addition, we have deleted from the confidential submission inconsequential information such as the names of 3M employees for the purpose of protecting their privacy.

Should additional correspondence be necessary on this matter, please contact:

Larry Magill
Manager, Regulatory Affairs Department
Commercial Chemicals Division
3M
3M Center, 223-6S-04
Saint Paul, MN 55144
Telephone: 612/733-7062

Yours very truly,


George L. Hegg
Group Vice President
Chemicals, Film & Allied Products

GLH:sue

Attachments

cc: Acting Director, NIOSH
Park Lawn Building
5600 Fishers Lane
Rockville, MD 20855

bc: R. J. Davis/T. J. Scheuerman - 220-12E
W. G. Ewert - 220-12W
F. D. Griffith/W. C. McCormick - 220-2E
C. W. Hanson - 223-6
G. L. Hegg - 220-13C
L. C. Krogh - 223-6
J. D. LaZerte/R. A. Prokop - 236-1
L. F. Ludford - 225-5N
W. H. Pearlson - 223-6
D. R. Ricker - 53-4
P. F. Riehle - Chemolite
W. F. Scown - 223-6
S. D. Sorenson - 220-2
F. A. Ubel/D. E. Roach

ALP002954

EID079617

000103

Report Number: M-601

Date: March 12, 1980

Oral Rangefinder Study of T-2998CoC in Pregnant Rats

Experiment No.:

0680RR0018

Conducted At:

St. Paul, Minnesota

Dosing Period:

January 20, 1980 to January 29, 1980

Study Director:

2/24/81
Date

2/24/81
Date

2/25/81
Date

AJP002955

EID079618

000104

Introduction

This oral rangefinder study^a was conducted to determine the upper dose level of T-2998CoC^b for a subsequent oral teratology study in rats. The study was sponsored by 3M Commercial Chemical Division, St. Paul, Minnesota and was conducted by the Safety Evaluation Laboratory, St. Paul, Minnesota. The study was conducted in accordance with the Safety Evaluation Laboratory's Standard Operating Procedures for such studies. The storage location for the raw data and a copy of the final report is maintained in the Safety Evaluation Laboratory's record archives.

Methods

Thirty-six time-mated Sprague-Dawley derived female rats from Charles River Breeding Laboratory were used in the study. The animals were indiscriminately removed from the shipping boxes by Animal Care personnel and placed in the rack of cages from the left to right starting at the top and working down. Later the Study Director assigned dose groups by vertical rows. The rats were housed individually in hanging stainless steel cages with wire mesh floors and fronts in a temperature and humidity controlled room. Purina Laboratory Chow and water were available ad libitum. The lights were on a 12 hour light/dark cycle.

The animals were observed daily from day 3 through day 20 of gestation for abnormal clinical signs. Body weights were recorded on days 3, 6, 9, 12, 15 and 20 of gestation and the rats dosed accordingly using a constant dose volume of 5 ml/kg of body weight. T-2998CoC was suspended in corn oil and administered daily by oral intubation at doses of 150, 100, 75, 50 or 25 mg/kg/day to groups of 6 rats on days 6 through 15 of gestation. A control group of 6 rats received only corn oil by oral intubation on the same days. On day 20 of gestation the rats were killed by cervical dislocation and each uterus, including its contents, was examined immediately to determine if the animal was pregnant. Because two previous teratology studies (Experiment Nos: 0680TR0008 and 0680TR0010) with chemically related compounds resulted in fetuses with teratogenic changes in the lens of the eye, a few fetuses were also taken at day 20 of gestation and examined for eye abnormalities.

Blood samples from three rats in each dose group were taken before the first dose and at day 20 of gestation. Liver specimens were also taken from the same rats on day 20 of gestation. The plasma samples and liver specimens were frozen and submitted to the sponsor.

Results and Discussion

The oral administration of T-2998CoC at 150, 100, 75, 50 or 25 mg/kg/day to rats during the period of organogenesis (days 6 through 15 of gestation) did not result in any deaths. A toxic effect of reduced body weight gain occurred between days 6 and 9 of gestation in the 150 mg/kg/day dose group (Table 1).

The two nonpregnant 150 mg/kg/day rats had a more severe effect on body

^a
^b Experiment No. 0680RR0018
FC-143

AIP002956

weight on day 9 of the study than the pregnant high dose dams (Appendix I). They lost a considerable amount of weight and one was observed to have urinary incontinence on days 11, 12 and 13. The pregnant dams of the 100, 75, 50 and 25 mg/kg/day dose groups did not have abnormal clinical signs and gained weight at comparable levels to the 0 mg/kg/day group.

Four fetuses were examined from each of four dams in the 150 and 25 mg/kg/day dose groups for eye changes. All of the readable fetuses sectioned had eye changes consisting of one or more of the following: large lens clefts, dark streak running one-half to three-quarters of the way through the lens or disorganized lens fibers (Table 2). The lens abnormalities occurred in the same location as those observed in the two previous teratology studies (Experiment Nos: 0680TR0008 and 0680TR0010) on chemically related compounds. The abnormalities in this study appeared more pronounced than in the previous studies. In the previous studies, the teratogenic effect was a developmental eye abnormality which appeared to be an arrest in development of the primary lens fibers forming the embryonal lens nucleus, followed by secondary aberrations of the secondary lens fiber of the fetal nucleus. The same general morphological changes occurred in this rangefinder study with T-2998CoC.

Conclusion

The objective of determining an upper dose level for an oral rat teratology study was met in this study. The above results suggest that the 150 mg/kg/day dose level would be an appropriate high dose in a rat teratology study because of the toxic effect of reduced body weight gain. In addition to the toxic effect of reduced body weight gain, the teratogenic effect of lens abnormality was observed and is likely to be reproduced in a teratology study.

EID079620

000106

AJP002957

Table 1
 Oral Rangefinder Study of T-2998CoC in Pregnant Rats
 Mean Body Weight Gains of Pregnant Rats
 With Standard Deviations (g)

	Day				
	6	9	12	15	20
Control	20 4.2	18 7.4	21 7.5	29 1.6	76 10.7
150 mg/kg/day	21 5.5	5 17.8	30 ^a 8.8	12 13.8	84 12.1
100 mg/kg/day	29 4.1	15 5.1	17 4.4	19 12.6	84 13.5
75 mg/kg/day	27 6.6	11 10.6	21 2.7	19 10.5	74 12.6
50 mg/kg/day	10 6.5	16 3.7	23 5.6	27 7.3	75 10.6
25 mg/kg/day	24 2.6	16 6.6	24 6.9	29 9.3	82 5.8

^a Significantly higher than the control (Dunnett's t test $p < 0.05$)

AJP002958

EID079621

000107

Table 2

Oral Rangefinder Study of T-2998CoC in Pregnant Rats
Ratios of Fetuses with Eye Changes to Fetuses Examined^a

<u>High Dose Group</u> (150 mg/kg/day)	<u>Low Dose Group</u> (25 mg/kg/day)
16/16	15/15 ^b

^b Four fetuses examined from each of four dams
One fetus not examined because eye architecture destroyed in sectioning

AJP002959

EID079622

000108

Appendix I

Oral Rangefinder Study of T-2998CoC in Pregnant Rats

Individual Body Weights (g) and Mean Body Weights with Standard Deviation for Pregnant Rats

	Day						
	3	6	9	12	15	20	
0 MG/KG/DAY							
N1R	318	194	223	244	269	297	382
N1R	317	188	214	238	262	292	376
N1R	318	192	217	227	253	282	365
N1R	319	207	239	250	258	285	360
N1R	346	195	231	257	280	311	369
MEAN	318	195	225	243	264	292	369
STAN. DEV.	7.7	10.3	11.5	10.5	11.5	11.5	8.2
NON PREGNANT ANIMALS							
N1R	326	184	211	224	215	222	222

	Day						
	3	6	9	12	15	20	
150 MG/KG/DAY							
O1R	321	262	222	216	257	287	367
O1R	324	192	218	217	257	261	344
O1R	325	177	191	222	244	242	314
O1R	347	266	232	226	262	278	378
MEAN	328	195	216	220	255	267	351
STAN. DEV.	12.9	17.5	4.6	7.7	19.4	28.2	
NON PREGNANT ANIMALS							
O1R	322	207	228	198	200	219	246
O1R	323	181	200	181	196	215	231

EID079623

AJP002960

000109

Appendix I (Continued)

Oral Rangefinder Study of T-2998CoC in Pregnant Rats
 Individual Body Weights (g) and Mean Body Weights
 with Standard Deviation for Pregnant Rats

	Day						
	3	6	9	12	15	20	
1000 MG/KG/DAY							
P1R	326	464	193	210	229	253	327
P1R	327	214	240	248	268	265	331
P1R	328	262	286	302	317	349	452
P1R	329	200	235	245	256	268	353
P1R	330	185	218	234	248	268	363
P1R	348	189	218	240	263	296	371
MEAN	302	232	247	264	282	306	366
STAN. DEV	33.6	31.3	20.4	29.6	34.9	45.5	

	Day						
	3	6	9	12	15	20	
75 MG/KG/DAY							
Q1R	331	192	221	243	265	268	346
Q1R	332	198	212	228	249	271	346
Q1R	333	172	203	215	235	263	346
Q1R	334	211	242	236	261	270	326
Q1R	335	193	216	225	244	268	331
Q1R	349	206	231	248	265	293	282
MEAN	194	221	233	253	272	346	
STAN. DEV	12.9	14.1	13.2	12.4	10.6	20.0	

AIP002961

EID079624

000110

Appendix I (Concluded)

Oral Rangefinder Study of T-2998CoC in Pregnant Rats

Individual Body Weights (g) and Mean Body Weights
with Standard Deviation for Pregnant Rats

	Day						
	3	6	9	12	15	20	
50 MG/KG/DAY							
R1R	336	193	219	236	253	276	300
R1R	337	177	201	213	235	259	308
R1R	338	226	251	262	283	314	397
R1R	339	170	198	218	237	254	308
R1R	340	187	226	245	267	304	378
R1R	350	192	229	242	276	308	382
MEAN	191	221	236	259	286	359	
STAN. DEV	19.4	19.6	18.2	20.1	26.2	33.8	

	Day						
	3	6	9	12	15	20	
25 MG/KG/DAY							
S1R	342	216	239	266	283	304	388
S1R	343	207	234	249	279	304	383
S1R	344	185	208	227	253	292	369
S1R	345	200	219	233	249	270	348
S1R	351	205	233	238	268	307	398
MEAN	203	227	243	266	290	377	
STAN. DEV	11.4	12.8	15.4	15.2	15.3	19.4	

NON PREGNANT ANIMALS

S1R 341 187 203 219 220 228 238

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AJP002963

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E

WILLIAM W. WILSON

AR 226 - 1377



E. I. DU PONT DE NEMOURS & COMPANY
INCORPORATED

WILMINGTON, DELAWARE 19898

POLYMER PRODUCTS DEPARTMENT

J. T. SMITH
N. J. IRSCH
H. E. SERENBETZ
M. A. SMOOK
R. D. INGALLS
E. D. CHAMPNEY
A. L. DADE - F&F
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B. W. KARRH - ER
B. C. MC KUSICK - CR&D, HASKELL
R. L. RHODES - TF
J. H. TODD - WASH. WORKS

April 1, 1981

TO: R. L. RICHARDS

FROM: J. W. RAINES *JWR*

AMMONIUM PERFLUOROOCCTANOATE (C-8)
RANGEFINDER STUDY

Dr. R. E. Staples, Teratologist, and Taisan Chiu, Pathologist, from Haskell Lab visited 3M on March 27 to review results of the Oral Rangefinder Study of perfluorooctanoate (C-8) in pregnant rats. They concluded that the study was valid and that the observed fetus eye changes were due to the C-8. Since the sole purpose of this test was to determine the upper dose level for a subsequent oral teratology study in rats, 3M did not examine the eyes of fetuses from unexposed (control) rats.

3M plans to start the new oral teratology study with rats on April 6 to determine a no-effect level. The top dose level will be 150 mg/kg/day, the same as the top dose level in the Rangefinder Study. Other dose levels will be 15, 5, 0.05 and 0 mg/kg/day.

3M are still planning to communicate to their employees the second week of April.

There has been some confusion of the concentration of C-8 in the blood of rats. Twenty-five ppm was quoted from memory as being the C-8 blood level for the female rats fed 25 mg/kg/day in the Rangefinder Study. This was in error. 3M told Dr. Staples during his visit that blood levels were in the range of 1-3 ppm for the low and high dosing levels, respectively.

It had been previously established with both 3M and Du Pont tests that the half life for decay of C-8 in male rat blood was 7-9 days (after exposure). Earlier 3M work with female (not pregnant) rats, suggested that the decay rate was much higher. In fact, in an intravenous injection test with radioactive C-8, all the C-8 material was accounted for in the female rat urine in a matter of

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minutes. In a 90-day feeding test with 300 ppm C-8 in their diet (equivalent to dosing about 30 mg/kg/day), male rats had 38 ppm C-8 in their blood and female (not pregnant) rats had only 0.25 ppm.

The great difference between male and female rats in their reaction to dosing with C-8 is a very strange phenomenon. This is being considered by Haskell in designing newly planned studies.

JWR:ldr

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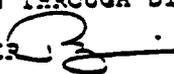
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- 21-P -

CC: J. H. Todd
G. T. Rosenlund
W. A. Bower
D. D. Dalton
O. L. Darby
W. T. Darnell
H. D. Ramsey, Jr.
A. R. Stoltenberg
R. N. Taylor
E. P. Waltzer

March 31, 1981

TO: SUPERVISION THROUGH DIVISION SUPERINTENDENTS
FROM: R. J. BURGER 

C-8 COMMUNICATION

Attached information will be communicated on the following schedule.

- All Division Superintendents 9:00 a.m.,
Tuesday,
3/31/81
- All Fluoropolymer Supervision 4:00 p.m.,
Through Foremen -- Completed By: Tuesday,
3/31/81
- All Other Supervision Through 1:00 p.m.,
Supervisors -- Start At: Tuesday,
3/31/81
- All Supervision Through Foremen 9:00 a.m.,
Wednesday,
4/1/81
- All Fluoropolymers Employees 12:00 Noon,
Wednesday,
4/1/81
- All Other Employees 2:00 p.m.,
Wednesday,
4/1/81

RJB/djp

Attachment

* DuPont's registered trademark for its fluorocarbon resin

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- 21-Q -

EMPLOYEE COMMUNICATION

We have been informed by the 3M Company about the preliminary results of a new animal study involving the fluorosurfactant, C-8, which is an essential material that has been used in excess of twenty years in fluoropolymer resins manufacture at Washington Works. 3M is our principal supplier for this chemical.

We were advised on March 20, 1981, that C-8, also known as FC-143 or ammonium perfluorooctanoate, caused birth defects in the unborn when fed by stomach tube to female rats in a laboratory experiment. This was a preliminary study designed to determine dosage limits prior to a full-scale study on C-8's potential to cause birth defects in rats.

At this time, we do not know the significance, if any, of the preliminary animal experiment as it may relate to employee exposure. Further studies are planned to define possible reproductive effects.

As a precaution based on the new study we have decided, that until further information is obtained, all female employees will be removed from areas where there is potential for exposure to C-8 and loaned immediately to other divisions. These female employees will consult with our Plant Medical Division, and those of non-childbearing capability will be given the option to return to the Fluoropolymers area. Women of childbearing capability will be allowed to bid for other plant jobs after a permanent plant posting has been made. Present pay rates will be maintained and vacation selections previously made will be honored for those females reassigned.

During the period that C-8 has been used at Washington Works, there has been no known evidence that our employees have been exposed to C-8 levels that pose adverse health effects. A preliminary acceptable exposure limit of 0.01 mg/m³ (0.56 parts per billion) was established which we believe has adequately protected our employees. At exposure levels experienced by our employees, there is no evidence to suggest there is any impairment of the male reproductive function.

3M first notified us in 1978 that exposure to C-8 could result in elevated organic fluoride levels in the blood of its employees and that these elevated levels could persist for extended periods of time. At that time, we notified employees, embarked on an extensive program to reduce exposure levels, and began blood monitoring analyses. Employees have been kept advised on new developments and of blood test results.

We ask your cooperation with job reassignments and participation in a program for additional blood sampling.

We will inform you promptly as new information is obtained.

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03-Apr-1987

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- 21-R -

QUESTIONS AND ANSWERS

- To Be Used As Needed To Answer Questions -

If there are any questions not answered below, they should be referred to Plant Management.

1. Q: How many female employees at your Parkersburg plant may have been exposed to C-8?
A: About sixty worked in areas where there is potential for exposure.
2. Q: Have you sampled the blood of these employees to determine if they have elevated organic fluoride levels?
A: Some but not all female employees have been sampled as part of our existing programs.
3. Q: Do they have levels of C-8 above normal?
A: Yes, some do.
4. Q: Are any of the sixty female employees pregnant?
A: Yes, two that we know of.
5. Q: Are there any former employees you know of who may have been exposed to C-8 and who are now pregnant?
A: Yes, one that we know of.
6. Q: What have you advised these pregnant women to do?
A: We have advised these employees to consult the plant physician for an explanation of the potential risks and will have them consult also with their personal physician. The exact significance of the animal test results to the human offspring is yet unknown. However, we believe it prudent to eliminate any further exposure that results in blood levels greater than background until additional data are obtained.
7. Q: Have you attempted to locate former female employees to advise them of the 3M Company's animal study which indicated that C-8 may be teratogenic?
A: We are in the process of reviewing our employment records and where appropriate, former employees will be notified.
8. Q: Do you have any knowledge of Du Pont employees or former employees who have been exposed to C-8 whose children suffered birth defects?
A: No. There is no evidence of birth defects among children born of mothers who have been exposed to C-8 compounds at Du Pont.

* DuPont's registered trademark for its fluorocarbon resin

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9. Q: Do you have any knowledge of 3M Company employees or former employees who have been exposed to C-8 whose children suffered birth defects?

A: No. We are not knowledgeable of the pregnancy outcome of any 3M employees or former employees who were exposed to C-8.

10. Q: What is the possibility that employees or former employees of childbearing age with elevated organic fluoride levels may give birth to children with defects.

A: We do not know, but we are taking appropriate steps to avoid further exposure.

11. Q: Is there any indication that male employees or former male employees exposed to C-8 may have suffered loss of reproductive function?

A: We have no indication that C-8 has an effect on the male reproductive system or its function. The reproductive organs of the male laboratory animals exposed to C-8 were closely examined and were normal, with no evidence of abnormalities attributable to C-8 exposure.

12. Q: Are there any tests that can assure the fetus is all right?

A: There are no tests which can assure that the fetus is all right. There are tests which can detect fetal abnormalities in some cases. If these tests are done and are normal, there is a good likelihood that the fetus is all right.

13. Q: What advice do we have for women of childbearing capability who have been exposed, about becoming pregnant?

A: This is a personal subject between the woman and her physician.

14. Q: Will elevated organic fluoride levels in the blood decrease in time?

A: Yes.

15. Q: How long does it take for these levels to fall to background levels?

A: It is not known at this time. Blood samplings is continuing.

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16. Q: Can employees and former employees with elevated organic fluoride levels donate blood safely?
- A: Blood donating is a deferrable option. Persons who have elevated blood levels of C-8 or who have worked in areas of potential exposure to C-8 and the blood level has not been determined should not donate blood until the blood level of C-8 returns to background levels.
17. Q: What is the background level?
- A: In our experience in blood tests conducted among employees with little chance for potential exposure, organic fluoride blood levels ranged up to 0.4 ppm.
18. Q: Have you resampled employees' blood recently?
- A: Yes, and we are taking additional samples in an ongoing program.
19. Q: Were the levels lower in the recent blood samples?
- A: So far there is no obvious trend with the data available.
20. Q: Is there danger to the families of employees who work in the area?
- A: By following the established practices and procedures, use of personal protective equipment and following good personal hygiene practices, there should be no hazard to the employee's family.
21. Q: What operating procedures were instituted by Du Pont after the first 3M report in 1978?
- A: Extensive engineering programs were developed which included equipment modifications and increased use of personal protective equipment. In addition, we instituted blood monitoring and air sampling programs as well as more stringent housekeeping standards.
22. Q: What additional changes in operating procedures do you plan now?
- A: This has not been determined. We are reviewing the situation.
23. Q: Are you looking for a substitute for C-8?
- A: Yes, we have been for some time.
24. Q: What are the possible substitutes?
- A: We have not identified one at present.

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25. Q: Why did the 3M Company test C-8 for teratogenicity?
A: We understand that C-8 is chemically similar to other compounds made by 3M and that in earlier testing were found to be teratogenic.
26. Q: When did Du Pont learn of the latest study results?
A: March 20, 1981.
27. Q: Has the appropriate Federal regulatory agencies been notified?
A: Yes. 3M, our supplier, has notified EPA of the study and its results.
28. Q: What were the birth defects noted by 3M in the unborn fetus?
A: Eye defects are reported but complete testing will be required.
29. Q: What additional animal testing is planned?
A: Elaborate C-8 teratology evaluations of laboratory results to confirm 3M preliminary results and to identify safe exposure level for females.
30. Q: What is Du Pont's policy on employing women around embryotoxins?
A: Women of childbearing capability are allowed to work in areas of potential exposure to teratogens where a safe exposure level is known and the exposures can be maintained below these levels. Women of childbearing capability are not allowed to work in areas where safe levels are not known or where the potential exposures are above safe levels. Women who are not of childbearing capability can work in areas of potential exposure to teratogens.
31. Q: Has Du Pont ever required or suggested that an employee be sterilized?
A: No.
32. Q: Are there any other chemicals used at your Parkersburg plant that are embryotoxic?
A: Yes, DMF (dimethyl formamide) and HFA (hexafluoroacetone).

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03-Apr-1987

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33. Q: What products are sold by Du Pont using C-8 (ammonium perfluorooctanoate)?
A: Various fluorocarbon resin and dispersion products.
34. Q: Is there any problem involved with cookware which has been coated with fluorocarbon resin?
A: No
35. Q: Will Du Pont be notifying its customers of the most recent findings reported by JM?
A: Yes.
36. Q: Have women been removed from exposure at all Du Pont locations?
A: No, not at those locations where blood levels are at background.

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* DuPont's registered trademark for its fluorocarbon resin

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03-Apr-1987

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AR 226 - 1379

CC: B. W. Culpepper, M.D.
J. J. Gooch
S. Pell

TO: CARL DE MARTINO

FROM: BRUCE W. KARRH, M.D. *BWK*

April 2, 1981

EPIDEMIOLOGY STUDY - C-8 (FC-143)

We discussed an epidemiology study for reproductive effects from potential workplace exposures to C-8. A study can be done, but several factors need to be considered.

- (1) To adequately study the reproductive effects of exposure to C-8 will require studies of fertility, reproduction, and pregnancy outcome. Adequate data can be developed only by involving the husband and wife in answering specific questions related to methods of birth control, frequency of intercourse, outcomes of pregnancies, and similar such questions. Employee relations considerations are very important.
- (2) Few such studies have been done. Du Pont has its first similar study underway now, a pregnancy outcome study among all Victoria Plant employees.
- (3) Pregnancy outcomes can be studied to answer a single question-- does C-8 exposure cause abnormal children?
- (4) 3-M is developing a protocol to study all 3 parameters among employees potentially exposed to C-8. If the group is large enough to obtain meaningful results, that study may be adequate. We will monitor closely as 3-M proceeds.

Medical Division proposes to delay starting such a study until the Victoria results are obtained in order to evaluate our ability to do such studies and at least until 3-M has finished developing its protocol so we can determine if additional work is indicated. Please give me your non-objection to this proposal.

BWK:ceb

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THE UNIVERSITY OF CHICAGO

CC: B. W. Culpepper, M.D.
W. E. Fayerweather
J. J. Gooch
S. Pell

PERSONAL & CONFIDENTIAL

AR 226 - 1380

TO: CARL DE MARTINO

FROM: BRUCE W. KARRH, M.D. *BWK*

April 6, 1981

EPIDEMIOLOGY STUDY - C-8 (FC-143)
(Ref.: Letter B. W. Karrh-Carl De Martino 4/2)

The subject letter requested non-objection to Medical Division delaying a study of pregnancy outcome among C-8 exposed male and female employees. Since then, however, recently obtained information indicates there may be a need to do such a study.

Medical Division epidemiologists are evaluating how such a study can be accomplished and are communicating with Parkersburg Plant personnel to determine the number of people who may be in the group to be studied.

We will keep you informed of our progress.

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AR 226-1381 * Put together package on Confidentiality Protection *

: Study 3 teratogens instead of 1 [C-8, DMF, HFA] ? F22?

STUDY OF PREGNANCY OUTCOME IN WASHINGTON WORKS EMPLOYEES:

RESEARCH PROPOSAL

- Company Wide

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Why not define ^{exposure by} Blood Levels

1. Don't know blood levels during pregnancy
2. Don't know what signif. of OF level is in relation to pregnancy.

As blood data become available, we will include in analyses.

William E. Fayerweather
Employee Relations Department
Medical Division
Epidemiology Section
April 13, 1981

Why not add Circleville?
Asci " is lower exposure therefore might dilute effect

- Waste disposal question: potential C-8 exposure
- M.D. meets with wives; handle study
- Keep I.O. information separate from questions on pregnancy outcome

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I. Objectives

The study's objectives are to determine whether

- a. Pregnancy outcome among female Washington Works employees is causally related to their occupational exposure to C-8.
- b. Pregnancy outcome among wives of Washington Works employees is causally related to their husbands' exposure to C-8.

II. Background and Rationale

There have been five toxicologic experiments in which C-8 was administered repeatedly to experimental animals and in which the male reproductive system was examined. In none of the studies were treatment-related testicular changes observed.

Recently 3M conducted an oral rangefinder study of C-8. The purpose of this study was to determine the upper dose level of C-8 for a subsequent oral teratology study in rats. Suspensions of C-8 and corn oil were given by oral intubation to 5 groups of time-mated female rats (Charles River Sprague-Dawley derived). The doses received were 150, 100, 75, 50, or 25 mg/kg/day of C-8. These doses were given on days 6 through 15 of gestation (i.e., the period of organogenesis). There was one control group that received only corn oil by intubation on these same days. Each dosed and control group consisted of 6 time-mated female rats.

At day 20 of gestation the rats from the 3M study were sacrificed. Four fetuses were examined from each of four dams in the 150 and 25 mg/kg/day dose groups. All of the readable fetuses

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sectioned had eye lens abnormalities. The authors noted that two previous teratology studies with chemically related compounds resulted in fetuses with similar abnormal changes in the lens of the eye.

At Washington Works significant occupational exposure to C-8 is limited to the Teflon area. C-8 is a dispersing agent that is used in nearly all Teflon polymer and copolymer processes. The monomers do not contain C-8. Based on previous analyses of blood organic fluoride levels of workers, the greatest potential for C-8 exposure occurs in four jobs: TFE process operator, FEP process operator, TFE service operator, and FEP service operator.

In the proposed study of pregnancy outcome, exposed female employees and wives of exposed male employees will be studied. Female workers are studied because they may have been exposed to C-8 during or immediately prior to their pregnancies. Wives of male workers are studied because the husbands may somehow bring C-8 home with them and expose their wives at home. There is no evidence at present to suggest that C-8 exposure affects the husband's reproductive system.

III. Specific Aims

Histories of pregnancy outcome and of potential exposure to C-8 will be ascertained for

- a. Washington Works active female employees, and
- b. Wives of Washington Works active male employees.

Potential exposure to C-8 will be determined from personal records, medical records, and employee interviews. Pregnancy outcome will be determined via self-administered questionnaires given to female employees and wives of male employees.

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If an association is observed between pregnancy outcome and having had potential exposure to C-8, the association will be assessed as to whether it is causal or whether it is due to other confounding factors.

IV. Methods

A. Study Groups

1. Workers with potential C-8 exposure

a. Definition of exposure: Teflon area

All Teflon area jobs will be defined as having potential exposure to C-8. These jobs will be further categorized as having either high or low potential for exposure.

Table I shows the exposure categorization scheme used in the previous liver function study of C-8 workers. Notice that several job titles appear in both the high and low exposure potential columns. This happens because exposure potentials for most Teflon area jobs depend on the particular time period and task considered. Within the high potential category, current TFE/FEP service and process operators have the highest potential for exposure based on blood organic fluoride levels.

Some mechanics, non-semiworks laboratorians, and chemists/engineers occasionally come in contact with C-8. However, the natures of their jobs and of the personnel record keeping system make it very difficult to determine these workers' exposure to

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C-8 or to other chemicals. For this reason, mechanics, non-semiworks laboratorians, and chemists/engineers will be defined as having unknown exposure potential.

b. Selection of exposed workers

All active male and female workers who have ever worked in a C-8 exposure job (as defined above) will be identified. Brief questionnaires will be given to these workers to determine who has ever been married. All ever married workers will be included and all never married will be excluded from the study.

2. Workers with no potential C-8 exposure

a. Definition of non-exposure

All non-Teflon area jobs, with the exception of the jobs with unknown exposure potential (e.g., mechanic), will be defined as having no potential for C-8 exposure.

b. Selection of non-exposed workers (controls)

All of the plant's non-exposed active female workers will be selected as controls for the exposed female workers.

For each C-8 exposed active male employee, one matched non-exposed male employee will be chosen as a control. Matching will be on payclass, birth date (+ 3 years), and adjusted service date (+ 3 years). The control for each exposed worker will

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be the first eligible employee appearing in the yearly employee roster after the exposed worker's name.

Each male and female control will be given a questionnaire to determine whether he/she has ever been married. All never married controls will be dropped from the study. For the male subjects, new controls will be chosen to replace those controls who either were never married or who refused to participate in the study.

B. Sources of Data

1. Exposure histories

Plant personnel will be responsible for:

- determining which active employees have ever had potential exposure to C-8.
- collecting detailed exposure histories on the study subjects.

These histories will be assembled from personnel records, medical records, and employee interviews. The work histories should contain:

- name
- color (white/non-white)
- birth date
- payclass
- date hired
- all jobs having C-8 exposure potential
- month and year the worker moved in and out of C-8 jobs

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- each job's exposure potential (high or low)
- blood organic fluoride level and date taken

Exposure histories will be recorded on code sheets that will be designed and supplied by Medical Division.

2. Pregnancy outcome data

All female study subjects will be asked to complete a self-administered questionnaire on pregnancy outcome.

All male subjects will be given an initial questionnaire to determine whether they have ever been married and whether they are now living with their wives. Males who have been married but who no longer live with their wives (e.g., because of divorce, separation, or death) will be asked to complete the pregnancy outcome questionnaire themselves. Males who are now living with their wives will be asked to give the questionnaire to their wives to complete. Never married workers will be dropped from the study.

C. Major Response Variables

The major measures of pregnancy outcome, which are to be ascertained via a self-administered questionnaire, include:

1. # Pregnancies
2. # Spontaneous abortions/miscarriages
3. # Stillbirths
4. # Induced abortions (for medical or personal reasons)
5. # Live-born children
6. # Live-born children with birth defects or other problems at birth

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7. Types of birth defects or problems observed at birth

8. Birth weights

D. Potentially Confounding Variables

Information on a number of potentially confounding factors will be ascertained via the pregnancy outcome questionnaire. These include:

1. Maternal age
2. Paternal age
3. Infectious diseases (e.g., rubella)
4. Family history of malformations/miscarriages/stillbirths
5. Medications/drugs
6. Ionizing radiation
7. Smoking
8. Chemical exposures outside the plant (e.g., other occupations)
9. Alcohol
10. Number of previous marriages
11. Birth control/desire for more children
12. Color/ethnicity (to be determined by plant personnel).

E. Quality Control

If the final product of this study is to fair well against peer review from outside of the Company, steps must be taken to assure, measure, and document the quality of the data collected.

1. Validation of pregnancy outcome supplied by female workers

The responses on 100% of the female workers' questionnaires should be validated. A worker's responses could be validated by checking existing Du Pont medical records and by contacting the worker's personal physician. This

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last step would only be done after having obtained the worker's informed consent to do so.

2. Validation of pregnancy outcome supplied by husbands

The responses on 10% of the questionnaires given to workers' wives should also be compared with the responses given independently by their working husbands. This comparison will help document the quality of the responses given by husbands.

3. Validation of work histories supplied by the plant

After work histories for exposed and nonexposed subjects have been sent to Medical Division, data from a 10% sample of these subjects will be audited. For this audit the plant will be asked to supply the records from which these work histories have been assembled.

F. Pilot Study

Prior to giving questionnaires to all study subjects, a pilot study should be done. This pilot study should include about 5 male and 5 female workers who have had no potential C-8 exposure. It will allow us to pre-test the pregnancy outcome questionnaire and other study procedures.

V. Sample Size

A. Female Employees

Currently there are 32 exempt, 130 non-exempt, and 159 wage roll females actively employed at the plant. As of April 1, about 50 of these women worked in the Teflon

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area. Only about one dozen of these women were in jobs having a high potential for C-8 exposure.

From 1965 through 1980 there were 103 leaves of absence due to pregnancy (table II). Thirteen of these leaves were among wage roll employees.

B. Male Employees

Over 300 men, or about ten percent of the plant's workforce currently work in the Teflon area. Within the Teflon area, 60 to 70 workers are in jobs that have high potential for C-8 exposure. Since each exposed male will be matched with one non-exposed male, the total number of males included in the study will be over 600. The number of active workers who no longer work in the Teflon area is unknown. The number of births to wives of male employees is also unknown.

C. Statistically Significant Excesses

The national incidence rate for craniofacial malformations is about 2 per 1000 live births, and the rate for malformations of all types is about 20 per 1000. Given these background rates, table III shows the minimum number of births with malformations that must be observed in the study group to say that there is a statistically significant excess ($p < 0.05$). For instance, 2 malformations in 10 exposed live births is a significantly higher rate than a national rate of 2 per 1000. Two malformations per 10 exposed live births is also significantly higher than a plant rate of 0 per 50 nonexposed births.

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VI. Analyses

1. Data on C-8 exposed female workers will be analyzed separately from data on wives of exposed male workers.
2. C-8 exposed female workers and wives of exposed male workers will be compared with four control groups:
 - Female W.W. workers never exposed to C-8
 - Wives of male workers at W.W. never exposed to C-8
 - Non-W.W. female employees at another Du Pont plant
 - Wives of non-W.W. employees at another Du Pont plant.
3. All of the measures of pregnancy outcome mentioned in the earlier section on major response variables will be analyzed.
4. The analyses will be adjusted for the effects of the potentially confounding variables mentioned earlier. Binary regression and Mantel-Haenszel methods will be used for these adjustments.
5. Analyses will take into account that only exposures occurring immediately prior to conception or during the first trimester of the pregnancy are likely to produce malformations.
6. Hypothesis testing will be two-tailed, and significance will be judged at the 0.05 probability level.

WEF000126

VII. Confidentiality and Informed Consent

Any female employees, male employees, or wives of male employees who are asked to participate in this study will be

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asked to first read, understand, and then sign an informed consent statement. This informed consent statement will clearly describe:

- The study's purpose and design.
- Potential risks and benefits to individuals who decide to participate in the study.
- How the data will be used.
- The individual's right to refuse to participate at any time in the study without prejudice to him/her.
- How the study's results will be reported back to the individual.

All completed questionnaires, data forms, and raw data will be stored under lock and key or in limited-access computer files. Only the principal investigators will have unlimited access to these data.

When the study is finished, the collected data will be stored in Du Pont's Hall of Records.

All results will be published in aggregate or group forms only. Individual workers will not be identified.

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WIEF000127

TABLE I: EXPOSURE CATEGORIZATION SCHEME USED IN LIVER FUNCTION STUDY OF C-8 WORKERS AT WASHINGTON WORKS

<u>HIGH EXPOSURE POTENTIAL</u>		<u>LOW EXPOSURE POTENTIAL</u>	
<u>NO.</u>		<u>NO.</u>	
4-1	TFE Service Operator	4-2	TFE Service Operator
6-3	TFE Process Operator	6-4	TFE Process Operator
4-5	FEP Service Operator	4-6	FEP Service Operator
6-7	FEP Process Operator	6-8	FEP Process Operator
6-9	Semiworks Laboratorian	6-10	Semiworks Laboratorian
8-11	Mechanic (good possible)	6-12	TEFZEL-TELOMER A Operator
8-13	Mechanic (possible)	7-14	MONOMER Operator
6-15	Laboratorian (Tech Assistant)	8-16	Mechanic (unlikely)
WS-17	Engineer or Chemist	WS-18	TFE Production Foreman
		6-20	Laboratorian
		WS-20	Chemist or engineer

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TABLE II: NUMBER OF PREGNANCIES BY YEAR (OF LEAVE OF ABSENCE) AND BY PAYCLASS:
 WASHINGTON WORKS FEMALE EMPLOYEES 1965 - 1980

WIEF000129

	Year of leave of absence																
	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	65 - 80
WAGE	0	0	0	0	0	1	0	0	0	1	1	2	1	2	3	2	13
SALARY	6	7	7	4	7	10	12	8	7	4	4	3	2	3	3	3	90
TOTAL	6	7	7	4	7	11	12	8	7	5	5	5	3	5	6	5	103

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TABLE III: MINIMUM NUMBER OF MALFORMATIONS NEEDED TO SHOW STATISTICAL SIGNIFICANCE

Type of malformation	Malformation incidence nation-wide	Minimum number of births with malformations that must be observed in the study group to be significantly higher than the national incidence, given a study group with N live births:			
		N=5	N=10	N=50	WEF000130
craniofacial	2 per 1000	1	2	2	
all malformations	20 per 1000	2	2	4	

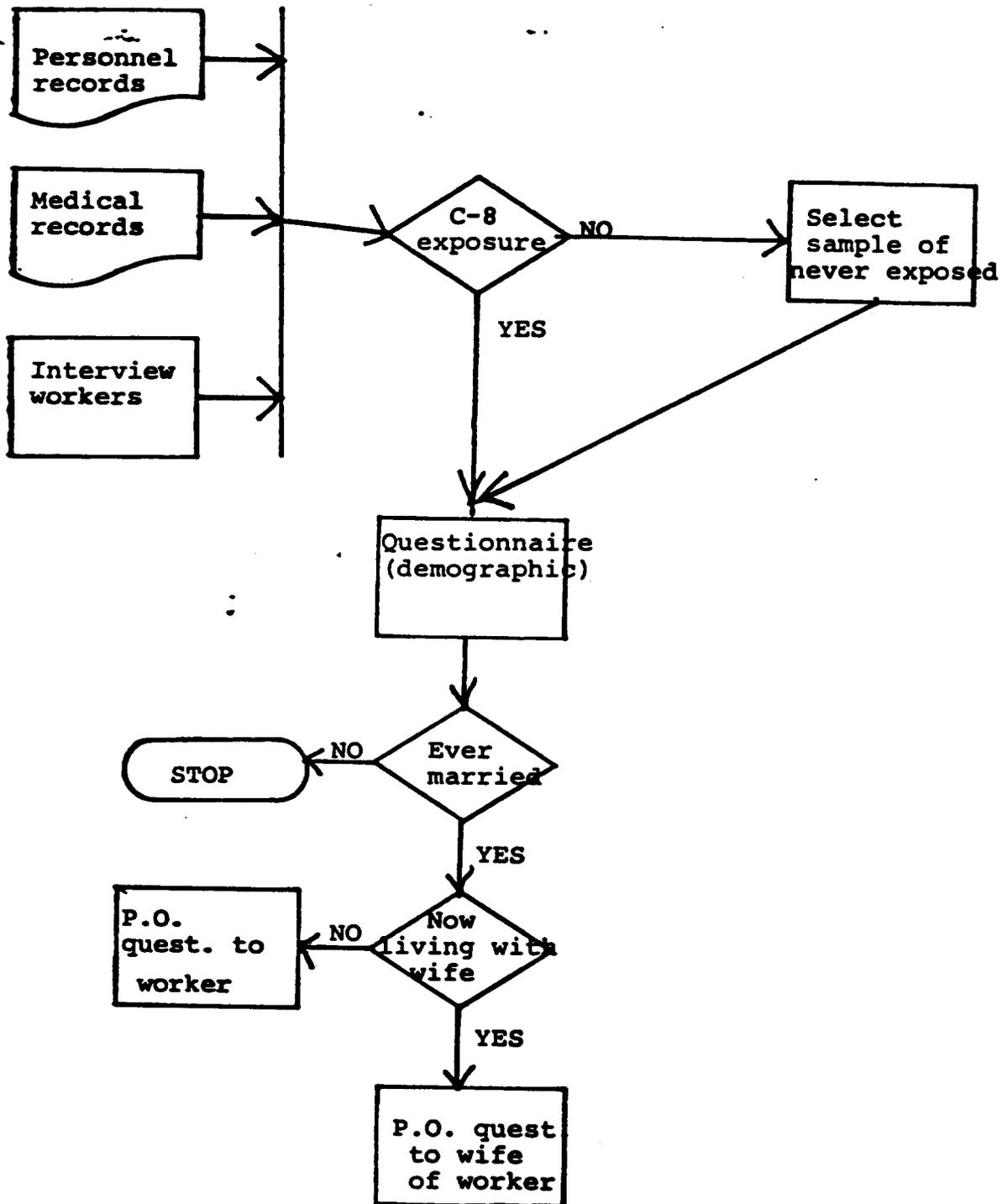
Minimum number of births with malformations that must be observed in the study group to be significantly higher than the national incidence, given a study group with N live births:

Number of live births in the plant control group	# births with malformations in the control group	Minimum number of births with malformations that must be observed in the study group to be significantly higher than the control group's incidence, given a study group with N live births:			
		N=5	N=10	N=50	
50	0	2	2	6	
50	1	2	3	8	
50	2	3	4	10	

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STUDY OF PREGNANCY OUTCOME IN WIVES OF C-8 EXPOSED WORKERS

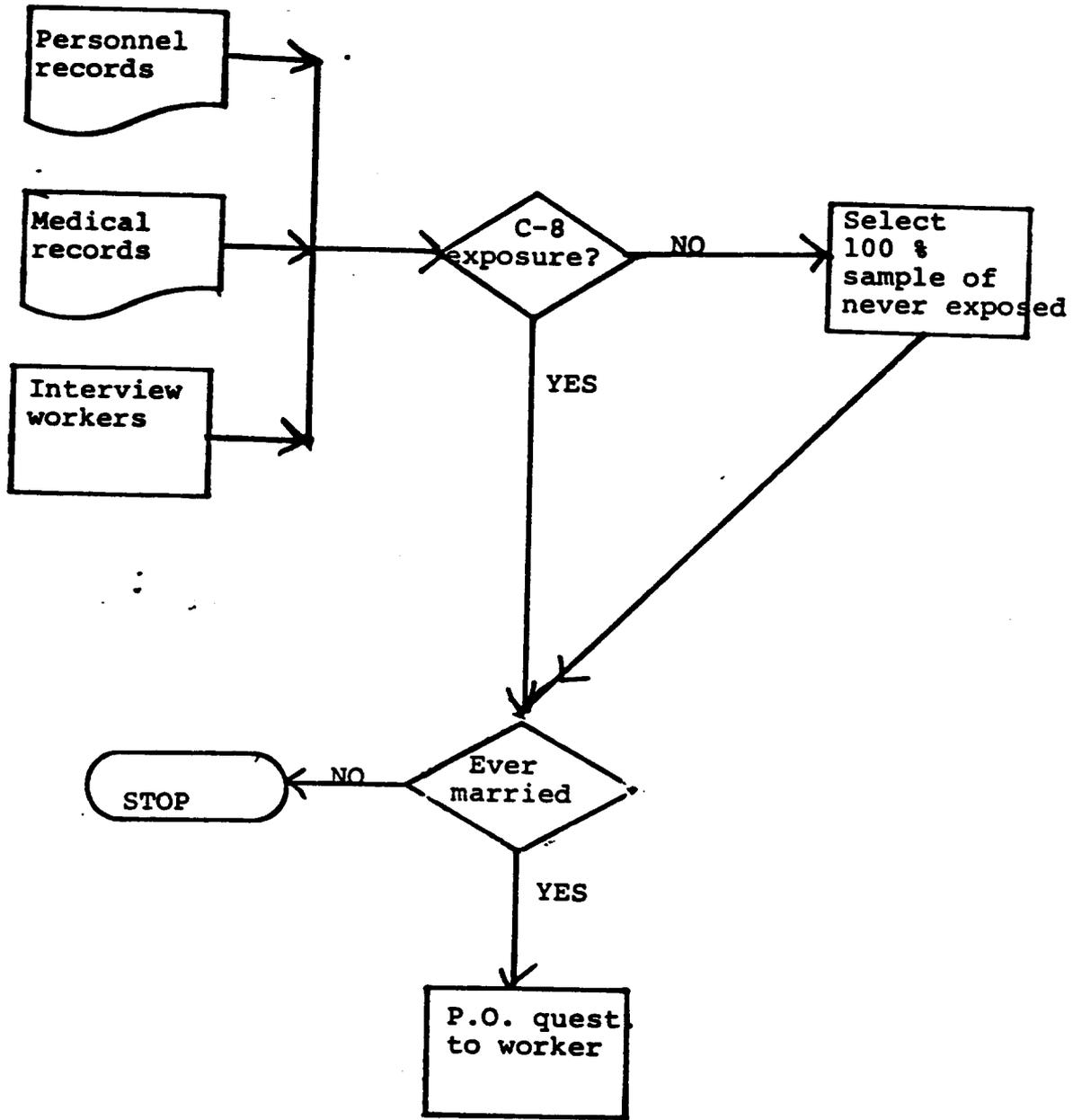


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STUDY OF PREGNANCY OUTCOME IN FEMALE WORKERS EXPOSED TO C-8



WEF000167

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UNIT 10

OUTLINE OF C-8 BLOOD SAMPLING PROGRAM

The sampling program to determine levels of C-8 in employees' blood has several purposes. These are listed below in order of priority. It is felt that an overall communication of intent of program would have a negative impact at this time. Blood sampling as an "overall" program has already been covered in the April 1 communication to employees.

- Pregnant Females - Washington Works

Provide information for physician to use to counsel or reassure about possible pregnancy outcome. Physician's statement and Q&A required (see next page). Prepared by 4/20. Data available for discussing with employees by 4/20.

- Nonpregnant Females - Washington Works

Provide information that the physician can use to advise females on pregnancy planning. Physician's statement, Q&A, and data available 4/20 (see next page).

- Sampling at Germay Park, Circleville, etc.

To confirm previous assessment of exposure for females. Statement and Q&A to be prepared by 4/27. Sampling start _____.

- Sampling of Males at Germay Park

To be included to confirm background level.

- Washington Works - Males

Provide information on decay rate of C-8. Sampling in progress.

- Washington Works - Various Groups

Provide data for pregnancy outcome study and confirm background level. Communications to be included in that for epidemiology study if decision is made to proceed.

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WASHINGTON WORKS
OUTLINE OF EMPLOYEE COMMUNICATIONS:
BLOOD SAMPLING PROGRAM

In order of priority:

- Inform females removed from Teflon of their blood results - by plant doctor in private.

To do: develop Q&A for doctor to advise:

(A) those with blood levels below "background" of 0.4 ppm.

(B) those with blood levels above background.

(C) those in (A) and (B) who are pregnant.

(D) those in (A) and (B) who desire advice on future pregnancies.

(E) effects of blood level on overall health of individual.

(F) those who may wish to consult their physician.

When: Target Date - approved Q&A - 4/20/81

- Inform males of recent blood sampling results.

To do: existing communication procedures are adequate.

When: Ongoing.

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OTHER EMPLOYEE COMMUNICATIONS

- Introduce and encourage support for the "pregnancy outcome" study.

To Do: (a) Communicate study objectives.
(b) Communicate employee participation.

When: Prior to study.

- Update evaluation of blood level results:

To Do: ● Define trends for those still in Teflon Division.

● Define decay rate for those no longer exposed.

● Possible redefinition of "background" levels.

- Update Haskell (and 3M) animal test program.

To do: Define new studies - objectives and timing.

Note: Items 3, 4 and 5 could be combined in one package.

L. F. Percival

4/14/81

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UNIT 10

PROJECT CONTROL #: 57

INVESTIGATOR: WEF

SPONSORING DEPT: PPD

AR 226 - 1383

PRIMARY OBJECTIVES:

- (1). TO DETERMINE WHETHER PREGNANCY OUTCOME AMONG FEMALE WW EMPLOYEES IS CAUSALLY RELATED TO THEIR OCCUPATIONAL EXPOSURE TO C-8, DMF, OR HFA.
- (2). TO DETERMINE WHETHER PREGNANCY OUTCOME AMONG WIVES OF WW EMPLOYEES IS CAUSALLY RELATED TO THEIR HUSBANDS' EXPOSURE TO C-8, DMF, OR HFA.

STUDY DESIGN:

LOCATION: WASHINGTON WORKS
 TYPE OF STUDY: CROSS-SECTIONAL.
 STUDY GROUP: ALL MALE AND FEMALE ACTIVE EMPLOYEES AT PLANT; WIVES OF MALE EMPLOYEES.
 REFERENT GROUP: COMPARISONS BETWEEN EXPOSED AND NON-EXPOSED WW EMPLOYEES, SPOUSES; COMPARISONS WITH ANOTHER DU PONT PLANT.
 EXPOSURE DEFINITION: C-8, DMF, HFA; WORK AREA (TEFLON AREA ESPECIALLY); BLOOD ORGANIC FLUORIDE LEVELS.
 DATA SOURCES: SELF-ADMINISTERED QUESTIONNAIRES; PERSONNEL RECORDS (WORK HISTORY).
 OUTCOME VARIABLES: PREGNANCY OUTCOME (EG., ABNORMALITIES IN THE NEWBORN, ETC.)

STATUS OF PROJECT:

- 04/13/81: STUDY PROPOSAL WRITTEN AND CIRCULATED AMONG MEDICAL DIV AND PPD.
- 04/15/81: QUESTIONNAIRE DRAFTED. QUESTIONNAIRE APPROVED BY BWK/BWC.
- 04/16/81: MEETING WITH MEDICAL AND PPD (SERENBETZ, RAINES, LIGO, IRSCH, NACE, INGALLS, CULPEPPER, FAYERWEATHER).
- 04/23/81: MEETING WITH MEDICAL AND PPD (HES, JMR, NJI, ROI, BWK, WEF). WW PREGNANCIES BY YEAR AND PAYCLASS PRESENTED; SAMPLE SIZES FOR STATISTICAL SIGNIFICANCE PRESENTED;
- 05/08/81: ABNORMAL PREGNANCY OUTCOME RATES WERE CALCULATED FOR ENTIRE COMPANY, 1979-1980.
- 05/15/81: INFORMED CONSENT AND CONFIDENTIALITY OF DATA PACKAGE WERE SENT TO BWK
- 06/12/81: RD INGALLS SUBMITTED PREGNANCY OUTCOME COMMUNICATION PACKAGE TO IRSCH "FOR ACTION." WEF OBJECTED TO PACKAGE, SINCE IT INCLUDED A QUESTIONNAIRE THAT HAD NOT BEEN DISCUSSED OR APPROVED BY MEDICAL. THIS OBJECTION WAS BROUGHT TO THE ATTENTION OF INGALLS, KARRH, AND IRSCH.
- 07/22/81: MEETING WITH MEDICAL AND PPD (HES, BWC, SP, JJC, WEF); HES SAID THAT STUDY WAS "ON HOLD" UNTIL FURTHER NOTICE.

DATES (MONTH/DAY/YEAR):

DATE PROPOSED ...	4/ 6/81	DATE WORK APPROV ...	0/ 0/ 0
EST COMPLETION DATE ...	0/ 0/ 0	DATE WORK COMPLETED ...	0/ 0/ 0

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THE UNIVERSITY OF CHICAGO

TO: EMPLOYEE RELATIONS DEPARTMENT
WORD PROCESSING CENTER - N-12533

AR 226 - 1384

FROM: Fayerweather Room: _____ Tel: _____ Date _____

Retain Diskette: Perm. Other _____

Format: Draft Final Copy Spacing: Single Double As Shown

Job Title: Preparing Outline Questions Author _____

Previous Author (if Applicable) _____

Special Instruction: _____

Your requested typing is attached. If you desire revision, please note and return to me with this slip. Please keep this sheet with your work.

NOTE: In order to keep our records current, please indicate when tape may be erased by returning this sheet to us with your signature. DO NOT SIGN UNTIL THIS WORK IS NO LONGER NEEDED. WHEN THE TAPE IS ERASED THE WORK WILL HAVE TO BE TYPED AGAIN.

Signature _____

Type output requested: Final Copy Draft Corrections Call when ready

Type output requested: Final Copy Draft Corrections Call when ready

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Type output requested: Final Copy Draft Corrections Call when ready

PLEASE MAKE ALL CORRECTIONS IN RED OR GREEN INK - ON ORIGINAL

EID106216

FOR WORD PROCESSING CENTER USE ONLY

Received		Input Typed	Rev.	Total Pages Printed	Operator	Date & Time (Min.)	Pages Scanned	By
Date	Time							
					<u>md y-22</u>			

WEF000168

PREGNANCY OUTCOME QUESTIONNAIRE

**CONTAINS
PERSONAL AND CONFIDENTIAL MEDICAL
INFORMATION**

CASE # _____

EID106217

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WEF000169

OCCUPATION

Have you ever worked outside of the home in any of the following industries, jobs, businesses, or conditions?

	YES	NO	If yes, give dates: from Mo/Yr to Mo/Yr
● Clerical worker			
● Factory worker.			
● Physician/dentist/chemist/pathologist . . .			
● Other professional worker			
● Chemical operator in a factory.			
● Farmer, farm hand, or field worker.			
● Maintenance worker or craftsman			
● Service worker/janitor.			
● Construction.			
● Painter			
● Textile plant worker.			
● Beauty salon hairdresser or beautician. . .			
● Plant where dyes were made or used.			
● Surgical operating room			
● Where you worked around anesthetic gases. . .			
● Dusty job			
● Where X-rays were used.			
● Where radioactive materials were used . . .			
● Where drugs/medicines were made/packaged. .			
● Dry cleaning shop			
● Where solvents were used.			
● Where degreasers were used.			
● Where it was very hot			
● Where it was very cold.			
● Where you worked around exhaust fumes . . .			
● Where plastics were made.			
● Where you had to wear a respirator.			
● Where you worked around fumes/gas vapor . .			
● Where you worked around mists or sprays . .			
● Where you worked with lead.			
● Where you worked with other metals.			
● Where you worked with laboratory chemicals.			
● Job involving heavy lifting			
● Job involving continual standing.			
● Job involving continual sitting			
● Laboratory/medical/dental technician. . . .			

EID106219

W/EF000171

MENSTRUAL HISTORY

The next few questions are about your menstrual periods. You may feel that some of this is a little personal, but it is very important for us to get a complete picture of your health.

How old were you when you had your first period? _____ years
 Are you still having periods at all? a. yes b. no

IF NO,

At what age did you have your last period? _____ years
 Did your periods: a. stop naturally?
 b. stop due to surgery?
 c. stop due to radiation?
 d. stop for some other reason?
 e. stop for some unknown reason?

IF YES,

About how many days are there from the first day of one period to the first day of your next period? _____ days
 About how many days does your period last, that is until the bleeding completely stops?..... _____ days

Below is a list of changes that women sometimes notice in their menstrual cycles. Since you were 18 years old, have you noticed any of the following changes in your periods?

	YES	NO
skipping periods.		
irregular periods		
increased flow.		
decreased flow.		
increased pain or cramping.		
someother kind of change.		

MARITAL HISTORY

Do you think you have ever been pregnant? a. yes b. no

IF YES, how many times have you been pregnant? _____ times

Are you now: a. married b. divorced c. separated d. widowed
 e. never have been married

	PRESENT HUSBAND	PREVIOUS HUSBAND	PREVIOUS HUSBAND												
What is your husband's birth date? (mo/yr) . . .	/ /	/ /	/ /												
In what year were your married?.	19__	19__	19__												
In what year were you widowed/separated/divor.?.	19__	19__	19__												
How many times were you pregnant?.	_____	_____	_____												
Have you ever wanted to be pregnant, but were unable to?.	<table border="1"><tr><td>YES</td><td>NO</td></tr><tr><td></td><td></td></tr></table>	YES	NO			<table border="1"><tr><td>YES</td><td>NO</td></tr><tr><td></td><td></td></tr></table>	YES	NO			<table border="1"><tr><td>YES</td><td>NO</td></tr><tr><td></td><td></td></tr></table>	YES	NO		
YES	NO														
YES	NO														
YES	NO														
Did you ever see a doctor because you had trouble getting pregnant?.	<table border="1"><tr><td></td><td></td></tr></table>			<table border="1"><tr><td></td><td></td></tr></table>			<table border="1"><tr><td></td><td></td></tr></table>								
Did your husband ever see a doctor because you had trouble getting pregnant?.	<table border="1"><tr><td></td><td></td></tr></table>			<table border="1"><tr><td></td><td></td></tr></table>			<table border="1"><tr><td></td><td></td></tr></table>								

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PREGNANCY OUTCOME

If you have never been pregnant, stop here. Otherwise, please continue.

1. How many live-born children have you had?

a. None

b. I have had live-born children. Their dates of birth (month/year) are listed below:

- | | | | |
|---------------------------|---------------------------|---------------------------|----------------------------|
| (1) <u> </u> / <u> </u> | (4) <u> </u> / <u> </u> | (7) <u> </u> / <u> </u> | (10) <u> </u> / <u> </u> |
| (2) <u> </u> / <u> </u> | (5) <u> </u> / <u> </u> | (8) <u> </u> / <u> </u> | (11) <u> </u> / <u> </u> |
| (3) <u> </u> / <u> </u> | (6) <u> </u> / <u> </u> | (9) <u> </u> / <u> </u> | (12) <u> </u> / <u> </u> |

2. Were any of the live-births born with birth defects or malformations?

a. None

b. Yes. The dates of birth (month/year) and type of defect or malformation are listed below:

- | | |
|---------------------------------|---------------------------------|
| (1) Date: <u> </u> / <u> </u> | (2) Date: <u> </u> / <u> </u> |
|---------------------------------|---------------------------------|

Type,
part of body affected:

Type,
part of body affected:

3. How many pregnancies did you have that ended with a miscarriage less than 20 weeks after you became pregnant?

a. None

b. I have had miscarriages. The dates (month/year) that the miscarriages occurred, and the number of weeks pregnant were:

- | | | | |
|--|--|--|--|
| (1) <u> </u> / <u> </u>
<u> </u> weeks | (2) <u> </u> / <u> </u>
<u> </u> weeks | (3) <u> </u> / <u> </u>
<u> </u> weeks | (4) <u> </u> / <u> </u>
<u> </u> weeks |
|--|--|--|--|

4. How many pregnancies did you have that ended in a stillbirth 20 weeks or more after you became pregnant?

a. None

b. I have had stillbirths. The dates (month/year) that the stillbirths occurred and the number of weeks pregnant were:

- | | | | |
|--|--|--|--|
| (1) <u> </u> / <u> </u>
<u> </u> weeks | (2) <u> </u> / <u> </u>
<u> </u> weeks | (3) <u> </u> / <u> </u>
<u> </u> weeks | (4) <u> </u> / <u> </u>
<u> </u> weeks |
|--|--|--|--|

5. How many pregnancies did you have that ended with a therapeutic or induced abortion (an abortion performed for medical or personal reasons)?

a. None

b. I have had abortions. The dates (month/year) and number of weeks pregnant are listed below:

- | | | | |
|--|--|--|--|
| (1) <u> </u> / <u> </u>
<u> </u> weeks | (2) <u> </u> / <u> </u>
<u> </u> weeks | (3) <u> </u> / <u> </u>
<u> </u> weeks | (4) <u> </u> / <u> </u>
<u> </u> weeks |
|--|--|--|--|

6. Are you pregnant right now. a. no b. yes: how many months? month

7. Are there any conditions or diseases that repeat in your family?

a. no b. yes IF YES, describe the condition:

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8. Are there any conditions or diseases that repeat in your husband's family?

a. no b. yes IF YES, describe the condition:

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PLEASE COMPLETE THE TABLE BELOW. REPORT ON PREGNANCIES IN THE ORDER IN WHICH THEY OCCURRED.

Pregnancy	Pregnancy outcome: live-birth, stillbirths, miscarriage, or abortion (specify)	Date of live-birth, stillbirths, miscarriage, or abortion (month/year)	Illness with a rash or fever?		Accidents, injuries or falls		Worked outside of home?		X-rays taken?		Number of cigarettes smoked per day
			YES	NO	YES	NO	YES	NO	YES	NO	
1		___/___									
2		___/___									
3		___/___									
4		___/___									
5		___/___									
6		___/___									
7		___/___									
8		___/___									
9		___/___									
0		___/___									
11		___/___									
12		___/___									

WEP000174

Pregnancy	Number of alcoholic drinks consumed per week	Type of birth control method practiced during the 12 months prior to pregnancy (Pill, IUD, diaphragm, other, none)	Type of medications/drugs taken during pregnancy (choose from list in lower right of page)
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			

- aspirin
- anti-nausea pills
- cold pills
- antihistamines
- diet pills
- artificial sweeteners
- diet drinks
- antibiotics
- sleeping pills
- nerve medication
- tranquilizers
- medicines to prevent miscarriage
- diuretics or water pills
- tylenol
- other pain killers
- vitamins
- other medications (specify which one)

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For each live born child, please complete the table below:

Child	Birth date (Month/year)	Sex (M or F)	Doctor said baby was early, late, or on-time	Birth weight (pounds/oz.)	Birth length (inches)
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					

If any of your children were born with a birth defect or other problem, does anyone else in your family have a similar problem?

a. ___ No b. ___ Yes IF YES, please complete the table below:

Child	Child's birthday (month/year)	Child's problem	Family member's problem
1	/		
2	/		

Have you ever been told that you had a hereditary or genetic problem?

a. ___ no b. ___ yes

IF YES, please describe the condition:

Has your husband ever been told that he had a hereditary or genetic problem?

a. ___ no b. ___ yes

IF YES, please describe the condition:

END OF QUESTIONNAIRE. THANK YOU FOR YOUR COOPERATION.
PLEASE RETURN THIS QUESTIONNAIRE TO _____.

EID106223

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AR 226 - 1385

CC: ERD Division Directors
F. W. Rappaport - N-13519
J. C. Bonnett, M.D.
B. W. Karrh, M.D.

TO: H. G. SMYTH

FROM: BURFORD W. CULPEPPER, M.D. *BWC*

April 28, 1981

WEEKLY NOTES

C-8 (FC-143)

C-8 (FC-143) blood level testing continues with exposed employees and controls recruited from the Corporate headquarters. 13 controls tested thus far have had non-detectable levels of C-8; i.e., < 0.004 ppm.

Haskell has initiated an animal study this week that may help determine a "no-effect" level in rats. Results will not be available for 60 days.

In the interim, our standard of 0.-0.4 ppm total organic fluorides will continue to be used as a blood level that will not mandate removal of females from the workplace.

BWC:ceb

EID096481

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BWK000121

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AR 226 - 1386



E. I. DU PONT DE NEMOURS & COMPANY
INCORPORATED
WILMINGTON, DELAWARE 19898

cc: A. J. Dahl - 353
B. W. Karrh - N11400
L. J. Papa - 269
Pral File
I.C.

POLYMER PRODUCTS DEPARTMENT
EXPERIMENTAL STATION

PERSONAL AND CONFIDENTIAL

May 14, 1981

TO: DR. Y. L. POWER - PPD, Washington Works

FROM: S. S. STAFFORD *S. Stafford*

ANALYSIS OF BLOOD SAMPLES FOR PERFLUOROOCCTANOATE
(Job No. 810-190; PRAL Nos. 81-1420-81-1467; Notebook Nos. E22514, E26238)

As requested in your letter of 4/8/81 to L. J. Papa, the 48 blood samples submitted then have been analyzed for perfluorooctanoate (C₈). Results and sample identification are given in the attached table.

As noted there, the analysis was done using a gas chromatographic method specific for C₈ (Lab Method Number ES-567) but results have been reported as ppm F for comparison with total organic fluorine analyses. Precision is $\pm 10\%$ relative standard deviation over most of the concentration range, somewhat less at the lowest values. The lower limit for quantitation is 0.007 ppm F (0.01 ppm perfluorooctanoic acid), with a detection limit of ~ 0.004 ppm which can be distinguished from the reagent background but not well quantitated.

Please contact me (772-4440) or L. J. Papa (772-2745) if you have any questions regarding the analyses. General questions on blood sampling can be directed to J. W. Raines or L. F. Percival.

Attachment
jah

KeyWords:

Perfluorooctanoic Acid
Perfluorooctanoate
Blood Analysis
GC

000154

TABLE I

CONCENTRATION OF PERFLUOROCCTANOATE IN BLOOD (a)

Sample				GC Analysis	
<u>P.RAL No.</u>	<u>Date Sampled</u>	<u>P.R.No.</u>	<u>Name</u>	<u>Date Analyzed</u>	<u>[C₈], µg F/g blood^(b)</u>
81-1420	4/1/81			4/11/81	0.078
				4/15/81	0.074
81-1421	4/1/81			4/11/81	1.5
81-1422	4/2/81			4/11/81	0.013
81-1423	4/2/81			4/11/81	0.048
81-1424	4/3/81			4/11/81	0.62
81-1425	4/3/81			4/13/81	0.13
81-1426	4/6/81			4/13/81	0.072
81-1427	4/6/81			4/13/81	0.051
81-1428	4/6/81			4/13/81	0.11
81-1429	4/6/81			4/13/81	0.061
81-1430	4/6/81			4/13/81	0.19
81-1431	4/6/81			4/13/81	1.0
81-1432	4/6/81			4/14/81	5.1
81-1433	4/6/81			4/15/81	0.44
81-1434	4/6/81			4/13/81	0.052
81-2435	4/6/81			4/14/81	0.23
81-1436	4/6/81			4/14/81	0.11
81-1437	4/6/81			4/14/81	0.17
81-1438	4/6/81			4/13/81	0.31
81-1439	4/6/81			4/14/81	0.054
81-1440	4/6/81			4/14/81	0.077
81-1441	4/6/81			4/15/81	0.31
81-1442	4/6/81			4/24/81	4.3
81-1443	4/6/81			4/14/81	0.64
81-1444	4/6/81			4/15/81	1.3
81-1445	4/6/81			4/15/81	0.14
81-1446	4/6/81			4/16/81	0.57
81-1447	4/6/81			4/16/81	0.18
81-1448	4/6/81			4/16/81	0.15
81-1449	4/6/81			4/16/81	0.83
81-1450	4/6/81			4/18/81	3.8
81-1451	4/6/81			4/16/81	0.22 (c)

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EID713272

TABLE I (CONT'D)

CONCENTRATION OF PERFLUOROOCCTANOATE IN BLOOD (a)

Sample				GC Analysis	
PRAL NO.	Date Sampled	P.R.No.	Name	Date Analyzed	[C ₈], $\mu\text{g F/g blood}^{(b)}$
81-1452	4/6/81			4/16/81	0.019
81-1453	4/6/81			4/18/81	0.11
81-1454	4/6/81			4/18/81	0.14
81-1455	4/6/81			4/18/81	2.1
81-1456	4/6/81			4/18/81	0.19
81-1457	4/6/81			s 4/18/81	4.3
81-1458	4/7/81			4/20/81	4.5
81-1459	4/7/81			4/20/81	0.81
81-1460	4/7/81			a 4/23/81	1.7
81-1461	4/7/81			4/20 & 4/24/81	4.5
81-1462	4/7/81			4/20/81	1.9
81-1463	4/7/81			4/23/81	2.4
81-1464	4/7/81			4/20/81	0.10
81-1465	4/7/81			4/20/81	0.47
81-1466	4/7/81			4/24/81	3.6
81-1467	4/7/81			4/20/81	0.092

(a) Analysis as described in Lab Method ES-567 ("Determination of Perfluorooctanoic Acid in Blood, Gas Chromatographic Method", S. Stafford, 4/3/81), using the packed column GC analysis with perfluoro-n-octanoic acid as calibration standard.

(b) Although the analysis is specifically for perfluorooctanoate (acid or salts), concentrations are given in ppm fluorine for comparison with the results of total organic fluorine analyses. (ppm F = 0.688 x ppm perfluorooctanoic acid) Estimated uncertainty is $\pm 10\%$ relative standard deviation. The lower limit for quantitation is 0.007 $\mu\text{gF/g}$. The detection limit is $\sim 0.004 \mu\text{gF/g}$, but concentrations in that range cannot be well quantitated and are reported as < 0.007 . "None detected" is reported for samples with $[\text{C}_8] \lesssim 0.004 \text{ ppm}$, which cannot be distinguished from reagent background.

(c) In GC analysis of this sample one unusual large peak was observed in the region of interest, but no interference with the C₈ peak was apparent.

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EID713273

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SECRET

AR 226 - 1387

810-190



ESTABLISHED 1802

E. I. DU PONT DE NEMOURS & COMPANY
INCORPORATED

WILMINGTON, DELAWARE 19898

POLYMER PRODUCTS DEPARTMENT
EXPERIMENTAL STATION

cc: A. J. Dahl - 353
B. W. Karch - N11400
L. J. Papa - 269
Pral File
I.C.

PERSONAL AND CONFIDENTIAL

May 19, 1981

TO: DR. Y. L. POWER - PPD, Washington Works

FROM: S. S. STAFFORD *S. Stafford*

ANALYSIS OF BLOOD SAMPLES FOR PERFLUOROCTANOATE
(Job No. 810-190; PRAL Nos. 81-1488-1501; Notebook Nos. E22514, E26238)

As requested in your letter of 4/14/81 to L. J. Papa, the 14 blood samples submitted then have been analyzed for perfluorooctanoate (C₈). Results and sample identification are given in the attached table.

As noted there, the analysis was done using a gas chromatographic method specific for C₈ (Lab Method Number ES-567) but results have been reported as ppm F for comparison with total organic fluorine analyses. Precision is $\pm 10\%$ relative standard deviation over most of the concentration range, somewhat less at the lowest values. The lower limit for quantitation is 0.007 ppm F (0.01 ppm perfluorooctanoic acid), with a detection limit of ~ 0.004 ppm which can be distinguished from the reagent background but not well quantitated.

Please contact me (772-4440) or L. J. Papa (772-2745) if you have any questions regarding the analyses. General questions on blood sampling can be directed to J. W. Raines or L. F. Percival.

Attachment
jah

KeyWords:

Perfluorooctanoic Acid
Perfluorooctanoate
Blood Analysis
GC

000157

EID713274

TABLE I

CONCENTRATION OF PERFLUOROOCCTANOATE IN BLOOD (a)

Sample SERIAL No.	Date Sampled	P.R.No.	Name	GC Analysis (b)	
				Date Analyzed	[C ₈], µg F/g blood
81-1488	4/7/81			4/22/81	0.53
81-1489	4/7/81			4/22/81	0.23
81-1490	4/7/81			4/22/81	0.41
81-1491	4/7/81			4/22/81	0.062
81-1492	4/7/81			4/23/81	0.94
81-1493	4/7/81			4/22/81	0.048
81-1494	4/7/81			4/23/81	0.45
81-1495	4/8/81			4/23/81	0.59
81-1496	4/8/81			4/23/81	3.5
81-1497	4/8/81			4/23/81	1.3
81-1498	4/9/81			4/15/81	2.5
81-1499	4/10/81			4/15/81	0.28
81-1500	4/10/81			4/15/81	0.070
81-1501	4/10/81			4/15/81	0.055

(a) Analysis as described in Lab Method ES-567 ("Determination of Perfluorooctanoic Acid in Blood, Gas Chromatographic Method", S. Stafford, 4/3/81), using the packed column GC analysis with perfluoro-n-octanoic acid as calibration standard.

(b) Although the analysis is specifically for perfluorooctanoate (acid or salts), concentrations are given in ppm fluorine for comparison with the results of total organic fluorine analyses. (ppm F = 0.688 x ppm perfluorooctanoic acid) Estimated uncertainty is $\pm 10\%$ relative standard deviation. The lower limit for quantitation is 0.007 µgF/g. The detection limit is ~ 0.004 µgF/g, but concentrations in that range cannot be well quantitated and are reported as < 0.007 . None detected (n.d.) is reported for samples with [C₈] $\lesssim 0.004$ ppm, which cannot be distinguished from reagent background.

000158

EID713275

CONFIDENTIAL



E. I. DU PONT DE NEMOURS & COMPANY
INCORPORATED
WILMINGTON, DELAWARE 19898

CC: J. C. BESPERRA
J. T. SMITH
N. J. IRSCH
C. F. REINHARDT - CR&D
B. W. KARRH - ER
H. E. SERENBETZ
J. W. RAINES

AR 226-1388

POLYMER PRODUCTS DEPARTMENT

May 26, 1981

PERSONAL & CONFIDENTIAL

J. H. TODD
POLYMER PRODUCTS DEPARTMENT
WASHINGTON WORKS

C-8 PROGRAM STATUS

It has been several weeks since the announcement of 3M's findings of the teratogenic potential of C-8 and the subsequent reassignment and relocation of affected female employees from the "Teflon" area. Communications to employees at that time indicated that we planned further animal testing, further blood sampling, and some follow-up to see if birth defects may have resulted from exposure to C-8.

Although these programs are either just under way or still in the discussion stage, a status report is in order.

You may choose to share some of the more sensitive information with your immediate staff. Other parts of the program, such as the Haskell activities, may be of more widespread interest.

If you wish to prepare a general communication, we will be glad to assist with Medical or Haskell review.

RISK ASSESSMENT (Attachment I)

The latest risk assessment letter of May 6 from Drs. C. F. Reinhardt and B. W. Karrh is included for your information. It refers to an earlier letter of April 10, and this is also attached.

HASKELL LABORATORY STUDIES (Attachment II)

E. D. Champney's memo of 4/13/81 summarizes the extensive program being undertaken at Haskell Laboratory.

EID090076

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HASKELL LABORATORY STUDIES (Cont'd.)

- The inhalation teratology study aimed at determining a no-effect exposure level in female rats is proceeding on schedule. Facilities at the Experimental Station are being used beginning this week for blood analyses to support this study during a two-week period. Although there will be some results at the end of June, the full-term test will not be complete until year end.
- Screening studies for an alternate dispersing agent have started. In about three months we should know if we have a promising candidate. Full-scale testing of several months would then be required to confirm absence of teratogenic potential.
- Because of the rapid elimination of C-8 by female rats, it is difficult to relate a no-effect dosage and blood level in rats to an acceptable exposure level and blood level of C-8 in humans. A second species, more closely related to humans, will be chosen shortly. The radioactive C-8 is now available. Information about how it is accumulated and held in the body will come from experiments using it.
- A reproduction study is still in the planning stage.

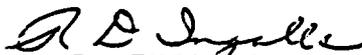
BLOOD SAMPLING RESULTS (Attachment III)

Attached is a summary of sampling results available through May 14.

As expected from previous sampling, sites where only the dispersion is being used are indicating low blood levels.

Samples from Dordrecht are just being received. When results are available, we will be able to compare this plant, where direct exposure to C-8 is possible, with Washington Works' experience.

We understand that strategies for further sampling at Washington Works are being discussed.



R. D. INGALLS
ENERGY & ENVIRONMENTAL AFFAIRS
MANUFACTURING DIVISION

RDI:tps
Attachments

EID090077

AJP002918

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E. I. DU PONT DE NEMOURS & COMPANY
INCORPORATED

WILMINGTON, DELAWARE 19898
CENTRAL RESEARCH & DEVELOPMENT DEPARTMENT

HASKELL LABORATORY
FOR
TOXICOLOGY AND INDUSTRIAL MEDICINE

May 6, 1981

PERSONAL & CONFIDENTIAL

MEMO TO: H. E. SERENBETZ
PPD, MONTCHANIN 642

FROM : C. F. REINHARDT, MD, CR&D, HASKELL *CFR*
B. W. KARRH, MD, ERD, N-11400 *BWK*

FC-143

(Ammonium perfluorooctanoate; C-8; CAS-3825-26-1)
Ref.: CFReinhardt & BWKarrh to HESerenbetz,
"FC-143," dated 4/10/81.

The reference memo describes a pilot study by 3M in which FC-143 caused abnormal eye lenses in rat fetuses. The memo recommends "that women of childbearing capacity be removed from jobs where it has been demonstrated that there is potential for exposure to FC-143 and blood levels of FC-143 are above defined background levels (0-0.4 ppm). Areas where the employees have blood levels of organic fluorine in the background range and where the airborne concentration of FC-143 is in compliance with our provisional acceptable exposure limit of 0.01 mg/m³ should present no significant risk to the fetus."

Originally we estimated blood concentrations of FC-143 by an imprecise measurement of total organic fluorine. The background concentration of organic fluorine, determined by measuring it in the blood of Wilmington office workers, was 0-0.4 ppm (as fluorine). Subsequently a method for measuring the blood level of FC-143 itself was developed. It is sensitive to about 0.004 ppm (4 ppb), as fluorine. It was presumed that background levels by either method would give values in the same range. However, initial measurements of Wilmington office workers indicate that the background level of blood FC-143 is below the level of detection, that is, less than 0.004 ppm. The question has arisen whether the acceptable blood level for female employees (0.4 ppm) should be lowered to the detection level of FC-143 (0.004 ppm).

EID090078

AJP002919

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H. E. SERENBETZ

-2-

May 6, 1981

We advise against this step because our information is limited.

1. *The evidence that FC-143 is a teratogen in the rat is inconclusive. Teratogenic tests meeting current standards are being carried out by 3M and Du Pont and results should be available by Q3-81.*
2. *Even if the preliminary 3M study is assumed to demonstrate teratogenicity, it is inadequate for setting acceptable exposure standards. The current animal studies should provide a basis for establishment of acceptable workplace standards. The human data now being collected should also help in setting standards.*
3. *Because of the unusual difference between male and female rats in their rate of excreting FC-143, the rat may not be the best model for man. A better model is being sought.*
4. *We need many more measurements before we can say that the background level of FC-143 in the population of the U.S. women is less than 0.004 ppm.*
5. *FC-143 has been in use for decades without apparent adverse effects in humans.*

We recommend that our acceptable blood level of 0.4 ppm not be changed until we have more definitive information. We should have enough information for a decision in a few months. The departments have already taken significant steps to lower exposure to FC-143. A few months, particularly with lowered exposure, should not significantly extend the hazard of a substance that has been in use for many years.

J. R. Gibson, Director of Health and Safety, concurs with our conclusions.

CFR/BWK/bjd

EID090079

AJP002920

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PERSONAL & CONFIDENTIAL

H. E. SERENBETZ

-3-

May 6, 1981

cc's to: J. R. Gibson, Admn, D-9058
W. E. Tatum, Admn, D-9064
F. E. French, Jr., C&P, B-17249
A. L. Dade, F&F, B-2202
A. C. Haven, Intl, D-3047
G. A. Hapka, Legal, B-13373
C. C. Griffith, Photo, RSQ-210
J. T. Smith, PPD, D-12008
J. L. Stowell, PA, D-8112
R. L. Rhodes, Fibr, N-4448
H. E. Simmons, Jr., CR&D, D-6036
B. C. McKusick, CR&D, Haskell
J. G. Aftosmis, CR&D, Haskell

EID090080

AJP002921

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E. I. DU PONT DE NEMOURS & COMPANY
INCORPORATED
 WILMINGTON, DELAWARE 19898
 CENTRAL RESEARCH & DEVELOPMENT DEPARTMENT

Page 1
 (cc's listed on page 2)

HASKELL LABORATORY
FOR
 TOXICOLOGY AND INDUSTRIAL MEDICINE

April 10, 1981

PERSONAL & CONFIDENTIAL

EID090081

MEMO TO: H. E. SERENBETZ
 PPD, M-642

FROM : C. F. REINHARDT, M.D., CR&D, HASKELL *CFR*
 B. W. KARRH, M.D., ERD, N-11400 *BWK*

FC-143

(Ammonium perfluorooctanoate; C-8; CAS-3825-26-1)

At your request, we have reviewed the information pertinent to whether FC-143 is a teratogen.

During the many years that Du Pont has used FC-143, there has been no known evidence of adverse health effects from employee exposure. However, our supplier of FC-143 (3M) informed Du Pont on March 20, 1981, that FC-143 caused defects (abnormal eye lenses) in rat fetuses when fed daily (days 6-15) to pregnant rats by stomach tube at doses of 25 or 150 mg/kg body weight. This observation was from a pilot study designed to determine the maximum dosage rate that pregnant females could tolerate in preparation for a full-scale study to assess FC-143's teratogenic potential.

On March 27 two Haskell scientists, Dr. R. E. Staples, Staff Teratologist, and Dr. T. Chiu, Senior Research Pathologist, visited 3M and reviewed the data with several 3M scientists. Staples and Chiu concurred with 3M that the lens defects were probably caused by FC-143.

Both Du Pont and 3M plan to start full-scale teratogenicity studies promptly. A major goal will be to determine a dosage or exposure concentration of FC-143 that does not cause birth defects and to relate this dosage to blood levels of FC-143. Until we have these data, we have no good basis for setting an acceptable exposure limit (AEL) for women of childbearing capacity. We recommend that women of childbearing capacity be removed from jobs where it has been demonstrated that there is potential for exposure to FC-143 and blood levels of FC-143 are above defined background levels (0-0.4 ppm). Areas where the employees have blood levels of organic fluorine in the background range and where the airborne concentration of FC-143 is in compliance with our provisional allowable exposure limit of 0.01 mg/m³ should present no significant risk to the fetus.

AJP002922

PERSONAL & CONFIDENTIAL

MEMO TO: H. E. SERENBETZ -2-

April 10, 1981

J. R. Gibson, Director of Health and Safety, concurs with our conclusions.

CFR/BWK/bjd

cc's to:

J. R. GIBSON, ADMN, D-9058
W. E. TATUM, ADMN, D-9064
F. E. FRENCH, JR., C&P, B-17249
A. L. DADE, F&F, B-2202
A. C. HAVEN, INTL, D-3047
G. A. HAPKA, LEGAL, B-13373
C. C. GRIFFITH, PHOTO, RSQ-210
J. T. SMITH, PPD, D-12008
J. L. STOWELL, PA, D-8112
R. L. RHODES, FIBR, N-4448
H. E. SIMMONS, JR., CR&D, D-6036
B. C. MCKUSICK, CR&D, Haskell
J. G. AFTOSMIS, CR&D, HASKELL

EID090082

AJP002923

000165

PERSONAL & CONFIDENTIALC-8 BLOOD SAMPLING RESULTS● Births and Pregnancies

<u>PPM C-8 in Blood</u>	<u>Status</u>
0.45	Normal child - born June 1980. Transferred out of Fluorocarbons 4/79.
0.28	Normal child - born April 1981.
0.078	Normal child - born April 1981. Umbilical cord blood 0.055 ppm.
1.5	Five months pregnant.
0.013	Five months pregnant.
2.5*	Child - 2 plus years. Unconfirmed eye and tear duct defect.
0.048	Child - 4 months. One nostril and eye defect.

*Current blood level - in fluorocarbons area only one month before pregnancy.

RDI:ldr

EID090083

AJP002926

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● C-8 Level - Current Washington Works Female Employees

Number of Samples 56

Range .0.013 - 5.1

Average 0.92 ppm C-8

Number Above	0.05	ppm	C-8	53
"	"	0.10	" "	46
"	"	0.20	" "	35
"	"	0.30	" "	29
"	"	0.40	" "	28

RDI:ldr

EID090084

AJP002927

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5/14/81

● C-8 Level Locations Other than Washington Works

<u>Location</u>	<u>No. of Samples</u>	<u>PPM C-8 Range</u>	<u>PPM C-8 Average</u>
Wilmington	32	ND	ND
Haskell	9	ND - 0.030	0.007
Chestnut Run	15	ND - 0.043	0.006
Spruance	27	ND - 0.070	0.027
Fairfield	5	ND - 0.048	0.014
Toledo	7	ND - 0.014	0.003
Circleville	10	ND - 0.030	0.014

RDI:ldr

EID090085

AJP002928

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THE END

AR 226 - 1389



E. I. DU PONT DE NEMOURS & COMPANY
INCORPORATED
WILMINGTON, DELAWARE 19898

cc: A. J. Dahl - 353
B. W. Karsh - N11400
L. J. Papa - 249
Pral File
I.C.

POLYMER PRODUCTS DEPARTMENT
EXPERIMENTAL STATION

PERSONAL AND CONFIDENTIAL

July 16, 1981

TO: DR. Y. L. POWER - PPD, Parkersburg
FROM: S. S. STAFFORD *S. S. Stafford*

ANALYSIS OF BLOOD SAMPLES FOR PERFLUOROCTANOATE
(Job No. 810-578; PRAL Nos. 81-2218-2232, 81-2600-2604, 81-2758;
Notebook Nos. E22514, E26238)

As requested in your letters of 5/18 and 6/12/81 to L. J. Papa, the 21 blood samples submitted then have been analyzed for perfluorooctanoate (C₈). Results and sample identification are given in the attached table.

As noted there, the analyses were done using a gas chromatographic method specific for C₈ (Lab Method Number ES-567) but results have been reported as ppm F. for comparison with total organic fluorine analyses. Precision is $\pm 10\%$ relative standard deviation over most of the concentration range, somewhat less at the lowest values. The lower limit for quantitation is 0.007 ppm F (0.01 ppm perfluorooctanoic acid), with a detection limit of ~ 0.004 ppm which can be distinguished from the reagent background but not well quantitated.

Please contact me (772-4440) or L. J. Papa (772-2745) if you have any questions regarding the analyses. General questions on blood sampling can be directed to J. W. Raines or L. F. Percival.

Attachment
jah

Key Words:
Perfluorooctanoic Acid
Perfluorooctanoate
Blood Analysis
GC

000169

EID713276

TABLE I

CONCENTRATION OF PERFLUOROOCCTANOATE IN BLOOD (a)

<u>Sample</u>				<u>GC Analysis</u>	
<u>PRAL No.</u>	<u>Date Sampled</u>	<u>P.R.No.</u>	<u>Name</u>	<u>Date Analyzed</u>	<u>[C₈], µg F/g blo.</u>
81-2218	4/29/81			6/12/81	0.034
81-2219	4/29/81			6/12/81	0.009
81-2220	4/30/81			6/12/81	0.76
81-2221	4/30/81			6/12/81	0.098
81-2222	5/1/81			6/12/81	0.64
81-2223	5/1/81			6/12/81	0.031
81-2224	5/1/81			6/11/81	0.17
81-2225	5/4/81			6/11/81	3.9
81-2226	5/7/81			6/11/81	4.8
81-2227	5/8/81			6/11/81	0.045
81-2228	5/11/81			6/8/81	0.042
81-2229	5/14/81			6/8/81	0.095
81-2230	5/14/81			6/8/81 & 6/9/81	0.25
81-2231	5/14/81			6/8/81	0.31
81-2232	4/30/81			6/8/81	1.3
81-2600	5/19/81			6/17/81	2.1
81-2601	5/19/81			6/17/81	0.019
81-2602	5/26/81			6/15/81	0.012
81-2603	5/28/81			6/17/81	0.057
81-2604	6/1/81			6/17/81	0.75
81-2758	6/19/81			6/26/81	0.095

(a) Analysis is described in Lab Method ES-567 ("Determination of Perfluorooctanoic Acid in Blood, Gas Chromatographic Method", S. Stafford, 4/3/81), using the packed column GC analysis with perfluoro-n-octanoic acid as calibration standard.

(b) Although the analysis is specifically for perfluorooctanoate (acid or salts), concentrations are given in ppm fluorine for comparison with the results of total organic fluorine analyses. (ppm F = 0.688 x ppm perfluorooctanoic acid) Estimated uncertainty is $\pm 10\%$ relative standard deviation. The lower limit for quantitation is 0.007 µgF/g. The detection limit is ~ 0.004 µgF/g, but concentrations in that range cannot be well quantitated and are reported as < 0.007 . None detected (n.d.) is reported for samples with $[C_8] \lesssim 0.004$ ppm, which cannot be distinguished from reagent background.

000170

EID713277

R

AR 226 - 1390

FROM: .

PAUL THISTLETON
Polymer Products Dept.
Teflon® Division
Washington Works

863-2387

PAC

Date:

9/16

TO:

John Doughty

Here's revised draft
Thanks for your
comments

P

EID079371

000171



E. I. DU PONT DE NEMOURS & COMPANY
INCORPORATED

P. O. Box 1217
PARKERSBURG, W. VA. 26101

CC: C. G. McGlone-Tokyo
S. Hayashi-Tokyo
D. K. Duncan - Wilm.

POLYMER PRODUCTS DEPARTMENT

September 15, 1981

MR. S. TAKADA
MITSUI FLUOROCHEMICALS CO. LTD.
MIHO 3600
SHIMIZU
SHIZUOKA PREFECTURE
JAPAN

PROPOSED EMPLOYEE BLOOD SAMPLING PROGRAM

We would like to obtain blood samples from a representative group of employees at Shimizu Works to determine if there is a significant difference between C-8 APFC dispersing agent values at Shimizu and Washington Works. About twelve samples should be enough. They should include several people who work around the TEFLON® fine powder dryers because we believe that they are a major source of exposure. Your plant has batch dryers whereas Dordrecht and Washington Works have continuous dryers. We will analyze the samples at Du Pont's Experimental Station and return the results to you so that they can be given to the employees as confidential medical information.

0139W

EID079372

There's a world of things we're doing something about

000172

AJP002509

BACKGROUND

We have used C-8 at Washington Works for more than 25 years and in earlier years it was handled less carefully than in recent years. Limited data indicates that C-8 is persistent in the human body and we have established a program to monitor selected employees regularly. We have established engineering controls to reduce potential exposure to C-8 and required the use of protective equipment for some jobs.

Significant additional control effort began in 1979 after 3M Company(our supplier of C-8 APFC dispersing agent) advised us of accumulation of organic fluorine in the blood of some of their workers. In March, 1981, 3M Company advised us that tests indicated that oral doses of C-8 caused birth defects in rats. As a result, we transferred all females of child bearing potential from jobs with significant potential for C-8 exposure and increased our efforts to prevent exposure.

Du Pont's Haskell Laboratory is making tests to determine if exposure by inhalation of C-8 causes birth defects and also is making tests with oral doses similar to the 3M tests. We expect results of these tests in about a month. 3M Company is repeating their original study and we expect to receive some information in October, 1981.

Samples of blood taken at Washington Works showed that polymerization operators had an average of about 5 ppm organic fluorine and the maximum value was about 29 ppm. Monomer operators and professionals generally had much lower values. We sampled some employees in the TEFLON® Division at Dordrecht Works in May, 1981, and we found that the C-8 content of their blood samples was very similar to results at Washington Works. There appears to be no background level of naturally occurring C-8 in blood samples. A thorough study of the employees health records showed no conclusive evidence of effects resulting from exposure to C-8.

We have asked Haskell Laboratory to establish an acceptable level for C-8 in workers blood that will be the basis for managing our blood monitoring programs.

We will be glad to answer any questions and provide more information that you may need.

Paul Thistleton
Senior Engineer
Technical Department

PT/nsw

0139W

EID079374

000174

AJP002511

PERSONAL & CONFIDENTIAL

C-8 BLOOD SAMPLING RESULTS

*Mnts type only
employee number
not name
calamba*

Births and Pregnancies

Employee
Number

Current (12)
PPM C-8
in Blood
(April 1981)

(10)

Status

0.45

Normal child - born June 1980.
Transferred out of Fluorocarbons 4/79.

0.28

Normal child - born April 1981..

0.078

Normal child - born April 1981.
Umbilical cord blood 0.055 ppm.

1.5

~~Five months pregnant.~~ *On pregnancy leave*

0.013

~~Five months pregnant.~~ *Normal child - born August 1981*

2.5*

Child - 2 plus years.
Unconfirmed eye and tear duct defect.

0.048

Child - 4 months.
One nostril and eye defect.
Babies blood 0.012 ppm

2.007

Normal child - born July 1981

*Current blood level - in fluorocarbons area only one month before pregnancy.

RDI:ldr

000175

EID079375

REDACTED

AMERICAN

AR 226 - 1391

cc: A. J. Dahl - 353
B. W. Harsh - 611400
L. J. Papa - 289
Pral File
I.C.



ESTABLISHED 1802

E. I. DU PONT DE NEMOURS & COMPANY
INCORPORATED
WILMINGTON, DELAWARE 19898

POLYMER PRODUCTS DEPARTMENT
EXPERIMENTAL STATION

PERSONAL AND CONFIDENTIAL

October 20, 1981

TO: DR. Y. L. POWER - PPD, Parkersburg

FROM: S. S. STAFFORD

ANALYSIS OF BLOOD SAMPLES FOR PERFLUOROCTANOATE
(Job No. 810-578; PRAL Nos. 81-4363-4386;
Notebook Nos. E22514, E26238, E27432)

As requested in your letter of 9/22/81 to L. J. Papa, the 24 blood samples submitted then have been analyzed for perfluorooctanoate (C8) by the usual gas chromatographic method ES-567. Results and sample identification are given in the attached table.

Attachment
jah

Key Words:

Perfluorooctanoate
GC
Blood Analysis

000176

EID713278

TABLE I

CONCENTRATION OF PERFLUOROOCCTANOATE IN BLOOD (a)

Sample PRAL No.	Date Sampled	P.R.No.	Name	GC Analysis	
				Date Analyzed	[C ₈], ug F/g bl
81-4363	9/8/81			10/5/81	2.8
81-4364	9/8/81			10/2/81	0.034
81-4365	9/8/81			10/2/81	0.26
81-4366	9/9/81			10/2/81	0.14
81-4367	9/9/81			10/5/81	2.0
81-4368	9/9/81			10/2/81	0.41
81-4369	9/9/81			10/5/81	0.36
81-4370	9/10/81			10/8/81	0.15
81-4371	9/10/81			10/5 & 10/6/81	1.5
81-4372	9/10/81			10/5/81	0.21
81-4373	9/11/81			10/5/81	0.090
81-4374	9/11/81			10/5/81	0.26
81-4375	9/14/81			10/5 & 10/6/81	0.33
81-4376	9/14/81			10/8/81	0.33
81-4377	9/15/81			10/9/81	2.6
81-4378	9/15/81			10/8/81	0.071
81-4379	9/16/81			10/8/81	1.1
81-4380	9/16/81			10/8/81	0.11
81-4381	9/16/81			10/8/81	0.060
81-4382	9/17/81			10/8/81	0.20
81-4383	9/17/81			10/11/81	6.5
81-4384	9/18/81			10/8/81	0.042
81-4385	9/20/81			10/6/81	1.0
81-4386	9/20/81			10/6/81	0.13

(a) Analysis as described in Lab Method ES-567 ("Determination of Perfluorooctanoic Acid in Blood, Gas Chromatographic Method", S. Stafford, 4/3/81), using the packed column GC analysis with perfluoro-n-octanoic acid as calibration standard.

(b) Although the analysis is specifically for perfluorooctanoate (acid or salts), concentrations are given in ppm fluorine for comparison with the results of total organic fluorine analyses. (ppm F = 0.688 x ppm perfluorooctanoic acid) Estimated uncertainty is +10% relative standard deviation. The lower limit for quantitation is 0.007 ugF/g. The detection limit is ~ 0.004 ugF/g, but concentrations in that range cannot be well quantitated and are reported as < 0.007. None detected (n.d.) is reported for samples with [C₈] < 0.004 ppm, which cannot be distinguished from reagent background.

T

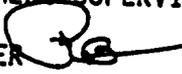
WEST VIRGINIA UNIVERSITY

AR 226 - 1392

CC: Manufacturing Superintendents
Process Superintendents
Maintenance Superintendents
Chief Chemist
Research Superintendents
Power & Services Superintendent
J. R. Farmer, Construction

December 15, 1981

TO: FLUOROPOLYMERS SUPERVISION

FROM: R. J. BURGER 

C-8 (FC-143) STATUS REPORT

On April 1 we advised you that 3M, in a preliminary study, had observed birth defects in the eyes of unborn rats when C-8, also known as FC-143 or ammonium perfluorooctanoate, was fed to pregnant female rats. Based upon those findings, we decided it was necessary to exclude female employees of childbearing capability from areas where there is potential for exposure to C-8.

We indicated that further studies by DuPont and 3M would be undertaken promptly to determine the significance, if any, of the findings as they might relate to employee exposure. We would like to share with you the results from these studies that we have to date.

Thus far, based on our review of the results of these further studies, it does not seem that the observed effects in the eyes of the unborn rats were due to C-8. Also in the new studies, rat pups delivered by C-8 exposed females showed no eye defects. Rather, it is believed that in the original studies, 3M's technique for the very difficult job of preparing the fetal eye tissue for microscopic examination resulted in the alterations noted.

3M has another toxicological test underway that will be completed the first quarter of 1982. At that time we expect to have all the data available and will assess if it is necessary to continue excluding female employees of childbearing capability from areas of potential exposure.

Until a final determination is made, we continue to advise that employees defer giving blood until the blood level of C-8 returns to background levels. We also advise that females who have an organic fluorine level above background should consult with their personal physician prior to contemplating pregnancy. We will provide pertinent information we have on C-8 to employees' personal physicians.

:ckc
Attachment
Ref:3962A

EID089462

000178

DDJ001720

QUESTIONS AND ANSWERS

(To be used by supervision as needed to answer questions.)

If there are any questions not answered below, they should be referred to Plant Management.

- Q1 - Will women who left the area be allowed to return if they choose?
- A1 - Not at the present time. This will be re-assessed in early 1982 when further toxicology tests are completed.
- Q2 - Well, what if you decide it's okay for women to work in the area? How will the women who left get back in?
- A2 - If it is finally determined that C-8 is not a teratogen, then females of childbearing capability will be allowed to return to the area. We are reviewing the procedure for return and will have an answer by the time the final studies are completed.
- Q3 - What will the Company do for those female employees who decided to become sterilized?
- A3 - We strongly recommended against sterilization for job-related reasons. Each woman was told that her employment, her pay rate, and her benefits would be fully protected and there was no need to consider a surgical procedure. Any decision for surgery was a personal matter, and the Company cannot assume responsibility for it.
- Q4 - It looks like the people in the laboratories may have fouled up. What do you say to that?
- A4 - The people at 3M conducting the experiments had the responsibility of trying to relate the effects seen in animals to those that might occur in humans. They needed to be very cautious. In this case in the preliminary study, they believed they saw an abnormal effect. They are required by law to report the preliminary results even though, as in this case, they knew further testing was required.
- Q5 - Why did you act on just the preliminary study instead of waiting for final results?
- A5 - We recognized that the test was preliminary, but it was a precaution we took until results of all follow-up studies were available.

EID089463

000179

DDJ001721



E. I. DU PONT DE NEMOURS & COMPANY
INCORPORATED
P. O. Box 1217
PARKERSBURG, W. VA. 26101

CC: R. N. Taylor
W. A. Bower
Y. L. Power, M.D.

AR 226 - 1393

POLYMER PRODUCTS DEPARTMENT

December 18, 1981

PERSONAL & CONFIDENTIAL

TO: R. D. INGALLS
WILMINGTON

FROM: J. F. DOUGHTY
WASHINGTON WORKS

TELECOPY TO:

R. D. INGALLS, M5625

FROM:

J. F. DOUGHTY - WASH. WORKS

(Pg. 1 of 1)

*sent 12/17/81
3:20 pm*

QUESTIONS ON C-8 STATUS REPORT

Ref: C-8 (FC-143) Status Report, December 15, 1981.

Dr. Power communicated the information in the reference document to several of the females. Two of them had questions that we could not answer. We would like help in obtaining these answers.

The first person has a child with birth defects around the eye. She would like to know if the 3M studies found any malformations other than right in the eye. She is especially concerned about the eye lid. She would also like to be able to read the reports from the Du Pont animal studies herself.

The second person has a child with 0.4 ppm C-8 in its blood. She would like to know what is the safe blood level for her and the baby. She would also like to know if a baby's liver is more susceptible to damage by C-8 than that of an adult and what signs and symptoms she should be alert to. Lastly, she would like to know if the studies showed any other embryological effects.

JFD:mah

000180

AIPO02872

EID079544



E. I. DU PONT DE NEMOURS & COMPANY

INCORPORATED

HASKELL LABORATORY FOR TOXICOLOGY
AND INDUSTRIAL MEDICINE

ELKTON ROAD, NEWARK, DELAWARE 19711

cc: C. F. Reinhardt, CR&D, Haskell
R. E. Staples
G. L. Kennedy

B. W. Karrh, M.D., ERD, N-11400

C-4124

AR 226 - 1394

CENTRAL RESEARCH AND DEVELOPMENT DEPARTMENT

February 4, 1982

CONFIDENTIAL

MEMO TO: M. A. SMOOK
PPD
CHS 314

FROM : B. C. MCKUSICK *B. C. McKusick*

MEETING WITH 3M ON C-8 (FC-143)

You, I, G. L. Kennedy and R. E. Staples met with E. Lamprecht (pathologist), F. D. Griffith (toxicology manager) and W. Pearlson (regulatory manager) of 3M in Chicago, February 3.

Lamprecht described two negative oral teratology studies with C-8, one in rats, one in rabbits. Griffith gave us a copy of the rat report. The rabbit report is circulating for approval and should be in official form in about two weeks.

Staples described the two Haskell teratology studies in rats, one feeding and one inhalation study. Both are negative. I gave Griffith a copy of each report.

Kennedy reported work on the rate of transfer of C-8 across the placenta to the fetus in pregnant rats. He also described studies to establish where C-8 concentrates in blood.

Pearlson reported on blood organofluorine of some 600 employees at two plants. Most employees had levels in the 1-5 ppm range, but a few were in the low twenties. Levels were similar in a plant using C-8 and in one using two other fluorosurfactants (probably R_pSO_3M and a fluoro-alcohol). Average levels have been slowly dropping with tighter standards and better work practices, but seem to be leveling off. An examination of liver enzyme levels confirmed earlier studies in showing no adverse health effects related to organofluorine in the blood.

EID071712

February 4, 1982

We set Wednesday, March 3, as a date to inform employees of the results of the teratology studies. I will exchange employee statements by phone with Griffith or Frank Ubel on March 1.

During the week of March 10, Pearlson and a 3M toxicologist will report the conclusions from the four teratology studies of C-8 to EPA. They will also report on related work on two other fluorosurfactants. They will give EPA the reports of their two studies. I will accompany them to give EPA the reports of the two Haskell studies and to answer questions on those studies if EPA has any. Plans for the EPA visit should be ready by March 1.

Staples will determine a suitable journal for publishing the teratology studies. He will prepare a paper on the Du Pont work and Lamprecht will prepare one on 3M's work. The papers will be submitted at the same time in the second quarter.

BCM/ms

EID071713

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DUP000/80

SECRET

W

March 1, 1982

C-8 (FC-143) EMPLOYEE COMMUNICATION

In April of last year we informed you of results of a preliminary 3M study in which birth defects were observed in the eyes of unborn rats when C-8 was fed to pregnant female rats. Extensive animal studies were initiated promptly by both DuPont and 3M. Results of these studies showed no eye defects or other birth defects in either the unborn or the rat pups. It was concluded that the alterations observed in the preliminary study were not caused by exposure to C-8 as originally suspected, but instead were caused by 3M's technique of preparing the fetal eye tissue for microscopic examination.

3M has just completed a study wherein pregnant rabbits were exposed to C-8. No eye or other birth defects were found in this study.

Since C-8 has not been shown to produce teratogenic effects in the several animal studies, we conclude that female employees of childbearing capability no longer need to be excluded from areas where there is potential for exposure to C-8.

All employees both male and female, are now eligible to work in TEFLON®. Normal plant bidding procedures will be followed for wage roll employees wanting to move to TEFLON®.

The following guidelines will apply for ex-TEFLON® wage roll females who were moved to other divisions last April and are successful bidders on gate postings of openings in TEFLON®:

- Upon their return via normal bidding procedures, employees group seniority will be calculated as though these employees never left. Therefore, time spent in other divisions since April 1981 will count as TEFLON® group service if these employees elect to bid back to the TEFLON® area.
- This group service provision will apply to each female wage roll employee who was removed from TEFLON® last April, for a period of one year or until each has at least one opportunity to be a successful bidder, whichever is later.

In view of the absence of teratogenic findings in the animal studies, and the absence of evidence of adverse health effects in employees at 3M and DuPont who may have been exposed to C-8, we are no longer advising against blood donation.

EID089464

000183

DD1001722

CONFIDENTIAL

X



E. I. DU PONT DE NEMOURS & COMPANY
INCORPORATED

HASKELL LABORATORY FOR TOXICOLOGY
AND INDUSTRIAL MEDICINE
ELKTON ROAD, NEWARK, DELAWARE 19711

CC: B. W. Karrh, ERD, N-11400
G. A. Hapka, Legal, D-7090
E. D. Champney, Jr., PPD, D-11070
J. T. Smith, Jr., PPD, D-12004
M. A. Smook, PPD, CHS-314
J. L. Stowell, PA, D-8135
C. F. Reinhardt, CR&D, Haskell
G. L. Kennedy, CR&D, Haskell
R. E. Staples, CR&D, Haskell

C-4124

CENTRAL RESEARCH AND DEVELOPMENT DEPARTMENT

March 15, 1982

PERSONAL & CONFIDENTIAL

AR 226 - 1396

MEMO TO: J. W. RAINES
PPD, M-5625

FROM : B. C. MCKUSICK

REPORT OF FC-143 TERATOGENIC STUDIES TO EPA

On March 12 Frank D. Griffith and William H. Pearlson of 3M and I reported results of teratogenic studies on three fluoro-surfactants to EPA. This was a follow-up to 8e notifications to EPA by 3M reporting teratogenic findings on a fluoroalcohol, a fluorosulfonate, and ammonium perfluorooctanoate (FC-143; C-8).

Thirteen people from the EPA Office of Toxic Substances, including Frank Kover, Terry O'Bryan, Joseph Seifter (an in-house toxicology consultant), and Elaine Francis (a teratologist) met with us for nearly two hours. Pearlson said that although full teratogenic studies on the alcohol and sulfonate and a dose-ranging study on FC-143 had earlier indicated that all three caused an eye defect in rat fetuses, 3M now believed that none of the substances caused this defect. He gave EPA copies of reports on two 3M studies of FC-143 that were subsequent to the 8e notifications, and said that no significant teratogenic effects were noted, in the eye or elsewhere. I supported his position by giving EPA reports of the two negative teratogenic studies of FC-143 by Haskell Lab. I said that few substances had been so extensively examined for teratogenic effects as FC-143, with a total of four full-scale studies carried out in two laboratories in two species of mammal by two routes of administration; that although the eye had received more attention than usual because of the initial indications of eye defects, both skeletal and soft tissue had been thoroughly examined for teratogenic effects and then none had been found; that the absence of eye defects had been reinforced by examining the eyes of juvenile rats born of exposed mothers and finding their eyes normal.

DUM/1/15

PERSONAL & CONFIDENTIAL

J. W. RAINES

-2-

March 15, 1982

Pearlson explained how, after FC-143 was shown not to be a teratogen, 3M reexamined the data on the other two fluorosurfactants, and concluded that they did not cause eye defects after all (he pointed out that the alcohol caused defects in other organs at high exposure levels). A few of the EPA people seemed to find it hard to understand how highly positive findings with good dose-response relationship could subsequently turn out to be negative. I don't think Pearlson and Griffith completely convinced the skeptics by their response, which included the factor of bias through not examining the slides blind. Hence, although the EPA people seemed to agree with the conclusion that there is no good evidence that FC-143 is a teratogen, some were hesitant about agreeing that the other two fluorosurfactants had not caused eye defects in rat fetuses.

EPA officials said that there is no mechanism for withdrawing an 8e notification or for EPA to declare it not a cause for concern. However, the 3M and Du Pont reports of studies on FC-143 will be placed in the same file as the 8e notice, and should anyone ask about the 8e notice on FC-143, he will be told about the conclusions of the reports.

BCM/bjd

EID071706

000185

201000/14

SECRET

Y



E. I. DU PONT DE NEMOURS & COMPANY
INCORPORATED
WILMINGTON, DELAWARE 19898
CENTRAL RESEARCH & DEVELOPMENT DEPARTMENT

HASKELL LABORATORY
FOR
TOXICOLOGY AND INDUSTRIAL MEDICINE

bcc: C. F. Reinhardt/B. C. McKusick
J. W. Raines - PPD - M-5625
S. G. Hundley/R. W. Hartgrove
R. E. Staples
H. J. Trochimowicz/J. G. Aftosmis

C-4124

AR 226 - 1397

March 16, 1982

Dr. Joseph Seifter
TS-792
Office of Toxic Substances
U. S. Environmental Protection Agency
401 "M" Street, S.W.
Washington, D.C. 20460

Dear Dr. Seifter:

We have studied the placental transfer of ¹⁴C-perfluoro-octanoate (C-8) in the albino rat by orally administering the chemical on Gestation Day 19 and following maternal blood and fetal tissue levels of the radiocarbon at 2, 4, and 8 hours after dosing. Maternal blood and placental levels of ¹⁴C increased between 2 and 4 hours then decreased between 4 and 8 hours after dosing. The μ g equivalents in maternal blood were approximately 12, 20 and 12 μ g/ml at 2, 4, and 8 hours post-dosing, respectively. Corresponding fetal levels (whole body assays) were 0.7, 3, and 3 μ g/ml. These data demonstrate that ¹⁴C-labelled C-8 does transfer across the placenta of the rat.

Please call me (302-366-5259) if you have any further questions.

Sincerely,

Gerald L. Kennedy, Jr.
Gerald L. Kennedy, Jr.
Section Supervisor,
Acute Investigations

GLK:scg

EID071704

MEMORANDUM FOR THE RECORD



E. I. DU PONT DE NEMOURS & COMPANY
INCORPORATED
WILMINGTON, DELAWARE

CC: J. N. Todd - PPD
H. F. Serenbetz - PPD

AR 226 - 1398

EMPLOYEE RELATIONS DEPARTMENT

November 23, 1982

PERSONAL & CONFIDENTIAL

J. W. RAINES
POLYMER PRODUCTS DEPARTMENT
M-5625

SCRUBBING OF FINE POWDER DRYER EXHAUSTS
(Letter J. W. Raines - B. W. Karrh 11/2)

I appreciate the opportunity to review and comment on the information attached to your referenced letter (October 27 letter T. M. Kemp to H. V. Bradley - same title).

All of our presently available data indicate there is no chronic health effect due to the low levels of exposure to C-8 that Washington Works employees are experiencing. We do know, however, that the material accumulates in the blood and has a relatively long half-life. Also, our C-8 human exposure experience is quite limited in time.

Based on ESD's evaluation, Kemp states that the annual mean concentration on site of emitted C-8 will be $0.35 \mu\text{g}/\text{m}^3$ or 3.5% of the $10 \mu\text{g}/\text{m}^3$ AEL but excursions to as high as 165% of the AEL can occur. Kemp further states that scrubbing will reduce the general Washington Works employee exposure to C-8 by more than 90% but he reasons that there will be small overall improvement for the general employee because of the low exposure anyway. It is somewhat intriguing that the lowest Washington Works levels are in the Teflon® area itself.

Even though the C-8 exposure to plant employees is small, I recommend that available practical steps be taken to reduce this exposure because:

- Our knowledge of the chronic health effects from long-term exposure to low levels of C-8 is quite limited.
- C-8 is retained in the blood for a long time, creating concern in other areas such as blood donations, etc.

EID096449

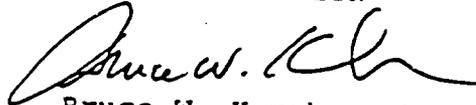
000187

BWK000014

- All employees, not just Teflon® area workers, are exposed.
- There is obviously great potential for current or future exposure of members of the local community from emissions leaving the Plant perimeter.

Please let me know if you wish to discuss this further.

MEDICAL DIVISION



Bruce W. Karrh, M.D.
Director

BWK:set

EID096450

000188

BWK000015

MEMORANDUM FOR THE RECORD

AR 226-1399

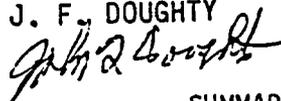
cc: T. A. Foster

August 29, 1984

PERSONAL AND CONFIDENTIAL

TO: J. A. SCHMID

FROM: J. F. DOUGHTY



SUMMARY OF C-8 IN WATER SAMPLING PROGRAM

This letter summarizes the sampling procedure and the results of the program to obtain C-8 concentration data for drinking water down river from the plant. The original set of samples were taken on March 15, 1984. A second set of samples was taken at selected locations on June 4, 1984.

The samples were taken by going to gas stations or small grocery stores in communities down stream of the plant and asking to have a plastic jug filled with drinking water. The sample obtained was then transferred to 8 oz. glass bottles. Two bottles were obtained. One bottle was used for analysis and the second was used as a retainer for future use if needed. Samples were also obtained up river to check for a background or blank and to insure that the samples were not being contaminated in the sampling procedure.

The original plan was to have the samples analyzed here on plant by a modification of the procedure used to determine C-8 in air. To get sensitivity below the concentration calculated for dilution of C-8 emissions by the river flow, a sample size of 100 ml was freeze dried. The subsequent analysis produced high and inconsistent blanks and data. When the analytical problems could not be resolved on plant, the samples were sent to the Experimental Station for analysis by a modification of the C-8 in blood procedure. The details of the analytical procedure are given in the attached letter from S. R. Laas to J. F. Doughty.

The table below shows the locations of the samples taken on 3/15/84, the sample designation, and any comments.

<u>SAMPLE</u>	<u>DESIGNATION</u>	<u>COMMENTS</u>
Parkersburg	P	Taken from my home.
Washington Works	WW	Taken from drinking fountain.
Distribution Center of Parkersburg	D	Private well back from river.

000189

EID079096

RIZ009213

AUGUST 29, 1984

<u>SAMPLE</u>	<u>DESIGNATION</u>	<u>COMMENTS</u>
Powell's Store Washington, WV	WB	Thought to represent Lubeck water.
Mason's Village Mkt Little Hocking, Ohio	L	
Oiler Exon Belleville, WV	B	Private well
Reeds Country Store Reedsville, Ohio	RD	
Randy's Amoco Route 68 Ravenswood, WV	RW	
Gulf Station Racine, Ohio	R	Known to be city water.
Gulf Station Route 2 Point Pleasant, WV	PP	
Sohio Station past bridge to WV Gallipolis, Ohio	G	First community to take water directly from the river.

The table below shows the locations of the samples taken on 6/4/84, the sample designation, and any comments.

<u>SAMPLE</u>	<u>DESIGNATION</u>	<u>COMMENTS</u>
Du Pont	WW	Taken from drinking fountain.
Powell's General Store Washington, WV	WB	
Lubeck Pennzoil Lubeck, WV	LB	In middle of Lubeck.
Mason's Village Mkt Little Hocking, Ohio	L	

The attached letter to J. A. Schmid from J. F. Doughty summarizes the data and the location of the samples in relation to the plant. Note that the original value for the Little Hocking sample should be changed to 0.6 instead of 0.8. This change is made by hand in the letter attached.

JFDoughty:0072t
Attachments

EID079097

000190.

RJZ009214

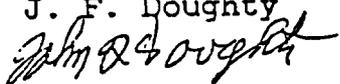
PERSONAL AND CONFIDENTIAL

CC: T. A. Foster

June 14, 1984

TO: J. A. Schmid

FROM: J. F. Doughty



UPDATE on C-8 IN WATER SAMPLES

The attached table shows the C-8 in water data including the most recent data. I conclude the new data confirm the original data.

1. The Du Pont data shows that the test does not see C-8 up river and the sampling system does not contaminate the sample.
2. The second Washington sample had essentially the same C-8 content as the first.
3. The new Lubeck sample shows essentially the same concentration as the Washington sample. Thus the Washington sample is from the Lubeck Water System as I suspect or at least the Lubeck system has the same concentration.
4. The original Little Hocking sample was very close to the detection limit for the test. The concentration now appears to be below the detection limit.

I do not plan to do additional sampling unless further information is needed. The concentrations are very low and in my judgement are not cause for concern.

EID079098

000191

RJZ009215

C-8 IN WATER (3/15/84) and (6/4/84)

LOCATION	DISTANCE (MILES)	SIDE	ppb C-8***
PARKERSBURG	7.5 up stream	WV	ND
DU PONT (3/15/84) (6/4/84)	0.5 up stream	WV	ND ND
DISTRIBUTION CENTER OF PARKERSBURG	0.25 down stream*	WV	ND
WASHINGTON (3/15/84) (6/4/84)	0.25 down stream	WV	1.27 ^{AVG} 1.0 ^{1.1}
LUBECK (6/4/84)	0.25 down stream	WV	1.5 .
LITTLE HOCKING (3/15/84) (6/4/84)	3 down stream	OHIO	0.6 ³²⁹ 0.8 ^{8/24/84} ND
BELLEVILLE	12 down stream	WV	ND
REEDSVILLE	14 down stream	OHIO	ND
RAVENSWOOD	29 down stream	WV	ND
RACINE	50 down stream	OHIO	ND
POINT PLEASANT	74 down stream	WV	ND
** GALLIPOLIS	79 down stream	OHIO	ND

*well is back from the river

**first community to take water directly from the river

***values obtained from Experimental Station multiplied by 1.5 to convert to C-8 vs F content originally reported

ND = below the detection limit of 0.6 as C-8 (0.4 as F)

EID079098.01

000192

R17009216

Polymer Products Department
Research and Development Division
Experimental Station

cc: S. C. Croft - 256
M. A. Kaiser - 256
T. K. Wu - 323
PRAL File - 256
I.C. - 323

ANALYTICAL REPORT

June 25, 1984

TO: J. F. DOUGHTY - PPD, WASHINGTON WORKS

FROM: S. R. LAAS *SR Laas*

PERFLUOROOCCTANOATE (C8) IN WATER

(Job No. 840-0670; PRAL Nos. 84-3201-6; 3464-68; 3979-82, Notebook No. E27552)

Fifteen samples of water have been analyzed for perfluorooctanoate (C8) by electron capture gas chromatography. Method ES-567 was used with the following modifications: sample size was 10g; lyophilization was ~18-20 hours; concentration of perfluorodecanoate internal standard was decreased 10 fold. Spiked standards at concentrations of 0.1, 0.2, 0.3, 0.4 ppb were examined. A reproducible detectable peak was observed for 0.4 ppb and we have used this as our detection limit. No C8 peak was detected in the spiked standards < .4 ppb. For the quantitation we had linear calibration curves over the range of 0.4 to 1 ppb. The samples were freeze dried, derivitized, and analyzed in duplicate. The results are expressed as ppb fluoride where $\text{ppb F} = 0.688 \times \text{ppb perfluorooctanoate}$.

The results are given in the attached table. If you have any questions, don't hesitate to call.

msg
Attachment

Keywords:
GC
Perfluorooctanoate
Water

EID079099

000193

RJZ009217

TABLE I

Perfluorooctanoate in Water

<u>Pral No.</u>	<u>Designation</u>	<u>ng F/g Water (ppb)^(a)</u>
84-3401	P	n.d.
84-3402	D	n.d.
84-3403	L	0.4
84-3404	G	n.d.
84-3405	RD	n.d.
84-3406	WB	0.8
84-3464	B	n.d.
84-3465	WW	n.d.
84-3466	R	n.d.
84-3467	RW	n.d.
84-3468	PP	n.d.
84-3979	WB	0.7
84-3980	L	n.d.
84-3981	WW	n.d.
84-3982	LB	1.

(a) n.d. = none detected; detection limit = 0.4 ppb.

000194

EID079100

RJZ009218

CONFIDENTIAL

AR 226 - 1400

D u P o n t

I N T E R O F F I C E M E M O R A N D U M

Date: 12-May-1987 03:06pm EST
From: TONY PLAYTIS
PLAYTIS
Dept: TEFTECH
Tel No: 2775

TO: ROGER ZIPFEL (ZIPFEL)

CC: JOHN CRUM (CRUM)

Subject: C8 In Water

Attached is a copy of the analytical report for our five water samples, which are identified as follows.

#1 - Washington Works drinking fountain, B3.

#2 - Powell's General Store, Washington WV

#3 - Lubeck Pennzoil, Lubeck WV

#4 - Mason's Village Market, Little Hocking OH

#5 - 812 20th Street, Vienna WV

C. L. Hill obtained samples 1-4 by driving to each location and asking to have a plastic bottle filled with drinking water. Sample 5 was taken by D. K. Moore at his home. All samples were taken on 3/13/87.

Note that the results are expressed as ppb F. When converted to ppb C8, the result of 1.3 ppb becomes 1.9 ppb. This result is higher than those from 1984, but considering how close we are to the detection limit of the test, the difference is probably not significant.

EID079091

000195

RJZ009208

Polymer Products Department
Research & Development Division
Experimental Station

cc: M. A. Kaiser - 256
S. R. Laas - 256
M. Lombarski - 269
B. S. Shepard - 323
G. J. Sloan - 323
PRAL File - 256
I.C. - 323

ANALYTICAL REPORT

May 7, 1987

To: A. J. Playtis - PPD, Washington Works

From: M. J. Vilone and R. M. Vasta - PPD, ESL 269

mgv

QWJ

PERFLUOROOCCTANOATE (C8) IN WATER
(Job No. 870-441; PRAL Nos. 87-2933 - 2937, Notebook No. E44875)

Five samples of water have been analyzed for perfluorooctanoate (C8) by electron capture gas chromatography. Method ES-567 was used with the following modifications: sample size was 10 g; lyophilization was -18-20 hours; concentration of perfluorodecanoate internal standard was decreased 10 fold. Spiked standards at concentrations of 0.4, 0.5, 0.8, 1.0 and 1.9 ppb were examined. A reproducible detectable peak was observed for 0.4 ppb and we have used this as our detection limit. No C8 peak was detected in the spiked standards <.4 ppb. For the quantitation we had linear calibration curves over the range of 0.4 to 1.9 ppb. The samples were freeze dried, derivitized, and analyzed in duplicate. The results are expressed as ppb fluoride where $\text{ppb F} = 0.688 \times \text{ppb perfluorooctanoate}$.

The results are given in the attached table. If you have any questions, don't hesitate to call.

gmn
Attachment

Keywords:
GC
Perfluorooctanoate
Water

EID079092

000196

RJZ009209

Perfluorooctanoate in Water

<u>PRAL</u>	<u>Designation</u>	<u>ngF/g. H₂O (ppb)</u> *
87-2933	#1	n.d.
87-2934	#2	1.3 1.9 ∞ C-8
87-2935	#3	1.3 1.9 ∞ C-8.
87-2936	#4	n.d.
87-2937	#5	n.d.

* n.d. = none detected; detection limit = 0.4 ppb

.58 at C-8

000197

EID079093

RJZ009210

D u P o n t

I N T E R O F F I C E M E M O R A N D U M

Date: 4-May-1987 02:09pm EST
From: TONY FLAYTIS
FLAYTIS
Dept: TEFTECH
Tel No: 2775

TO: ROGER ZIPFEL

(ZIPFEL)

Subject: CB in Water

The following results have been received by phone; a letter will follow by the end of the week. The detection limit of the test is 0.4 ppb.

Sample	ppb_CB
Washington Works drinking fountain, B3	<0.4
Powell's General Store, Washington WV	1.3
Lubeck Pennzoil, Lubeck WV	1.3
Mason's Village Market, Little Hocking OH	<0.4
812 20th Street, Vienna WV	<0.4

R1Z009211

000198

EID079094

CONFIDENTIAL

AR 226 - 1401

Z-49 REV. 3/81



E. I. DU PONT DE NEMOURS & COMPANY
INCORPORATED
WILMINGTON, DELAWARE 19898

POLYMER PRODUCTS DEPARTMENT

CC: R. J. ZIPFEL, WASHINGTON WORKS
J. B. ARMITAGE
W. L. SPROUT, CR&D
D. G. WIKA

June 12, 1987

G. L. KENNEDY
CR&D DEPARTMENT
HASKELL LAB

AMMONIUM PERFLUOROCTANOATE (C-8)

Please establish an acceptable level for C-8 in blood, and an acceptable level for C-8 in community drinking water.

H. A. SMITH
SAFETY, ENERGY & ENVIRONMENTAL AFFAIRS
MANUFACTURING DIVISION

HAS/is

000199

EID079034

RJZ009054

AR 226 - 1402

CENTRAL RESEARCH AND DEVELOPMENT DEPARTMENT
HASKELL LABORATORY FOR TOXICOLOGY
AND INDUSTRIAL MEDICINE

cc: J. B. Armitage-
PPD, M-5622
W. L. Sprout

Copy to Rosen Zippel on 7/2/87

Keep this limited to those who are involved in calculations and Green

June 25, 1987

TO: H. A. SMITH
PPD
M-5625

FROM: G. L. KENNEDY, JR. *GLK*

② New to kids 50% in 8-12 hrs
① this is in air 3 min 100 (new research) the amount is 5 ppm

AMMONIUM PERFLUOROCTANOATE
(Ref.: Letter HAS-GLK, 6/12/87)

An acceptable level for ammonium perfluorooctanoate (C-8) in the blood of workers would be 0.5 ppm. This value has been calculated using the average daily C-8 accumulation rate observed in new employees who were exposed to airborne concentrations of 0.008 mg/m³ (memo, J. G. Loschiavo to R. J. Zipfel, 7/29/82). From this data, a steady-state concentration of 0.546 ppm, which represents the dynamics of exposure and elimination, was estimated (Memo, T. P. Pastoor to J. G. Loschiavo, 2/25/82). These estimates appear consistent with most of the reported human data but the data base is not too extensive. In addition, in rat inhalation experiments, no signs of toxicity were detected following exposure to 1 mg/m³, an atmospheric concentration corresponding to a blood level in the male rat of 12 ppm. Extrapolation of the data relating the concentration of C-8 in the air to blood levels in the rat suggests that inhalation of 0.01 mg/m³ would result in blood level of approximately 1 ppm (equation is blood level = 12 $\sqrt{\text{air concentration}}$).

An acceptable level for community drinking water would be 5 ppb. This value has been arrived at as follows:

1. The AEL (8-hr TWA) is 0.01 mg/m³; a worker breathing 10m³/day would take in 0.1 mg. Assume 100% absorption.
2. Daily ingestion by man of 2 L of water/day: 0.1 mg/2L (assume 100% absorption) = 50 ppb (a concentration in water).

(needs to be in blood)
2.1 mg in blood
2.1 mg in blood

000200

EID078779

RJZ005408

3. However, community populations are not equivalent to worker populations. Therefore, factor in a 10X reduction - 5 ppb (concentration in water).

This doesn't take into account the time factor (worker exposed 8 hours, not-exposed 16 hours, etc. whereas drinking water intake could be anytime during 16 hours, off 8 hours, etc.). However, the long half-life of this chemical in the blood might make this consideration less important.

I hope that these suggested guidelines will be useful. Please call if you have any questions.

GLK:me

000201

EID078780

RJZ005409

CONFIDENTIAL

AR 226 - 1403

INTEROFFICE MEMORANDUM

Date: 01-Apr-1991 11:07am
From: VMSSMail User ANDERSWP
ANDERSWP@ISDCV2@CDCIL1@MRGATE
Dept:
Tel No:

To: BERGAS@CSOC@MRGATE

Subject: Request for CEG for Ammonium Perfluorooctanoate in Drinking Water

Date: 04/01/91 11:02:15
To: BERGAS --CSOC Berg, Amy

From: W. P. Anderson, Jr.

** Resending note of 03/28/91 15:26

Subject: Request for CEG for Ammonium Perfluorooctanoate in Drinking Water
After our discussion, I am requesting you to ask the AEL Committee to establish a CEG for Ammonium Perfluorooctanoate in Drinking Water. Per the Haskell Lab Guide, "Setting Acceptable Exposure Limits," I assume that the value we will get will be based on 20% of total intake allocated to water; and 80% to air since a CEG for C-8 has already been established for air.

I am also requesting that the committee, or some special group from Haskell, consider the actual health effects to residents adjacent to our Washington Works Plant from exposure to C-8. We believe that the level in drinking water is ca. 2.7 ppb. An air model by The Engineering Department estimates annual air exposure to nearest residents of 0.025 ug/m3.

We would also like to know if the CEG value is by definition one that we can expect "life-time" exposure of community residents without any expected ill effects.

We would like to have this request honored as soon as possible so we can decide on our future path of action.

cc: SEPULVF --ISDCV2 Sepulveda, Fabiola ANDERSWP--ISDCV2 Bill Anderson

EID072215

000202

AR 226 - 1404



DU PONT **POLYMERS**
Achieving greatness through people

JUNE 11, 1991

TO: POLYMERS OCCUPATIONAL HEALTH SITE CONTACTS

FROM: AMY S. BERG

Amy S. Berg

AELs - ACCEPTABLE EXPOSURE LIMITS

The following changes were made in the AEL list at the June meeting. Please replace the corresponding pages in your AEL list with the attached.

Ammonium Perfluoro- CEGw = 1 ug/L.
octanoate (C-8)
(Polymers) [3825-26-1]

DPX-E9636 (Used in AEL = 5 mg/m3 (8- and 12-hour TWA),
Titus\ Herbicide) total dust.
(AG) [122931-48-0]

Propylene Glycol AEL = 10 ppm (8- and 12-hour TWA).
Monomethyl Ether
Acetate (IMG) [108-65-6]

RODA (Chemicals) AEL = 0.5 mg/m3 (8- and 12-hour
[2479-46-1] TWA).

Siduron (AG) AEL = 10 mg/m3 (8- and 12-hour TWA),
[1982-49-6] total dust).

Hydrazine (Fibers). An AEL of 0.05 ppm (8-hour TWA),
skin was established in 1990. When hydrazine came up for
finalization, it was decided to look at the data once
more. After reviewing these data, it was decided to
reduce the AEL to 0.01 ppm (8- and 12-hour TWA), skin.
These data will be part of an updated hazard
determination letter that will be released on June 7,
1991.

Dimethylacetamide AEL = 10 ppm (12-hour TWA), skin.
[127-19-5]

HCFC-123 EEL = 1000 ppm (2-60 minutes)
[306-83-2] with a 2500 ppm 1-minute
ceiling concentration.

EID097177

Note that you were mailed a complete new list in May. Any pages
from old revisions or lists (with dates in the lower left corner earlier
than May 15, 1991) should be discarded.



000203

RA11000001

April 23, 1991

FOR DU PONT USE ONLY

ACCEPTABLE EXPOSURE LIMITS (AEL) LIST - PREFACE

AELs

AELs are exposure limits for chemicals (or for levels of physical agents) set by the Du Pont AEL Committee. AELs specify Time-Weighted Average (TWA) airborne concentrations, doses or biological limits which should not be exceeded, and applicable time periods.

AELs may be set to prevent health effects from exposures for full workshifts (e.g., 8-hour or 12-hour TWA); or to prevent effects from shorter period exposures such as irritation, narcosis, odor or nuisance (e.g., 15-minute TWA). As a general guide, excursions to which short-period AELs apply should occur no more than four times per shift and a recovery period of approximately 30 minutes is required between excursions. In addition, the corresponding full shift (8-hour or 12-hour) AELs should not be exceeded.

AELs are set by the Du Pont AEL Committee, which includes experts in toxicology, industrial hygiene, occupational medicine, pathology, and epidemiology. AELs are based on the best available information from industrial experience, animal studies, and controlled human studies. They are guidelines based on informed judgment, and are not fine limits between safe and dangerous concentrations. They are not for use as relative toxicity indexes, limits for continuous uninterrupted exposure, or proof or disproof of health effects. They should be interpreted and applied by appropriately qualified personnel. Specific questions or consequences of occasional excursions above an AEL should be addressed to the Safety, Health and Environmental Affairs (SHEA) Manager for your business or staff function. Du Pont Engineering Standard S-12-T, "Strategy for Workspace Sampling for Exposures to Chemicals", provides guidelines for evaluation of air sampling data.

An AEL is established in three basic steps. The first step is a request for an AEL by a staff or business function. The second is review of the available toxicity and human health data followed either by a recommendation for a provisional AEL or a recommendation for additional information (i.e., additional testing, or more complete test data from another company). An AEL is in effect but provisional for six months; it is then reviewed to become a final AEL in light of workplace experience and any new data. This review, the third step, concludes the process. However, AELs are updated every five years, or sooner if warranted by new data, by a special subcommittee appointed by the AEL Committee. If this update indicates new data are available that might result in a change in the AEL, the chemical is referred back to the AEL Committee for review.

RAM000002

EID097178

000204

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COMMUNITY EXPOSURE GUIDELINES (CEGs)

CEGs are exposure guidelines that are expected to be without any effect to members of the community during continuous 24-hour a day exposure to a chemical or physical agent. CEGs may be recommended for air or water or for both. As with AELs, CEGs are based on the best available information from industrial experience, animal toxicity studies, controlled human exposure studies, and epidemiological findings. However, because of the variability of sensitivities of members of the community (e.g., the infirm, the old, the young, pregnant females, etc.), versus the healthy worker involved with an AEL, a larger uncertainty factor needs to be used in extrapolating these data to a CEG.

EMERGENCY EXPOSURE LIMITS (EELs)

EELs are set for emergency situations, such as a spill or accidental release of a chemical. They specify brief durations and concentrations from which escape is feasible without any escape-impairing or irreversible effects on health. EELs are only applicable to emergency situations where occurrence is expected to be rare in the lifetime of an individual.

OTHER SOURCES OF EXPOSURE LIMITS

AELs supplement any mandatory regulatory limits developed by national or local governmental agencies. The more stringent limit, either that developed by Du Pont or by the regulatory agency, shall apply.

The American Conference of Governmental Industrial Hygienists (ACGIH) annually publishes a booklet containing Threshold Limit Values (TLVs) for many chemical substances and physical agents. Also, the American Industrial Hygiene Association (AIHA) publishes Workplace Environmental Exposure Limits (WEELs) for some chemicals not found in the TLV booklet. ACGIH TLVs and AIHA WEELs should be used as guidelines for workplace exposures if no other more appropriate limit exists. If a staff or business function has some concern about the validity of a TLV or WEEL, then the AEL Committee should be asked to establish an AEL.

Other compilations of limits (e.g., American Society of Testing and Materials (ASTM) and American National Standards Institute (ANSI) should be used after consultation with your Safety, Health and Environmental Affairs Manager and with Haskell Laboratory.

RANM000003

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HAZARD DETERMINATION GUIDELINES

In Du Pont, hazard determination is defined in a corporate policy (1) quoted below:

When toxicologic and/or epidemiologic data indicate that a chemical might present a carcinogenic, reproductive, developmental, or mutagenic hazard, any staff or business function which proposes to initiate the hazard determination procedure shall inform other interested staff and business functions before issuing a formal request for such determination. Following receipt of the request, the Director of Haskell Laboratory and the Corporate Medical Director shall evaluate the data, and after review by the Vice President of Safety, Health and Environmental Affairs, shall discuss their evaluation with the involved staff and/or business functions. This discussion should cover the extent of knowledge about the hazard associated with the chemical and should also give an indication about the potency of the chemical. The Director of Haskell Laboratory and the Corporate Medical Director will confirm the results of the discussion by letter to the appropriate SHEA manager(s) or their representative.

Carcinogens, developmental and reproductive toxins, and mutagens are defined as follows:

Carcinogen - A substance or agent with the potential to produce or incite cancer. Potency is determined by consideration of the following factors:

- Amount of chemical (dose) required to produce the effect
- Route of exposure
- Type of tumor(s), site, benign or malignant
- Number of animal species affected
- Tumor incidence
- Time to tumor formation
- Metabolism
- Genotoxic effects
- Other factors such as hormonal status, target organ for non-carcinogenic lesions, etc.

Substances or agents considered potent are identified on the AEL List by a capital letter C; less potent substances or agents are identified by a small letter c; substances or agents not considered to be carcinogens are identified by a C in parentheses, e.g., (C).

(1) "Guidelines: Control of Carcinogenic, Reproductive, Developmental, and Mutagenic Risks Posed by Chemicals Made or Used within Du Pont". ELC Corporate Policy and Guidelines, IIC (February 1990). EID097180

FOR DU PONT USE ONLY

Developmental Toxin - An agent with the potential to interfere with the development of an individual while in utero or after birth.

Potency is determined by the Developmental Hazard Index (DHI) which is the ratio of the minimum dose toxic to the mother and the minimum dose toxic to the conceptus. Substances or agents with DHIs of greater than 5 are considered potent and are identified on the AEL List by a capital letter D; DHIs of 3 to 5 indicate a less potent substance or agent and are identified on the AEL List by a small letter d; substances or agents with a DHI of less than 3 are not considered developmental toxins and are identified on the AEL List by a D in parentheses, e.g., (D).

Reproductive Toxin - An agent with the potential to affect adversely the reproductive process of adult males and/or females.

Potency is determined as follows:

- Reproductive toxicity occurred at a dose level considerably below that resulting in other signs of toxicity. These substances or agents are considered potent and are indicated on the AEL List by a capital letter R. Male or female will also be indicated if reproductive toxicity occurred only in one sex.
- Reproductive toxicity occurred at a dose level at or just below that resulting in other signs of toxicity. These substances or agents are considered less potent and are identified on the AEL List by a small letter r. Male or female will also be indicated if reproductive toxicity occurred only in one sex.
- If reproductive toxicity occurred, but only at a dose level considerably greater than that resulting in other signs of toxicity, these substances or agents are not considered reproductive toxins and are identified on the AEL List by an R in parentheses, e.g., (R).

RAM000005

EID097181

FOR DU PONT USE ONLY

Mutagen - A mutagen is an agent with the potential to cause permanent heritable damage in germ (reproductive) cells of exposed individuals. A substance is identified as a mutagen if it is:

- A proven germ cell mutagen,
- Positive in a mammalian in vivo germ cell assay for gene mutations or chromosome aberrations, and/or
- Positive in a mammalian in vivo somatic (non-reproductive) cell assay for gene mutations or chromosome aberrations, and, in addition, the substance is either positive in a mammalian in vivo germ cell assay for DNA damage and repair, or is identified on the AEL List as a reproductive toxin.

Potency is determined by evaluating the following:

- The experimental design and route of administration.
- The dose required to produce genotoxicity.
- The magnitude of the genotoxic response and the presence of a dose-response relationship.
- The general concordance of positive findings among different germ cell genotoxicity assays (if known).
- The genetic endpoint assessed (gene mutations, chromosome aberrations, DNA repair).

Potent mutagens are identified on the AEL List by a capital letter M whereas less potent mutagens receive a small letter m. Agents not considered to be mutagens are identified by a capital letter M in parentheses, e.g., (M).

LIMITS FOR NON-FIBROUS AEROSOLS

The particle size distribution of inhaled material plays a major role in how much and where material is deposited within the respiratory tract. In general, particles having a mass median aerodynamic diameter greater than 30 micrometers are non-respirable. Respirable-size particles are typically defined as particles with a mass median aerodynamic diameter of less than or equal to 3 micrometers. Particles between 30 and 5 micrometers are deposited in the upper respiratory tract (nose) and do not pose a significant hazard to the airway and gas exchange region of the lung. Respirable particles which can deposit in the gas exchange region (< 1 micrometer) can interfere with oxygen transfer or pass directly into the blood. Some AELs for aerosols pertain only to the respirable fraction and these would be so designated on the AEL list. Compliance with respirable fraction AELs is determined from the fraction of aerosol passing a size selector. Thus, when sampling for particulate in air, the particle size (respirable fraction) must be established as follows:

RAM000006

EID097182

000208

FOR DU PONT USE ONLY

RESPIRABLE AEROSOL DEFINITION

Some AELs for aerosols pertain only to the respirable fraction, i.e., that portion of the aerosol which is small enough to reach the lower respiratory tract. Compliance with these AELs should be determined from the fraction of aerosol passing a size selector with the following characteristics (2).

<u>Aerodynamic Diameter (microns)</u>	<u>Percent Passing Selector</u>
≤ 2.0	90
2.5	75
3.5	50
5.0	25
10.0	0

The AEL for particulates is generally expressed as milligrams per cubic meter (mg/m^3) total particulate. Respirable fractions are routinely assumed to be not more than 1/2 of the total particulate limit. Limits are established on a respirable fraction basis only when the particulate poses a significant hazard to the airway gas exchange region of the lung.

LIMITS FOR FIBERS

Fibrous dusts present a special hazard because the physical properties of dust (length versus width of the particle) impart special aerodynamic and, as a result, toxicologic characteristics.

A fiber is defined as a particle having an aspect ratio (length:width) greater than 3. In addition, the fiber must be of respirable size.

Until recently, a mass standard was used for quantification of fiber exposure. However, it has now been demonstrated that the utilization of gravimetric concentrations for comparing the relative toxicities of different fiber types is misleading. For this reason, fiber concentrations are usually reported as fibers/cc.

The AEL Committee has established an upper limit of 2 fibers/cc which incorporates advancing understanding of the biological consequences of deposition of respirable fibers.

EID097183

(2) AIHA Aerosol Technology Committee: Interim Guide for Respirable Mass Sampling, Am. Ind. Hyg. Assoc. J., 31(2):133 (1970).

FOR DU PONT USE ONLY

NUISANCE DUST LIMITS

Nuisance dusts are those that appear to have no biological effects at exposure levels that do not overload lung clearance mechanisms. Total particulate concentration for nuisance dusts should not exceed 10 mg/m³. This limit is set to prevent reduced visibility, to prevent deposits in the eyes, ears and nasal passages, and to prevent injury to the skin or mucous membranes caused by chemical contact or by the mechanical process of cleansing. Respirable concentrations of nuisance dusts usually do not exceed 5 mg/m³. This limit for nuisance respirable particulate should 1) protect the architecture of the air space, 2) prevent the formation of significant amounts of collagen (scar tissue), and 3) protect against the development of non-reversible particle-induced lung injury.

EXPLANATION OF AEL LIST

Chemical [CAS Registry Number]

The more common chemical name used within Du Pont and its Chemical Abstracts Service (CAS) Registry Number are given.

AEL

AELs for particulates are expressed as mg/m³ and apply to actual site temperature and pressure conditions. Sampled air volumes should not be converted to 760 mm Hg and 25°C when calculating measured mg/m³ concentrations for comparisons with AELs.

AELs for gases and vapors are expressed as parts per million (ppm by volume) at 760 mm Hg and 25°C. Measured ppm air concentrations should be compared with these limits under comparable temperature and pressure conditions.

Biological limits are the allowable concentration of a chemical or its metabolites found in a body specimen (e.g., blood or urine). The units may vary depending on the body specimen used (e.g., a blood limit would be expressed as ug of chemical per 100 g (dL) of blood).

REMARKS

This column contains additional information such as AEL averaging time (e.g., 8-hour TWA), regulatory classifications (e.g., OSHA Regulated), other appropriate limits (e.g., TLV or WEEL), particulate information (e.g., total dust), and any skin notation.

The skin notation indicates that the chemical may be absorbed through the skin or mucous membranes in toxicologically significant amounts. This notation implies that measures must be taken to minimize cutaneous contact. Corrosive chemicals are not identified by this notation.

RAM000008

"ATTORNEY-CLIENT PRIVILEGED INFORMATION"

September 19, 1991

To: Walt Stewart
 From: Terry Vandell

Subject: Meeting Minutes Of The On-Site Washington Works Meeting (September 11, 1991, 9:00 AM-11:00 AM)
 Regarding The September 4, 1991 Proposed C-8 Sampling Program

Present: John Doughty, Tony Eichstadt, Wendell Goin, Penny Mahoney, Mike McClusky, Carl Musca, Dave Ramsey,
 Walt Stewart, Terry Vandell

- o Introduction: Walt Stewart, See Attachment 1
- o Chemical Data Results: Penny Mahoney, See Attachment 2

Key Points: Appendix IX constituent levels and presence are inconsistent under the site, whereas the C-8 presence and levels are much more consistent; C-8 found at low ppb level on-site in wells TW27 & TW4, but at much higher levels in wells TW32 and TW33 which are closer to the old supernate ponds (the exact quantitative results from wells 32 & 33 are still pending but are believed to be > 1 ppm).

- o Historical Data Results: Mike McClusky, See Attachment 3

Key Points: In 1984 C-8 found <1.5 ppb .25 to 3 miles downgradient from Washington Works. No C-8 found 12+ miles downstream. C-8 concentration trends on-site at well TW 27 difficult to analyze due to change in analytical technique. However, data do not indicate large increases in C-8 concentration since 1987, (from 2.0 to 5.9 ppb). Off-site water samples from home taps (i.e. from the existing Lubeck wellfield) indicate C-8 from .7 to 3.9 ppb, with the 3.9 ppb measured from a sample taken on 8/8/91. C-8 was detected in a new well in the new Lubeck wellfield (2.7 miles south-southwest of Washington Works), at 2.4 ppb on 6/23/91. No C-8 was found in nearby private water wells, however.

- o C-8 Test Development: Mike McClusky, See Attachment 4

Key Point: CH2M Hill has been authorized to develop a C-8 detection analytical technique to 0.1 ppb.

- o Proposed & "Revised" Sampling Plan: Terry Vandell, See Attachments 5 & 6.

Key Points: On-site C-8 travel time from the supernate ponds to the Lubeck wellfield is approximated at 8 yrs.; off-site to the new Lubeck wellfield, the travel time could range from 49 to 117 years, strongly indicating that "IP" C-8 is even present in the new wellfield, that the transport mechanism was not groundwater, but "possibly" the Ohio River. Calculated $\frac{1}{2}$ of C-8 in the Ohio River is about 1 ppb - 0.5 ppb.

The purpose in conducting the proposed extensive C-8 sampling program is to "verify or dismiss" the presence of C-8 in the new Lubeck wellfield, and to obtain sufficient river water quality data to address the question of whether the river serves as a transport mechanism for C-8. Such an evaluation of the potential transport mechanisms (by the ground water or river) was discussed and agreed to at the August 14, 1991 meeting in Wilmington (called by Mike Deak).

000212

The September 4, 1991 proposed C-8 sampling plan was altered as a result of the September 11, 1991 meeting. The following changes were made:

1. The addition of wells TWM4, TW27^{TW33} and water supply well W331 for C-8 analysis, to compare the historic C-8 results from these wells (TWM4 and TW27) to the results we will obtain from CH2M Hill and the Experimental Station. Well W331 should be tested since it never has been and it is an on-site water supply well, *and well TW33 should have relatively elevated C-8 concentrations.*
2. The deletion of all of the riverbank soil samples, since John Doughty informed us during the meeting that the current analytical technique for C-8 in soils is only accurate for large C-8 concentrations (i.e. uses a simple burn/weight technique to determine the volume of C-8 present in the ppm range). This technique must be refined soon for the EPA VI soil sample analyses...
3. The revised Sept. 4, 1991 sampling plan is included as Attachment 5.

NOTE: Sampling was conducted and completed on 9/11, 12 & 13th/91 by Jim Yoak, Penny Mahoney, Nina Mazdai, Terry Vandell (of DuPont), with assistance from Bill Packard (Lubeck City). All samples were collected on 9/11 and 9/12 and shipped out on 9/12/91, with the exception of well TWM4, which was sampled on 9/13/91, with the sample shipped on 9/13/91.

Limited Distribution Only To:

Jim Allen
Mike Deak
Wendell Goin
Carl Musca

000213

USEPA 10322

DF 000213

ATTACHMENT 1 WALT STEWART

DU PONT CONFIDENTIAL
ATTORNEY/CLIENT COMMUNICATION

AIM

To review a proposed sampling plan for C-8 and F-113 in surface and groundwater, in a way that reviews all existing data available to-date, so that agreement can be reached on the purpose and procedures for obtaining additional quality information.

AGENDA

- | | | |
|----|--------------------------|----------|
| 1) | Introduction | Stewart |
| 2) | Status | Mahoney |
| | • Site Overview | |
| | • Chemicals Detected | |
| 3) | Historical Data | McClusky |
| | • Off-site Sampling | |
| | • Current Test Results | |
| 4) | Test Development | McClusky |
| | • Limits and Guidelines | |
| | • Experimental Station | |
| | • CH ₂ M Hill | |
| 5) | Proposed Sampling Plan | Vandell |
| | • Hydrogeologic Data | |
| | - Plant | |
| | - Off-site | |
| | • Sampling Locations | |

DI:000247

000214

C-8 BACKGROUND INFORMATION

- GROUNDWATER FLOW REVIEW
- OVERVIEW OF HISTORICAL CHEMICAL ANALYSIS
- RECENT CHEMICAL ANALYSIS
- NEW LUBECK WELL RESULTS

000215

RIVER LEVEL

RIVER

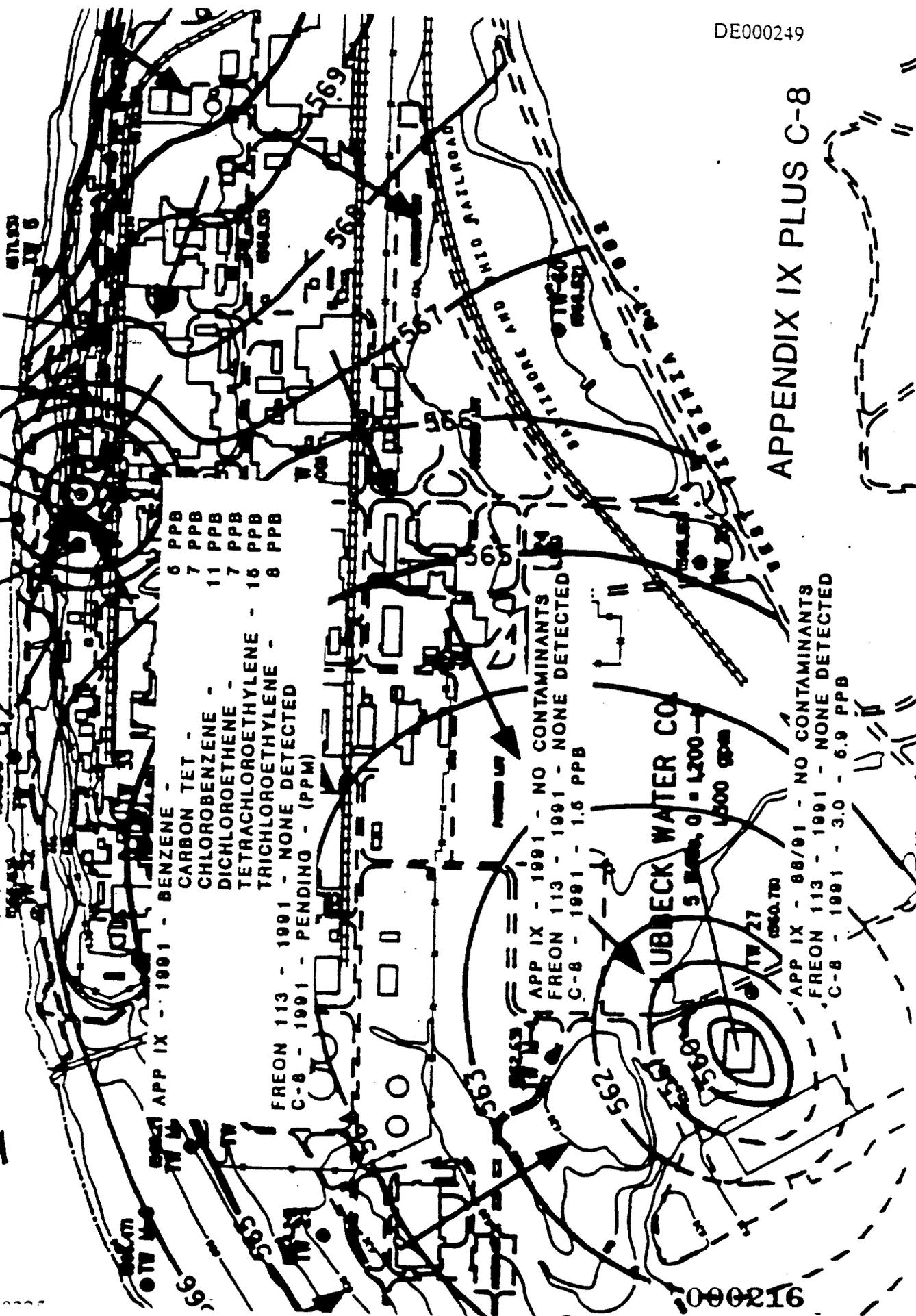
RANNEY WELL

4 PPB
7 PPB
18 PPB

CHLOROFORM -
TRANS-DICHLOROETHYLENE -
TRICHLOROETHYLENE -

APP IX - 1988 -
C-8 - 1991 - PENDING

APP IX - 1991 - NO CONTAMINANTS
FREON 113 - 1991 - 260 PPB
C-8 - 1991 - PENDING - (PPM)



6 PPB
7 PPB
11 PPB
7 PPB
16 PPB
8 PPB

BENZENE -
CARBON TET -
CHLOROBENZENE -
DICHLOROETHENE -
TETRACHLOROETHYLENE -
TRICHLOROETHYLENE -

FREON 113 - 1991 - NONE DETECTED
C-8 - 1991 - PENDING - (PPM)

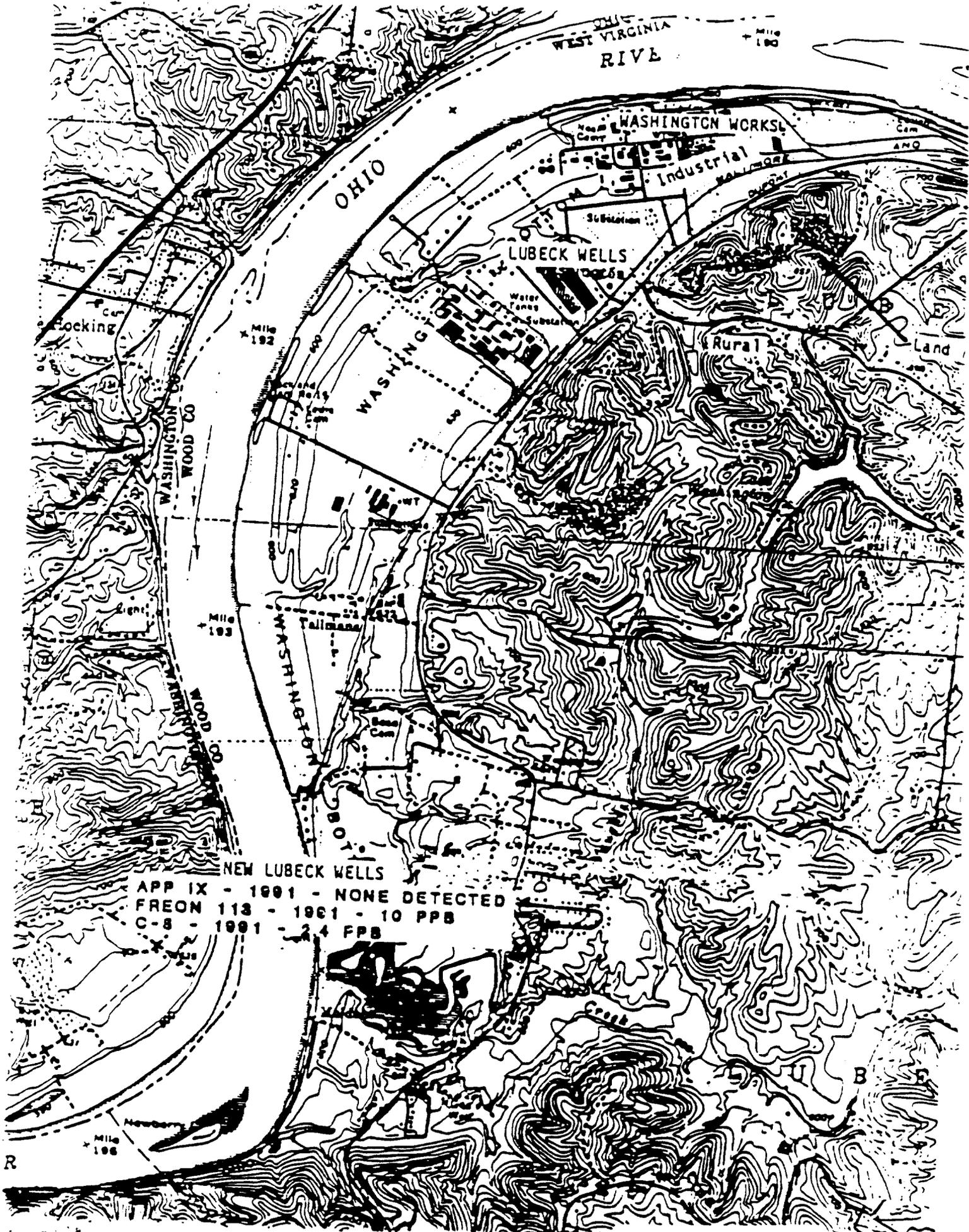
APP IX - 1991 - NO CONTAMINANTS
FREON 113 - 1991 - NONE DETECTED
C-8 - 1991 - 1.6 PPB

LUBBECK WATER CO

5.000, 0 = 1200 -
1600 GPM

APP IX - 88/91 - NO CONTAMINANTS
FREON 113 - 1991 - NONE DETECTED
C-8 - 1991 - 3.0 - 6.9 PPB

APPENDIX IX PLUS C-8



NEW LUBECK WELLS
 APP IX - 1991 - NONE DETECTED
 FREON 113 - 1991 - 10 PPB
 C-8 - 1991 - 24 PPB

ATTACHMENT 3 MIKE MCCKLUSKY

C-8 SAMPLING (MARCH - JUNE 1984)

<u>LOCATION</u>	<u>DISTANCE (MILES)</u>	<u>C-8 PPB (0.6 LIMIT)</u>
PKSBG-HOME TAP	7.5 UPSTREAM	<
WH-DRINK FTN	---	<
DIST. CTR-WELL	0.25 DOWN	<
WASHINGTON-STORE TAP	0.25 DOWN	1.2, 1.0
LUBECK-STORE TAP	0.25 DOWN	1.5
L. HOCKING-STORE TAP	3 DOWN	0.8, 0.6
BELLEVILLE-PRIVATE WELL	12 DOWN	<
REEDSVILLE-STORE TAP	14 DOWN	<
RAVENSWOOD-STORE TAP	29 DOWN	<
RACINE-STORE TAP	50 DOWN	<
POINT PLEASANT-STORE TAP	74 DOWN	<
GALLIPOLIS-STORE TAP(*)	79 DOWN	<

Detection Limit

(*) NEAREST COMMUNITY TO TAKE WATER DIRECTLY FROM OHIO RIVER.

000218

152000-101

C-8 ON SITE SAMPLING

TEST WELL #27

6/ 4/87
5/11/88
11/ 4/88
5/ 4/89
8/ 1/89
10/24/89
2/27/90
4/20/90
7/13/90

8/ 9/90
10/19/90

C-8 PPB

2.0
1.5
1.3
<0.6
1.3
1.5
1.5
1.5
1.6

<10
<10 (3.0)
(3.0)

REVISED TEST Tw 27

1/15/91
4/18/91
7/24/91
8/ 2/91

2.9
3.0
5.9
5.0 } increase may
be from
revised test

ADJACENT WELL: MW-4

5/13/91
8/ 1/91

1.5
1.4

WW DRINKING WATER

3/13/87 BLDG 3
11/ 2/88 BLDG 212
5/12/88 BLDG 212
5/ 8/89 BLDG 212

<0.6
<0.6
<0.6
<0.6

* Due Rainey - suggest sampling w331 in East
Well Field for C-8 analysis

000219

USEPA 10328

DE000252

C-8 OFF SITE SAMPLING

C-8 PPS

3/13/87	LUBECK BUSINESS TAP (2)	
5/12/88	LPSD HOME TAP -P	1.9, 1.9
11/ 2/88	LPSD HOME TAP -P	2.2
5/ 7/89	LPSD HOME TAP -P	1.4
		0.7
5/23/91	LPSD HOME TAP -M	
5/29/91	LPSD HOME TAP -C	3.8
8/ 8/91	LPSD HOME TAP -M	3.8
		3.9

3/13/87	VIENNA HOME TAP -M	
3/13/87	LITTLE HOCKING BUSINESS TAP	<0.6
5/12/88	LITTLE HOCKING HOME TAP -R	<0.6
		<0.6

11/28/90	LUBECK PRIVATE WELLS (2)	<i>near new Lubeck well field</i>	<0.6, <0.6
8/ 9/91	LUBECK PRIVATE WELLS (2)		<1.0, <1.0

6/23/91	NEW LUBECK WELL	2.4 (*)
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(*) CH2MHILL CONFIRMED "PRESENCE" OF C-8

ATTACHMENT 4 MIKE MCCCLUSKY

C-8 HUMAN EXPOSURE

<u>LIMITS</u>	<u>UG/M3</u>
TLV (3M)	100
AEL (DUPONT)	10
CEG (AIR, WATER)	

HASKELL ESTABLISHED: 8 UG C-8 PER 24 HOURS

80% BY AIR 6.4 UG/ 20M3 = 0.32 OR 0.3 UG/M3

20% BY WATER 1.6 UG/ 2 L = 0.80 OR 1 PPB

8.0 ~ 8

OUTSIDE CONTRACT LAB: CH2MHILL

\$23M AUTH TO PROVIDE 0.1 PPB C-8 IN WATER ANALYSIS

000221

USEPA 10330

15200010

ATTACHMENT 5 TERRY VANDELL

1. HYDROGEOLOGY :

SAND & GRAVEL AQUIFER, ON-SITE 65-100 FT DEEP; OFF-SITE AT NEW LUBECK WELLS, 15-65 FT DEEP, YIELDS OF SEVERAL HUNDRED GPM. WELLS DRILLED VIA CABLE TOOL RIG, DEVELOPED @ SEVERAL HUNDRED GPM, 6 TO 32 HRS EACH.

2. C-8 TIME OF TRAVEL IN GW:

ON-SITE, TO LUBECK WELLS, 5 YRS.

OFF-SITE TO NEW LUBECK WELLS, 49-117 YRS.

3. PERCENTAGE OF C-8 IN OHIO RIVER:

20,000 LBS/YR C-8 / ^{20,000}~~10,000~~ CFS =
.000634 LBS/SEC / 623607 LBS/SEC
= .000000001, OR 1 PPB

4. C-8 & FREON 113 SAMPLING PLAN: REQUIRED BY MIKE DEAK, CORPORATE SHEA MANAGER (AUGUST 14, 1991), TO RESAMPLE NEW LUBECK WELLS, OLD LUBECK WELLS, & RIVER WATERS. PURPOSE: TO "VERIFY" THE PRESENCE, EXTENT AND PATH /OR THE ABSENCE, OF C-8 OFF-SITE, "ASAP".

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000222

SECRET

IN THE CIRCUIT COURT OF WOOD COUNTY, WEST VIRGINIA

JACK W. LEACH, et al.,

Plaintiffs,

v.

CIVIL ACTION NO.: 01-C-608
(Judge George W. Hill)

E. I. DU PONT DE NEMOURS AND COMPANY,
and LUBECK PUBLIC SERVICE DISTRICT

Defendants.

**RESPONSES OF E. I. DU PONT DE NEMOURS AND COMPANY TO
PLAINTIFFS' THIRD SET OF REQUESTS FOR ADMISSIONS TO DUPONT**

Pursuant to West Virginia Rule of Civil Procedure 36, Defendant, E. I. du Pont de Nemours and Company ("DuPont"), by counsel, makes its Responses to "Plaintiffs' Third Set of Requests for Admissions to DuPont" ("Third Set of RFAs"). Any admission made is for the purpose of this pending action only and is not an admission for other purposes, nor may it be used in any other proceeding. Any admission is also subject to all pertinent objections to admissibility interposed at trial. Information provided in these responses is based upon such information as presently is reasonably available to DuPont. DuPont responds and objects as follows:

I. GENERAL OBJECTIONS

DuPont's responses to Plaintiffs' Third Set of Requests for Admissions are subject to the general objections set forth below. These general objections form a part of the response to each and every Request for Admission and are set forth here to avoid duplication and repetition. DuPont's specific responses to each Request for Admission are made subject to, and without waiving, these General Objections, which are incorporated by reference to each of DuPont's responses. The failure to list a specific General Objection in a response should not be construed

as a waiver of that objection. By admitting or denying Plaintiffs' Requests for Admission, DuPont does not concede that the subject matter of such Requests are relevant in the present action or that DuPont's responses are admissible. DuPont reserves the right to amend or supplement its responses.

GENERAL OBJECTION 1: DuPont objects to Plaintiffs' Requests for Admissions to the extent that they seek to characterize the contents of documents, which documents speak for themselves.

GENERAL OBJECTION 2: DuPont objects to Plaintiffs' Requests for Admissions to the extent that they imply that DuPont's "acceptable exposure limits" ("AELs") and "community exposure guidelines" ("CEGs") are set at levels that are predictive of adverse human health effects. DuPont's processes for setting AELs and CEGs are analogous to regulatory agency risk assessments. These mathematically based risk assessments encompass a number of typically very conservative assumptions and safety factors, many of which are default versus actual figures. Risk assessments are designed to be overly protective of human health, with a wide margin of safety, are not predictive of any particular health effects, and should not be used in such a manner. Moreover, they cannot be used to support a claim for medical monitoring.

GENERAL OBJECTION 3: DuPont objects to Plaintiffs' Requests for Admissions to the extent that they seek information that is not relevant to the claims or defenses at issue in this litigation.

GENERAL OBJECTION 4: DuPont hereby preserves for trial its objections as to those of Plaintiffs' Requests for Admissions that ask DuPont to authenticate a document, except that DuPont admits to the authenticity of the documents as set forth below.

GENERAL OBJECTION 5: DuPont objects to Plaintiffs' Requests for Admissions to the extent that that they are deliberately incomplete and calculated to lead to a false conclusion.

II. OBJECTIONS AND ANSWERS TO REQUESTS FOR ADMISSIONS

REQUEST FOR ADMISSION NO. 1. Attached hereto at Exhibit A is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 2. In November of 1982, Bruce W. Karrh, M.D., Director of DuPont's Medical Division, recommended that available practical steps be taken to reduce C-8 exposures to DuPont plant employees because, among other things, C-8 is retained in the blood for a long time, all employees, not just Teflon area workers, are exposed, and there is great potential for current or future exposure of members of the local community from emissions leaving the DuPont Washington Works plant perimeter.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without waiving this objection, DuPont admits as follows: that after review of materials sent to Dr. Karrh from J.W. Raines about the scrubbing of fine powder exhausts, Dr. Karrh responded to J.W. Raines that even though the C-8 exposure to plant employees was small, Dr. Karrh recommended that available practical steps be taken to reduce this exposure, because, among other things, C-8 is retained in the blood for a long time, all employees, not just Teflon area workers, are exposed, and there is great potential for current or future exposure of members of the local community from emissions leaving the DuPont Washington Works plant perimeter.

REQUEST FOR ADMISSION NO. 3. Attached hereto at Exhibit B is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 4. By October of 1983, DuPont had begun evaluating the levels of C-8 discharged into the air from DuPont's Washington Works plant in Wood County, West Virginia.

RESPONSE: Denied, except admitted that by October of 1983, DuPont employees had begun ground level modeling for potential levels of C-8 discharged into the air from DuPont's Washington Works plant in Wood County, West Virginia in order to support installation of an air scrubber for a point of emission in the fine powder area.

REQUEST FOR ADMISSION NO. 5. Attached hereto at Exhibit C is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted, except denied as to marginalia.

REQUEST FOR ADMISSION NO. 6. By October of 1983, DuPont had begun evaluating the potential concentrations of C-8 in the Ohio River from DuPont's Washington Works plant in Wood County, West Virginia.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 7. By August of 1984, DuPont had calculated maximum average annual air concentrations of C-8 outside DuPont's Washington Works plant to be 0.0004 mg/m³.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 8. Attached hereto at Exhibit D is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 9. By August of 1984, DuPont had determined that the concentrations of C-8 that had been detected earlier in 1984 by DuPont in the public water supplies near the DuPont Washington Works facility probably came from the aquifer under the Ohio River.

RESPONSE: Denied. except admitted that in or around August 1984, DuPont determined that if the small amounts of C-8 detected were actually present in public water supplies around the Washington Works plant, rather than an artifact of the method of testing, that the source of the C-8 probably came from an aquifer under the Ohio River.

REQUEST FOR ADMISSION NO. 10. In 1984, DuPont had detected C-8 in concentrations exceeding 1ppb in drinking water supplied by the Lubeck Public Service District of Wood County, West Virginia.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 11. Attached hereto at Exhibit E is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 12. In 1984, DuPont had detected C-8 at a concentration exceeding 0.5 ppb in drinking water supplied by the Little Hocking Water Association of Ohio.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 13. By October of 1986, DuPont's management in Wilmington, Delaware had expressed concern about the possible liability resulting from long-term C-8 exposure to its employees and to the population in the communities surrounding DuPont's Washington Works plant and those down-river from the Washington Works plant.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without waiving this objection, denied, except admitted that in an October 20, 1986 memorandum to C.A. Dykes, R.J. Zipfel and G.R. Alms, D.A. Schneider stated, among other things, "Wilmington management is concerned about the possible liability resulting from long-term C-8 exposure to its employees and to the population in the surrounding communities those down-river from the [Washington Works] plant."

REQUEST FOR ADMISSION NO. 14. Attached hereto at Exhibit F is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 15. By December of 1986, DuPont was evaluating the possibility of purchasing the public water supply wells owned by the Lubeck Public Service District then located near DuPont's Washington Works plant, which wells supplied the drinking water in which DuPont had detected concentrations of C-8 exceeding 1 ppb.

RESPONSE: DuPont objects to this Request for Admission on the ground that it sets forth more than one matter to be admitted or denied in derogation of W. Va. R. Civ. P. 36(a).

DuPont objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without waiving these objections, DuPont admits as follows: by December 1986, DuPont was evaluating the possibility of purchasing the public water supply wells owned by the Lubeck Public Service District then located near DuPont's Washington Works plant and further admits that DuPont had detected concentrations of C-8 exceeding 1 ppb at two taps supplied by the Lubeck Public Service District.

REQUEST FOR ADMISSION NO. 16. Attached hereto at Exhibit G is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Denied.

REQUEST FOR ADMISSION NO. 17. One factor taken into consideration by DuPont in December of 1986 with respect to the possibility of purchasing the Lubeck Public Service District water wells was the value of protecting DuPont's Washington Works plant site from public liability, both from proximity of adjacent owners and possible accusation of contamination of groundwater.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without waiving this objection, admitted as phrased.

REQUEST FOR ADMISSION NO. 18. By January of 1987, DuPont had completed a "fenceline screening" survey of chemicals emitted into the atmosphere from DuPont's Washington Works plant (hereinafter the "Washington Works Fenceline Screening Survey").

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 19. Through its Washington Works Fenceline Screening Survey, DuPont calculated C-8 emissions to the atmosphere from its Washington Works plant to be 0.0048 mg/m³ at the DuPont Washington Works plant property line.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 20. Attached hereto at Exhibit H is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted, except denied as to marginalia.

REQUEST FOR ADMISSION NO. 21. As a result of DuPont's Washington Works Fenceline Screening Survey, H.A. Smith of DuPont's Safety, Energy & Environmental Affairs Manufacturing Division in Wilmington, Delaware requested on June 9, 1987, that DuPont's Haskell Laboratory develop community exposure guidelines ("CEGs") for C-8.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 22. Attached hereto at Exhibit I is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Denied, except admitted that the document attached to Plaintiffs' Third Set of RFAs as Exhibit I is an authentic and accurate copy of a portion of a business record of DuPont prepared and kept in the regular course of business of DuPont.

REQUEST FOR ADMISSION NO. 23. By June of 1987, DuPont had identified the elimination of certain supernate ponds that had been used for disposal of materials containing C-8 at DuPont's Washington Works plant as a potential mechanism for reducing public exposure to C-8 from DuPont's Washington Works plant.

RESPONSE: Denied, except admitted that by June of 1987, DuPont had identified that elimination of certain supernate ponds that had been used for disposal of materials containing C-8 at DuPont's Washington Works plant may have helped to eliminate the presence of C-8 in an aquifer from which the Lubeck Public Water System drew water.

REQUEST FOR ADMISSION NO. 24. Attached hereto as Exhibit J is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Denied, except admitted that Exhibit J is an authentic and accurate copy of two separate business records of DuPont (EID091378-401 and EID091402) prepared and kept in the regular course of business of DuPont. DuPont further specifically denies as to marginalia.

REQUEST FOR ADMISSION NO. 25. By June of 1987, DuPont had determined that elimination of certain supernate ponds at DuPont's Washington Works plant site that had been used for the disposal of materials containing C-8 could help to eliminate C-8 contamination of the aquifer from which water was then drawn by the Lubeck Public Service District.

RESPONSE: DuPont objects to this Request for Admission on the ground that it sets forth more than one matter to be admitted or denied in derogation of W. Va. R. Civ. P. 36(a). DuPont also objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without waiving these objections, admitted as phrased.

REQUEST FOR ADMISSION NO. 26. By June of 1987, DuPont had determined that the levels of C-8 detected in water supplied by the Lubeck Public Water District wells near DuPont's Washington Works plant had increased from levels detected in 1984 to 1.9 ppb in 1987.

RESPONSE: Denied, except admitted that in 1987 DuPont tested several samples of water supplied by the Lubeck Public Service District and one test measured 1.9 ppb of C-8.

REQUEST FOR ADMISSION NO. 27. By June of 1987, DuPont's Medical Director, Bruce W. Karrh, M.D., stated that DuPont needed to continue to pursue those programs aimed at reducing the public exposure to C-8 as vigorously as DuPont could.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without waiving this objection, admitted as phrased.

REQUEST FOR ADMISSION NO. 28. On June 12, 1987, H.A. Smith with DuPont's Safety, Energy & Environmental Affairs Manufacturing Division again requested that DuPont's Haskell Laboratory establish an acceptable level for C-8 in community drinking water, and also requested that DuPont's Haskell Laboratory establish an acceptable level for C-8 in blood.

RESPONSE: DuPont objects to this Request for Admission on the ground that it sets forth more than one matter to be admitted or denied in derogation of W.Va. R. Civ. P. 36(a). Subject to and without waiving this objection, denied, except admitted that on June 12, 1987, H.A. Smith with DuPont's Safety, Energy & Environmental Affairs Manufacturing Division requested that G.L. Kennedy with DuPont's Haskell Lab establish an acceptable level for C-8 in blood, and an acceptable level for C-8 in community drinking water.

REQUEST FOR ADMISSION NO. 29. Attached hereto at Exhibit K is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 30. On June 25, 1987, Gerald L. Kennedy of DuPont's Haskell Laboratory issued a Memorandum to H.A. Smith of DuPont stating that an acceptable level for C-8 in the blood of workers would be 0.5 ppm.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is vague and ambiguous. DuPont objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without waiving these objections, DuPont admits as follows: on June 25, 1987, Gerald L. Kennedy of DuPont's Haskell Laboratory issued a Memorandum to H.A. Smith of DuPont stating that an acceptable level for C-8 in the blood of workers would be 0.5 ppm. DuPont understands that the word "acceptable" was meant to denote a relative goal and not an absolute standard under which reported levels above 0.5 ppm would be viewed as not protective of human health.

REQUEST FOR ADMISSION NO. 31. Attached hereto at Exhibit L is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted, except denied as to marginalia.

REQUEST FOR ADMISSION NO. 32. On June 11, 1987, DuPont's Medical Director, Bruce W. Karrh, M.D., advised Roger J. Zipfel of DuPont's Washington Works plant that the plant needed to place the highest priority on issues relating to the presence of C-8 outside the Washington Works plant boundaries.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without waiving this objection, admitted as phrased.

REQUEST FOR ADMISSION NO. 33. Attached hereto at Exhibit M is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Denied, except admitted that the document attached to Plaintiffs' Third Set of RFAs as Exhibit M is an authentic and accurate copy of a portion of a business record of DuPont prepared and kept in the regular course of business of DuPont.

REQUEST FOR ADMISSION NO. 34. By July of 1987, DuPont's Washington Works plant had developed a C-8 control plan that included the removal of DuPont's Washington Works employees from C-8 exposure, if the level of C-8 in their blood exceeded 50% of the maximum safe level of C-8 in blood established by DuPont's Haskell Laboratory.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without waiving this objection, denied except admitted that in a July 7, 1987 memorandum, Roger J. Zipfel, an employee of DuPont's Washington Works plant, discusses a C-8 control plan that, among other things, included a provision that if any Washington Works employee had a level of C-8 in his or her blood at a level more than 50% of the maximum safe level in blood as to be set by Haskell Laboratory, that employee would be removed from C-8 exposure.

REQUEST FOR ADMISSION NO. 35. By July of 1987, A.C. Huston with DuPont's Washington Works plant strongly recommended that DuPont purchase the Lubeck Public Service District property near the DuPont Washington Works plant, noting that the elimination of the use of those wells as a public drinking source before USEPA's new corrective action requirements became effective and before any remediation actions were required would be a distinct advantage to DuPont, recognizing that remediation of the drinking water wells could cost millions of dollars.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without waiving this objection, denied except admitted that by July of 1987, A.C. Huston with DuPont's Washington Works plant strongly recommended that DuPont purchase the Lubeck Public Service District property near the DuPont Washington Works plant, noting that the elimination of the use of those wells as a public drinking source before USEPA's new corrective action requirements became effective and before any remediation actions were required would be a distinct advantage to DuPont, recognizing that remediation could cost millions of dollars.

REQUEST FOR ADMISSION NO. 36. Attached hereto at Exhibit N is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 37. Attached hereto at Exhibit O is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 38. By March of 1988, DuPont's Acceptable Exposure Limit Committee had accepted 0.3 ug/m3 as a provisional value for DuPont's community exposure guideline (CEG) for C-8 in community air, but did not recommend or accept any community exposure guidelines for C-8 in community drinking water.

RESPONSE: DuPont objects to this Request for Admission on the ground that it sets forth more than one matter to be admitted or denied in derogation of W.Va. R. Civ. P. 36(a). DuPont also objects to this Request for Admission on the ground that it is deliberately

incomplete and calculated to lead to a false conclusion. Subject to and without waiving these objections, denied, except admitted that by March of 1988, DuPont's Acceptable Exposure Limit Committee had accepted 0.3 $\mu\text{g}/\text{m}^3$ as a provisional value for DuPont's community exposure guideline ("CEG") for C-8 in community air.

REQUEST FOR ADMISSION NO. 39. In March of 1989, DuPont's Medical Director, Bruce W. Karrh, M.D., met with DuPont Washington Works employees to discuss the status of the DuPont Washington Works C-8 control plan and restated his position that DuPont should continue to place high priority to reduce the general public's exposure to C-8.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without waiving this objection, admitted as phrased.

REQUEST FOR ADMISSION NO. 40. Attached hereto at Exhibit P is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 41. By April of 1991, DuPont had closed on its purchase of the Lubeck Public Service District property that had been located near DuPont's Washington Works plant.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 42. Although requested several years earlier in 1987, DuPont's Acceptable Exposure Limit Committee did not place the issue of determining an acceptable community exposure guideline for C-8 in community water on its agenda until after

DuPont had closed on its purchase of the Lubeck Public Service District property near DuPont's Washington Works plant.

RESPONSE: DuPont objects to this Request for Admission on the ground that it sets forth more than one matter to be admitted or denied in derogation of W.Va. R. Civ. P. 36(a). Subject to and without waiving this objection, denied.

REQUEST FOR ADMISSION NO. 43. DuPont had hoped that moving the Lubeck Public Service District public drinking water supply wells approximately two miles further down the Ohio River from the DuPont Washington Works plant and purchase of the old Lubeck Public Service District water supply wells by DuPont would eliminate the presence of C-8 in drinking water supplied by the Lubeck Public Service District.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is vague and ambiguous. DuPont further objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without waiving these objections, DuPont admits as follows: DuPont considered one benefit of the Lubeck Public Service District drawing water from new wells located approximately two miles further down the Ohio River from the DuPont Washington Works plant than the old Lubeck wells to be elimination of the presence of C-8 in drinking water supplied by the Lubeck Public Service District.

REQUEST FOR ADMISSION NO. 44. By September of 1991, DuPont had received the results of sampling of one of the new Lubeck Public Service District water supply wells located approximately two miles further down river from the Lubeck Public Service District property sold to DuPont, indicating the presence of C-8 in the new Lubeck Public Service District water well at 2.4 ppb.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 45. By September 1991, DuPont had received the results of sampling of water at a home tap served by the Lubeck Public Service District confirming the presence of C-8 at 3.9 ppb.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 46. Attached hereto at Exhibit Q is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 47. Although DuPont prepared a standby press release to notify the public in 1991 of the presence of C-8 in the Lubeck Public Service District water supply, DuPont did not provide that release to the public.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without waiving this objection, denied, except admitted that a standby press release was prepared in 1991 discussing the presence of C-8 in the Lubeck Public Service District water supply and that DuPont did not issue the press release; however, DuPont informed Lubeck in 1991 of the presence of C-8 in the Lubeck Public Service District water supply.

REQUEST FOR ADMISSION NO. 48. Attached hereto at Exhibit R is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 49. By January of 1992, DuPont had detected what it considered to be "high" levels of C-8 in water used by a single family on a private well on the western edge of DuPont's Washington Works plant (the "Private C-8 Well").

RESPONSE: DuPont objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without waiving this objection, denied, except admitted that by January of 1992, DuPont was concerned that a private well located on property on the western edge of DuPont's Washington Works plant would draw water containing a high level of C-8.

REQUEST FOR ADMISSION NO. 50. Attached hereto at Exhibit S is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 51. DuPont did not disclose to the owner(s) of the Private C-8 Well the level of C-8 detected in that well.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is vague and ambiguous. DuPont also objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without waiving these objections, admitted as phrased.

REQUEST FOR ADMISSION NO. 52. DuPont eventually purchased the property on which the Private C-8 Well was located.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 53. DuPont destroyed records identifying the actual concentration of C-8 in the Private C-8 Well.

RESPONSE: Denied.

REQUEST FOR ADMISSION NO. 54. DuPont destroyed records identifying the terms of the sales agreement between DuPont and the private owner(s) of the Private C-8 Well.

RESPONSE: Denied.

REQUEST FOR ADMISSION NO. 55. By February of 1993, DuPont had stated that it will control C-8 exposure for the general public by being in full compliance with DuPont's community exposure guidelines for C-8 (0.0003 mg/m³ in air and 1 ppb in drinking water).

RESPONSE: DuPont objects to this Request for Admission on the ground that it is vague and ambiguous. DuPont also objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without waiving these objections, admits as follows: by February of 1993, DuPont had expressed the goal to control C-8 exposure for the general public by being in full compliance with DuPont's community exposure guidelines for C-8 (0.0003 mg/m³ in air and 1 ppb in drinking water).

REQUEST FOR ADMISSION NO. 56. Attached hereto at Exhibit T is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Denied.

REQUEST FOR ADMISSION NO. 57. By May of 1993, DuPont Washington Works employees Woody Ireland, David Ramsey, and Walter Stewart had completed their responsibilities with respect to eliminating what DuPont considered to be "high" levels of C-8 in the Private C-8 Well.

RESPONSE: Denied, except admitted that by May of 1993, DuPont Washington Works employees Woody Ireland, David Ramsey, and Walter Stewart had completed their

responsibilities with respect to eliminating any potential exposure to C-8 from a private well which DuPont was concerned may have drawn water with high levels of C-8.

REQUEST FOR ADMISSION NO. 58. DuPont has interviewed Woody Ireland, David Ramsey, and Walter Stewart and has confirmed that none of those individuals now remember anything with respect to the level of C-8 detected in the Private C-8 Well or remember anything with respect to what DuPont did in response to finding C-8 in that well.

RESPONSE: DuPont objects to this Request for Admission on the grounds that it is vague and ambiguous and makes unsupported assertions of facts. DuPont also objects to this Request for Admission on the ground that it sets forth more than one matter to be admitted or denied in derogation of W.Va. R. Civ. P. 36(a). Based upon such objections, denied.

REQUEST FOR ADMISSION NO. 59. Attached hereto at Exhibit U is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 60. By March of 1994, DuPont had received the results of a report prepared by the University of Delaware indicating that electroosmosis appeared to be a cost-effective technology for remediating C-8-contaminated Washington Works facility soil in situ, but DuPont decided not to implement that technology.

RESPONSE: DuPont objects to this Request for Admission on the ground that it sets forth more than one matter to be admitted or denied in derogation of W.Va. R. Civ. P. 36(a). DuPont also objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without waiving these objections, DuPont admits as follows: by March of 1994, DuPont had received the results of a

report prepared by the University of Delaware which indicated that electroosmosis under certain conditions appeared to be a cost-effective technology for remediating C-8-contaminated Washington Works facility soil in situ, but DuPont decided not to implement that technology.

REQUEST FOR ADMISSION NO. 61. Attached hereto at Exhibit V is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted, except denied as to marginalia.

REQUEST FOR ADMISSION NO. 62. Attached hereto at Exhibit W is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted, except denied as to marginalia.

REQUEST FOR ADMISSION NO. 63. Following a DuPont C-8 global meeting in October of 1994, an e-mail from DuPont's in-house counsel, James B. Allen, was distributed to certain DuPont employees reminding those employees that there is no need to retain documents relating to C-8 beyond DuPont's three year corporate documentation retention policy, unless the documents come within a special records category exception, and that all C-8 records that do not fall within one of the special records category exceptions must be properly destroyed at the end of their corporate document retention period.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without waiving this objection, admitted, as phrased.

REQUEST FOR ADMISSION NO. 64. Attached hereto at Exhibit X is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 65. By October of 1995, DuPont had determined that C-8 was present in groundwater under the DuPont Washington Works plant in areas that were not contained by DuPont's geohydrological containment system, thereby allowing the C-8 to flow into the Ohio River.

RESPONSE: DuPont objects to this Request for Admission on the ground that it sets forth more than one matter to be admitted or denied in derogation of W.Va. R. Civ. P. 36(a). Subject to and without waiving this objection, denied.

REQUEST FOR ADMISSION NO. 66. Attached hereto at Exhibit Y is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted, except denied as to marginalia.

REQUEST FOR ADMISSION NO. 67. By January of 1997, DuPont had developed a C-8 Program Concept Evaluation Plan, which included development of a risk analysis and assessment to evaluate the potential impact of DuPont's use of C-8 on human health and the environment.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 68. Attached hereto at Exhibit Z is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted, except denied as to marginalia.

REQUEST FOR ADMISSION NO. 69. Attached hereto at Exhibit AA is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 70. By the fall of 1998, DuPont had prepared proposals to conduct a general human health and environmental effects risk analysis on C-8 and an ecological risk assessment on C-8.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 71. Attached hereto at Exhibit BB is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Denied, except admitted that the document attached to Plaintiffs' Third Set of RFAs as Exhibit BB together with the document produced at EID 219509-521 is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

REQUEST FOR ADMISSION NO. 72. In its proposal to conduct a general human health and environmental effects risk analysis on C-8, DuPont proposed to summarize such risks according to the major routes of exposure (air, water, dermal, other oral) for each C-8 application and to characterize the risks by comparing the likely exposure concentrations to the dose-response relationship through a method referred to as a "Margin of Exposure."

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 73. In June of 1999, DuPont was sued by several members of the Tennant family of Wood County, West Virginia who alleged emissions from DuPont's Dry Run Landfill in Wood County, West Virginia had resulted in personal and property damage to the Tennants, including the death of several hundred head of cattle and physical injuries to the Tennants.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 74. At the time DuPont was sued by the Tennants in connection with the Dry Run Landfill, DuPont was aware that C-8 was among the contaminants present at the Dry Run Landfill and Dry Run Creek in Wood County, West Virginia.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 75. On June 24, 1999, DuPont submitted to the United States Environmental Protection Agency a RCRA Facility Investigation Report for its Washington Works facility (the "RFI Report").

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 76. Attached hereto at Exhibit CC is an authentic and accurate copy of portions of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted, except DuPont notes that the following are the portions that have been included at Exhibit CC: Section Six (EID109687 - EID109696), Table 4.6 (EID109767 - EID109768), Table 6.5 (EID109781), Table 6.6 (EID109782), Table 6.7 (EID109783), Table 6.8 (EID109784), and Table 6.10 (EID109786).

REQUEST FOR ADMISSION NO. 77. In its RFI Report, DuPont included a screening level health risk evaluation to identify the constituents and exposure pathways that may be a concern for human health and that may warrant further evaluation or action for DuPont's Washington Works plant.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 78. In its RFI Report, DuPont derived preliminary screening levels for C-8 from DuPont's community exposure guideline of 0.0003 mg/m³ for C-8 in air.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without waiving this objection, admitted as phrased.

REQUEST FOR ADMISSION NO. 79. In its RFI Report, DuPont calculated preliminary screening levels for C-8 in soil and groundwater using an allowable daily intake of 0.006 mg/day of C-8.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without waiving this objection, admitted as phrased.

REQUEST FOR ADMISSION NO. 80. In its RFI Report, DuPont selected 3 ppb as its preliminary screening level for C-8 in groundwater used as drinking water.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without waiving this objection, admitted as phrased.

REQUEST FOR ADMISSION NO. 81. In August of 1999, DuPont was proceeding with both its ecological and human health risk assessments for C-8 and still anticipated completing the projects by January of 2000.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 82. Attached hereto at Exhibit DD is an authentic and accurate copy of the business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 83. In September of 1999, DuPont was advised that the Supreme Court of West Virginia had released an opinion expanding the ability to recover medical monitoring costs in situations where there has been exposure to toxic chemicals.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without waiving this objection, denied, except admitted that in September of 1999, certain employees of DuPont were informed that the West Virginia Supreme Court of Appeals had recently entered an opinion that created a new legal claim allowing plaintiffs to sue for future costs of medical monitoring.

REQUEST FOR ADMISSION NO. 84. Attached hereto at Exhibit EE is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Denied.

REQUEST FOR ADMISSION NO. 85. DuPont never finalized either its ecological or human health risk assessments for C-8 in writing after the West Virginia Supreme Court

issued its medical monitoring decision in Bower v. Westinghouse Electric Corp., 522 S.E.2d 424 (1999).

RESPONSE: DuPont objects to this Request for Admission on the ground that it is vague and ambiguous. Subject to and without waiving this objection, denied, except admitted that DuPont had begun its extensive human health and ecological risk assessments prior to 1999, such risk assessments and research related to them are ongoing and portions have been reduced to writing after 1999.

REQUEST FOR ADMISSION NO. 86. By April of 2000, DuPont had performed modeling indicating that, at the then-current emissions levels of C-8 from the DuPont Washington Works plant, the concentration of C-8 in the Ohio River was predicted to be above DuPont's 1 ppb community exposure guideline for community water approximately 50% of the time.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is vague and ambiguous. DuPont also objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without waiving this objection, admitted as phrased.

REQUEST FOR ADMISSION NO. 87. Attached hereto at Exhibit FF is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 88. On August 15, 2000, attorneys for the Tennants advised DuPont's counsel that they had become aware that they had not received

all of DuPont's documents relating to C-8 in connection with the Tennant litigation and that the Tennants' counsel intended to seek immediate production of DuPont's C-8 documents.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is vague and ambiguous. DuPont also objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without waiving these objections, denied, except admitted that in August 2000, Plaintiffs' counsel in the Tennant litigation claimed that he had not received all of DuPont's documents related to C-8 and that he intended to seek immediate production of those documents.

REQUEST FOR ADMISSION NO. 89. Attached hereto at Exhibit GG is an authentic and accurate copy of a letter that DuPont's counsel received from counsel for the Tennants on or about August 15, 2000.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 90. On August 16, 2000, executive officers of DuPont, including Charles O. Holliday, Jr., Chairman of the Board and Chief Executive Officer, were notified that counsel for the Tennants was seeking additional time to study the impact of C-8 on the litigation.

RESPONSE: Denied, except admitted that in his August 16, 2000 Daily Communications Report, sent to executive officers of DuPont, including Charles O. Holliday, Jr., Chairman of the Board and Chief Executive Officer, R. Clifton Webb stated: "Plaintiffs counsel requested a 6 month extension to the proceedings for additional time to study the impact of C-8."

REQUEST FOR ADMISSION NO. 91. Attached hereto at Exhibit HH is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted, except that DuPont notes that the document was redacted prior to production to Plaintiffs.

REQUEST FOR ADMISSION NO. 92. In August of 2000, DuPont stated that its community exposure guideline of 1 ppb for C-8 in community drinking water is a self-regulated public health limit.

RESPONSE: Denied, except admitted that in a draft document prepared for discussion purposes, a DuPont employee stated that the community exposure guideline of 1 ppb for C-8 in community drinking water is a self-regulated public health limit.

REQUEST FOR ADMISSION NO. 93. In August of 2000, DuPont stated that its community exposure guideline of 0.0003 milligrams per cubic meter of C-8 in community air is a self-regulated public health limit for C-8.

RESPONSE: Denied, except admitted that in a draft document prepared for discussion purposes, a DuPont employee stated that the community exposure guideline of 0.0003 milligrams per cubic meter of C-8 in community air is a self-regulated public health limit for C-8.

REQUEST FOR ADMISSION NO. 94. Attached hereto at Exhibit II is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 95. Acute overexposure of humans to C-8 can cause eye irritation with discomfort, tearing or blurring of vision, irritation of the upper respiratory passages, and possible liver changes.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is vague and ambiguous and that it sets forth more than one matter to be admitted or denied in derogation of W.Va. R. Civ. P. 36(a). DuPont also objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without waiving these objections, denied, except admitted that, based on animal testing, acute overexposure of animals to C-8 can result in eye irritation, respiratory tract irritation and liver changes and it is assumed that acute overexposure of humans to C-8 may cause the same acute effects. However, DuPont specifically denies that acute overexposure to C-8 has produced chronic health effects in humans.

REQUEST FOR ADMISSION NO. 96. Attached hereto at Exhibit JJ is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 97. In March of 2001, DuPont received a copy of a letter sent by counsel for the Tennants notifying various government agencies and DuPont of certain facts related to DuPont's handling of C-8 issues and, among other things, the Tennant's request for governmental action in response (the "Tennant Letter")

RESPONSE: DuPont objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without waiving this objection, denied, except admitted that, in March 2001, DuPont received a copy of

a letter sent by counsel for the Tennants to various government agencies alleging certain things related to DuPont and C-8. DuPont specifically denies many of the allegations in the March 2001 letter.

REQUEST FOR ADMISSION NO. 98. Attached hereto at Exhibit KK is an authentic and accurate copy of the text of a letter DuPont received in March of 2001.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 99. DuPont received a draft of the Tennant Letter in November of 2000.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without waiving this objection, denied, except admitted that DuPont received a draft in November 2000 of a letter from counsel for the Tennants to various government agencies alleging certain things related to DuPont and C-8. DuPont specifically denies that the draft received in November 2000 is identical to the Tennant letter received in March 2001.

REQUEST FOR ADMISSION NO. 100. On March 9, 2001, Diane R. Shomper of DuPont stated that there are potential ramifications to the entire fluoropolymers industry if there is very negative fallout from the Tennant Letter.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without waiving this objection, admitted as phrased.

REQUEST FOR ADMISSION NO. 101. Attached here as Exhibit LL is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 102. On March 9, 2001, executive officers of DuPont, including Charles O. Holliday, Chairman of the Board and Chief Executive Officer, were advised of the Tennant Letter and were informed that leaders of DuPont's fluoroproducts business would be meeting with DuPont's legal staff and public and government affairs staff to refine its strategy in light of the Tennant Letter.

RESPONSE: DuPont objects to this Request for Admission on the ground that it sets forth more than one matter to be admitted or denied in derogation of W.Va. R. Civ. P. 36(a). Subject to and without waiving this objection, admitted.

REQUEST FOR ADMISSION NO. 103. Attached hereto at Exhibit MM is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 104. On March 22, 2001, DuPont was advised that counsel for the Tennants intended to make a presentation to the United States Environmental Protection Agency ("USEPA") relating to C-8 during an upcoming public hearing.

RESPONSE: Denied, except admitted that on March 22, 2001, certain DuPont employees were told that an attorney in the Tennant litigation had gotten on the agenda for an EPA meeting on PFOS and that the attorney's intent was to discuss APFO.

REQUEST FOR ADMISSION NO. 105. Attached hereto at Exhibit NN is an authentic and accurate copy of the business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 106. In March of 2001, DuPont's counsel filed papers with the United States District Court for the Southern District of West Virginia seeking a gag order to prevent the Tennants' counsel from publicly discussing certain C-8 issues.

RESPONSE: DuPont admits as follows: in March of 2001, in the United States District Court for the Southern District of West Virginia, DuPont's counsel filed a Motion for Temporary Restraining Order and Preliminary Injunction to prevent Tennants' counsel from making any extrajudicial statements regarding the Tennant case.

REQUEST FOR ADMISSION NO. 107. DuPont's attempt to obtain a gag order against the Tennants' counsel was rejected by the Federal Court in West Virginia in March of 2001.

RESPONSE: DuPont admits as follows: on March 26, 2001, the United States District Court for the Southern District of West Virginia denied DuPont's Motion for Temporary Restraining Order and Preliminary Injunction.

REQUEST FOR ADMISSION NO. 108. On May 23, 2001, a letter dated May 19, 2001, was received in the office of DuPont's Chairman of the Board in which an alleged former employee of DuPont stated that he had knowledge of facts indicating that the DuPont Washington Works plant and local drinking water supply was seriously contaminated with C-8 and alleged that DuPont management's response to the situation was illegal and immoral.

RESPONSE: Denied, except admitted that on May 23, 2001, the office of DuPont's Chairman of the Board received a copy of a letter addressed to Christine T. Whitman, EPA Administrator, authored by an unidentified person who claimed in the body of the letter to be

a former employee of DuPont. DuPont further admits that in the letter the alleged former employee stated that he had knowledge of facts indicating that the DuPont Washington Works plant and local drinking water supply was seriously contaminated with C-8 and alleged that DuPont management's response to the situation was illegal and immoral. DuPont specifically denies the allegations in the body of the letter.

REQUEST FOR ADMISSION NO. 109. Attached hereto at Exhibit OO is an authentic and accurate copy of a letter that was received in the office of DuPont's Chairman of the Board on or about May 23, 2001.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 110. In June of 2001, DuPont initiated discussions with the State of West Virginia's Department of Environmental Protection ("WVDEP") regarding a potential consent order to address the nature and extent of C-8 released from DuPont's Washington Works plant.

RESPONSE: Denied.

REQUEST FOR ADMISSION NO. 111. On November 1, 2001, DuPont publicly announced that it would begin the manufacture of C-8 at its Fayetteville, North Carolina facility

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 112. Attached hereto at Exhibit PP is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 113. On August 30, 2002, employees of USEPA met with, among others, employees of DuPont and discussed, among other things,

the USEPA's interpretation of existing PFOA toxicity studies, and the USEPA representatives specifically requested that any disagreements with USEPA's interpretation of PFOA toxicity studies be raised and resolved with USEPA's staff prior to any subsequent meeting with the USEPA.

RESPONSE: DuPont objects to this Request for Admission on the ground that it sets forth more than one matter to be admitted or denied in derogation of W.Va. R. Civ. P. 36(a). Subject to and without waiving this objection, denied except admitted that on August 30, 2002, employees of DuPont met with employees of the USEPA and discussed the interpretation of certain PFOA toxicity studies.

REQUEST FOR ADMISSION NO. 114. During a conference call among USEPA employees and, among others, DuPont representatives, on September 12, 2002, none of the DuPont participants on the call acknowledged any difference of opinion with the USEPA with respect to PFOA hazard issues.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is vague and ambiguous. Subject to and without waiving this objection, denied.

REQUEST FOR ADMISSION NO. 115. With respect to USEPA's interpretation of PFOA toxicity and hazard issues, USEPA advised DuPont, among others, in September of 2002 that the toxicology data submitted to USEPA suggests a potential for reproductive/developmental toxicity and low level C-8 exposures to the general population that were unexplained as of September 2002.

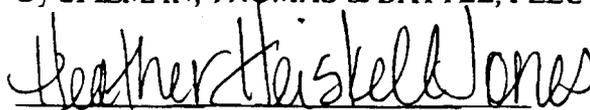
RESPONSE: DuPont objects to this Request for Admission on the ground that it sets forth more than one matter to be admitted or denied in derogation of W.Va. R. Civ. P. 36(a). DuPont also objects to this Request for Admission on the ground that it is vague and

ambiguous. Subject to and without waiving these objections, denied, except admitted that with respect to USEPA's interpretation of PFOA toxicity and hazard issues, USEPA advised DuPont, among others, in September of 2002 that the toxicology data submitted to USEPA suggests a potential for reproductive/ developmental toxicity.

Respectfully submitted,

E.I. DU PONT DE NEMOURS AND COMPANY

By SPILMAN, THOMAS & BATTLE, PLLC



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IN THE CIRCUIT COURT OF WOOD COUNTY, WEST VIRGINIA

JACK W. LEACH, ET AL.,

Plaintiffs,

v.

CIVIL ACTION NO. 01-C-608

(Judge George W. Hill, Jr.)

**E. I. DU PONT DE NEMOURS AND COMPANY,
and LUBECK PUBLIC SERVICE DISTRICT,**

Defendants.

CERTIFICATE OF SERVICE

I, Heather Heiskell Jones, do hereby certify that I have served a true and exact copy
"Responses of E. I. du Pont de Nemours and Company to Plaintiffs' Third Set of Requests
for Admissions to DuPont" upon the following counsel of record in the manner indicated
below on this 23rd day of January 2003, addressed as follows:

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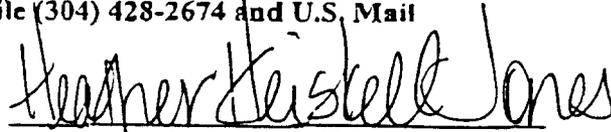
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MEMORANDUM FOR THE RECORD

IN THE CIRCUIT COURT OF WOOD COUNTY, WEST VIRGINIA

JACK W. LEACH, et al.,

Plaintiffs,

v.

CIVIL ACTION NO.: 01-C-608
(Judge George W. Hill)

E. I. DU PONT DE NEMOURS AND COMPANY,
and LUBECK PUBLIC SERVICE DISTRICT,

Defendants.

**RESPONSES OF E. I. DU PONT DE NEMOURS AND COMPANY TO
PLAINTIFFS' SECOND SET OF REQUESTS FOR ADMISSIONS TO DUPONT**

Pursuant to West Virginia Rule of Civil Procedure 36, Defendant, E. I. du Pont de Nemours and Company ("DuPont"), by counsel, responds to "Plaintiffs' Second Set of Requests for Admission to DuPont" ("Second Set of RFAs"), as follows. Any admission made is for the purpose of this pending action only and is not an admission for other purposes, nor may it be used in any other proceeding. Any admission is also subject to all pertinent objections to admissibility interposed at trial. Information provided in these responses is based upon such information as presently is reasonably available to DuPont. DuPont responds and objects as follows:

I. GENERAL OBJECTIONS

DuPont's responses to Plaintiffs' Second Set of Requests for Admissions are subject to the general objections set forth below. These general objections form a part of the response to each and every Request for Admission and are set forth here to avoid duplication and repetition. DuPont's specific responses to each Request for Admission are made subject to, and without waiving, these General Objections, which are incorporated by reference to each of DuPont's responses. The failure to list a specific General Objection in a response should not be construed

as a waiver of that objection. By admitting or denying Plaintiffs' Requests for Admission, DuPont does not concede that the subject matter of such Requests are relevant in the present action or that DuPont's responses are admissible. DuPont reserves the right to amend or supplement its responses

GENERAL OBJECTION 1: DuPont objects to Plaintiffs' Requests for Admissions to the extent that they seek to characterize the contents of documents, which documents speak for themselves.

GENERAL OBJECTION 2: DuPont objects to Plaintiffs' Requests for Admissions to the extent that they imply that DuPont's "acceptable exposure limits" ("AELs") and "community exposure guidelines" ("CEGs") are set at levels that are predictive of adverse human health effects. DuPont's processes for setting AELs and CEGs are analogous to regulatory agency risk assessments. These mathematically based risk assessments encompass a number of typically very conservative assumptions and safety factors, many of which are default versus actual figures. Risk assessments are designed to be overly protective of human health, with a wide margin of safety, are not predictive of any particular health effects, and should not be used in such a manner. Moreover, they cannot be used to support a claim for medical monitoring.

GENERAL OBJECTION 3: DuPont objects to Plaintiffs' Requests for Admissions to the extent that they seek information that is not relevant to the claims or defenses at issue in this litigation.

GENERAL OBJECTION 4: DuPont hereby preserves for trial its objections as to those of Plaintiffs' Requests for Admissions that ask DuPont to authenticate a document, except that DuPont admits to the authenticity of the documents as set forth below.

GENERAL OBJECTION 5: DuPont objects to Plaintiffs' Requests for Admissions to the extent that they are deliberately incomplete and calculated to lead to a false conclusion.

II. OBJECTIONS AND RESPONSES TO REQUESTS FOR ADMISSIONS

REQUEST FOR ADMISSION NO. 1. In 1978, after DuPont had been informed by 3M that 3M's workers exposed to certain fluorinated surfactants had elevated organic fluorine levels in their blood, DuPont's Medical Director, Bruce W. Karrh, M.D., recommended medical surveillance examinations for DuPont's fluorochemical workers consisting of: (1) a health history questionnaire; (2) an examination by or under the supervision of a physician; (3) urinalysis; (4) 12 blood chemistry tests (glucose, BUN, SGOT, LDH, alkaline phosphatase, bilirubin, total protein with albumin and globulin, calcium, phosphorous, creatinine, uric acid, cholesterol); (5) 7 hematology tests (white and red blood cell counts, hemoglobin, hematocrit, and red blood cell indices); (6) vision test; (7) audiogram; (8) 14x17 postero-anterior chest x-ray; (9) height, weight, blood pressure and pulse; (10) screening pulmonary function tests (FEV₁ and FVC); and (11) electrocardiograms at the routine intervals.

RESPONSE: DuPont objects to this Request for Admission on the ground that it sets forth more than one matter to be admitted or denied in derogation of W.Va. R. Civ. P. 36(a). Subject to and without waiving this objection, DuPont denies this Request for Admission, except as follows: DuPont admits that in 1978, 3M Company notified DuPont that some employees occupationally exposed to some of 3M's fluorinated surfactant compounds showed an increased level of organic fluorinated compounds in their blood, although no adverse health effects were detected among those employees. DuPont also admits that on July 24, 1978, Bruce W. Karrh, M.D., recommended to F. E. French that medical

surveillance for fluorochemical workers should be the regular DuPont periodic physical examination consisting of (1) a health history questionnaire; (2) an examination by or under the supervision of a physician; (3) urinalysis; (4) 12 blood chemistry tests (glucose, BUN, SGOT, LDH, alkaline phosphatase, bilirubin, total protein with albumin and globulin, calcium, phosphorous, creatinine, uric acid, cholesterol); (5) 7 hematology tests (white and red blood cell counts, hemoglobin, hematocrit, and red blood cell indices); (6) vision test; (7) audiogram; (8) 14x17 postero-anterior chest x-ray; (9) height, weight, blood pressure and pulse; (10) screening pulmonary function tests (FEV₁ and FVC); and (11) electrocardiograms at the routine intervals.

REQUEST FOR ADMISSION NO. 2. Attached hereto at Exhibit A is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 3. By 1979, DuPont had determined that operators at DuPont's Washington Works plant in Wood County, West Virginia, who handle C-8 were showing elevated blood organofluorine levels and liver enzyme activity (6 of 10 operators had high alkaline phosphatase and SGOT levels as compared to the 14% expected).

RESPONSE: Denied, except admitted that in a memorandum to A. A. Wright dated July 30, 1979, DuPont employees noted that operators who handle FC-143 at DuPont's Works plant in Wood County, West Virginia were showing elevated blood organofluorine levels and liver enzyme activity (6 of 10 operators had high alkaline phosphatase and SGOT levels as compared to the 14% expected), and there were no other clinical effects.

REQUEST FOR ADMISSION NO. 4. Attached hereto at Exhibit B is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 5. In 1979, a DuPont epidemiologist, William E. Fayerweather, reviewed liver function test results for DuPont workers with C-8 exposure and myocardial infarction cases and deaths at DuPont's Washington Works plant and preliminarily concluded that C-8-exposed workers may possibly have positive liver function tests more often than the Washington Works plant population as whole, and that the number of active wage roll employees at the Washington Works plant having myocardial infarctions from 1974 through 1977 was somewhat higher than was expected based on company-wide experience.

RESPONSE: DuPont objects to this Request for Admission on the ground that it sets forth more than one matter to be admitted or denied in derogation of W.Va. R. Civ. P. 36(a). Subject to and without waiving this objection, DuPont denies this Request for Admission, except as follows: DuPont admits that on August 28, 1979, a DuPont epidemiologist, William E. Fayerweather, reviewed liver function test results for DuPont workers with C-8 exposure. DuPont also admits that on August 28, 1979, Dr. Fayerweather reviewed myocardial infarction cases and deaths at DuPont's Washington Works plant. DuPont expressly denies any implication that the data related to the myocardial infarction cases and deaths at DuPont's Washington Works plant was limited to DuPont workers with C-8 exposure. DuPont admits that Dr. Fayerweather's preliminary results suggested that C-8-exposed workers may possibly have had positive liver function tests more often than the Washington Works plant population as whole. DuPont notes that these preliminary results were subsequently invalidated by a

report by Dr. Fayerweather dated January 15, 1981 entitled "Liver Study of Washington Works Employees Exposed to C-8: Results of Blood Biochemistry Testing," (hereinafter referred to as the "Liver Study"). DuPont also admits that the number of active wage roll employees at the Washington Works plant having myocardial infarctions from 1974 through 1977 was somewhat higher than was expected based on company-wide experience.

REQUEST FOR ADMISSION NO. 6. Attached hereto at Exhibit C is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted, except denied as to marginalia and except DuPont notes that the document was redacted prior to production to Plaintiffs.

REQUEST FOR ADMISSION NO. 7. A DuPont epidemiologist, William E. Fayerweather, prepared in January of 1981 a study entitled "Liver Study of Washington Works Employees Exposed to C-8: Results of Blood Biochemistry Testing" ("DuPont Liver Study"), the objective of which was to determine whether occupational exposure to C-8 adversely affects liver functions as measured by blood levels of glutamic oxaloacetic transaminase (SGOT), lactic dehydrogenase (LDH), alkaline phosphatase (AP), and bilirubin.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 8. Attached hereto at Exhibit D is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of the business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 9. According to the Liver Study, preliminary DuPont data from 1978 showed that the DuPont Washington Works plant population as a whole had an unusually large percentage of elevated SGOTs, with SGOTs elevated in 19% of the workers, whereas elevations would only have been expected by DuPont in about 5% based upon random statistical variation. AP, bilirubin, and LDH tests also showed plant-wide elevations in 8, 4 and 3% of the DuPont Washington Works plant workers, respectively.

RESPONSE: DuPont objects to this Request for Admission on the ground that it sets forth more than one matter to be admitted or denied in derogation of W.Va. R. Civ. P. 36(a). Subject to and without waiving this objection, DuPont denies this Request for Admission, except as follows: DuPont admits that according to the Liver Study, preliminary DuPont data from 1978 showed that the DuPont Washington Works plant population as a whole had an unusually large percentage of elevated SGOTs, with SGOTs elevated in 19% of the workers, whereas elevations would only have been expected by DuPont in about 5% based upon random statistical variation. DuPont admits that in the preliminary DuPont data from 1978, AP, bilirubin, and LDH tests also showed plant-wide elevations in 8, 4 and 3% of the DuPont Washington Works plant workers, respectively. DuPont expressly denies that the 1978 preliminary data were validly measured, and notes that the Liver Study indicates that the 1978 SGOT data was systematically higher than true blood levels and the observed range for "normal" SGOT data was considerably higher than the stated normal range.

REQUEST FOR ADMISSION NO. 10. According to the Liver Study, some of the SGOT data for the DuPont Washington Works suggested that there might be a liver effect among certain C-8-exposed workers, that the mean SGOT for the TFE process operators was significantly ($p < 0.05$) higher than the non-Teflon area control mean, that the TFE process

operators as a group had considerably higher organic fluoride blood levels than other Teflon-area workers, and that workers in the highest organic fluoride decile had a significantly higher SGOT mean than workers in the lower nine deciles.

RESPONSE: DuPont objects to this Request for Admission on the grounds that it sets forth more than one matter to be admitted or denied in derogation of W.Va. R. Civ. P. 36(a), and that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without waiving these objections, DuPont denies this Request for Admission, except as follows: DuPont admits that according to the Liver Study, after the data was evaluated, no association was found between exposure to C-8 and clinical end-points in man, although some of the SGOT data for the DuPont Washington Works suggested that there might be a liver effect among certain C-8-exposed workers, that the mean SGOT for the TFE process operators was significantly ($p < 0.05$) higher than the non-Teflon area control mean, that the TFE process operators as a group had considerably higher organic fluoride blood levels than other Teflon-area workers, and that workers in the highest organic fluoride decile had a significantly higher SGOT mean than workers in the lower nine deciles.

REQUEST FOR ADMISSION NO. 11. According to the Liver Study, mean AP was significantly ($p < 0.05$) higher among DuPont Washington Works FEP service and FEP process operators.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without waiving this objection, DuPont denies this Request for Admission except as follows: DuPont admits that according to the Liver Study, after the data was evaluated, no association was found between exposure to C-8 and clinical end-points in man, and although mean AP was

significantly ($p < 0.05$) higher among DuPont Washington Works FEP service and FEP process operators, none of the other blood tests were elevated among these workers, and AP did not correlate with blood organic fluoride levels.

REQUEST FOR ADMISSION NO. 12. For purposes of the Liver Study, DuPont compared results of workers from “Teflon area jobs” at DuPont’s Washington Works plant with a group defined as a “non-exposed control group” that included other DuPont Washington Works plant employees.

RESPONSE: Denied, except admitted that for purposes of the Liver Study, DuPont compared results of workers from “Teflon area jobs” at DuPont’s Washington Works plant with a group defined as a “non-exposed control group” which “consisted of a 10% systematic sample of all active WW employees who, as of August, 1979, had never worked in the Teflon area.”

REQUEST FOR ADMISSION NO. 13. In 1978 - 1980, the DuPont Washington Works employees working in “Teflon area jobs,” as defined in the Liver Study, were not the only DuPont Washington Works employees who were potentially-exposed to C-8.

RESPONSE: DuPont objects to this Request for Admission on the grounds that it is deliberately incomplete and calculated to lead to a false conclusion, and that the phrase “potentially-exposed to C-8” is vague and ambiguous. Subject to and without waiving these objections, DuPont admits this Request for Admission as phrased.

REQUEST FOR ADMISSION NO. 14. In 1978 - 1980, all DuPont Washington Works employees were potentially-exposed to C-8 by virtue of the presence of C-8 in the DuPont Washington Works plant air emissions.

RESPONSE: DuPont objects to this Request for Admission on the grounds that it is deliberately incomplete and calculated to lead to a false conclusion, and that the phrase

“potentially-exposed to C-8” is vague and ambiguous. Subject to and without waiving these objections, DuPont admits this Request for Admission as phrased.

REQUEST FOR ADMISSION NO. 15. The workers included within the “non-exposed control group” used in the Liver Study were not individuals who had no potential exposure to C-8.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion, and that the phrase “not individuals who had no potential exposure to C-8” is vague and ambiguous. Subject to and without waiving these objections, DuPont admits this Request for Admission as phrased.

REQUEST FOR ADMISSION NO. 16. In 1980, upon review of a draft of the Liver Study, DuPont’s Assistant Medical Director, Vann A. Brewster, M.D., expressed concern that a draft of the Liver Study implied that DuPont’s Medical Division would not continue the study of liver tests on those DuPont employees potentially-exposed to C-8 and recommended that, because DuPont still could not explain why the mean SGOT was significantly higher among DuPont’s TFE process workers at the Washington Works plant and that the mean AP was significantly higher among DuPont’s FEP process and service workers at DuPont’s Washington Works plant, DuPont should include language in the Liver Study to indicate that “it was recommended that the study of liver tests continue” and recommended that DuPont should include in the Liver Study a recommendation to “continue to evaluate the liver tests of employees with potential exposure to C-8.”

RESPONSE: DuPont objects to this Request for Admission on the grounds that it sets forth more than one matter to be admitted or denied in derogation of W.Va. R. Civ. P. 36(a), and that the cited document speaks for itself. Subject to and without waiving these objections,

DuPont denies this Request for Admission, except as follows: DuPont admits that in a memorandum to L. F. Percival dated June 9, 1980 (hereinafter referred to as the "June 9 Memorandum"), DuPont's Assistant Medical Director, Vann A. Brewster, M.D., commented on the Draft Washington Works Communication entitled "Fluorosurfactants in Blood" (hereinafter referred to as the "Draft Communication"). DuPont admits that in the June 9 Memorandum, Dr. Brewster expressed his concern that the Draft Communication implied that DuPont's Medical Division would not continue the study of liver tests on those DuPont employees potentially-exposed to C-8. DuPont admits that in the June 9 Memorandum, Dr. Brewster suggested various revisions to the Draft Communication to correct this implication.

REQUEST FOR ADMISSION NO. 17. Attached hereto as Exhibit E is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 18. In April of 1981, DuPont's Medical Division prepared and circulated a proposal to study whether pregnancy outcome among female employees of DuPont's Washington Works plant is causally related to their occupational exposure to, among other things, C-8 and to determine whether pregnancy outcome among wives of DuPont's Washington Works male employees is causally related to their husbands' exposure to, among other thing, C-8.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 19. In July of 1981, the pregnancy outcome studies proposed by DuPont's Medical Division in April of 1981 were put "on hold" until further notice.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without waiving this objection, DuPont denies this Request for Admission, except as follows: DuPont admits that in July 1981, the pregnancy outcome study proposed by DuPont's Medical Division in April of 1981 was put "on hold" pending the results of more definitive animal teratogenicity studies, and ultimately in 1982, upon completion of such studies, including teratogenicity results, the Medical Division determined that it was no longer necessary to undertake such a pregnancy outcome study.

REQUEST FOR ADMISSION NO. 20. Attached hereto as Exhibit F is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 21. In a January 1983 update to DuPont's 1981 Liver Study, DuPont compared test results of DuPont workers who allegedly had been exposed to C-8 at DuPont's Washington Works plant to the test results of other DuPont Washington Works employees, and not to a control group consisting of individuals who never had had any potential exposure to C-8.

RESPONSE: DuPont objects to this Request for Admission on the grounds that it is deliberately incomplete and calculated to lead to a false conclusion, that it is vague and ambiguous; and that it sets forth more than one matter to be admitted or denied in derogation

of W.Va. R. Civ. P. 36(a). Subject to and without waiving these objections, DuPont denies this Request for Admission, except it is admitted that in a draft report dated January 28, 1983, William E. Fayerweather provided an update to the 1981 Liver Study, and in that 1983 draft report, the study group was comprised of the same individuals as from the 1981 Liver Study, less 24 employees who left the Teflon ® area, and the control group consisted of the same individuals as from the 1981 Liver Study, less 21 employees who left the plant or had since worked in the Teflon ® area.

REQUEST FOR ADMISSION NO. 22. Attached hereto as Exhibit G is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 23. In March of 1990, H.A. Smith of DuPont estimated the drop-off rate for C-8 in human blood to have a half-life of approximately 4-5 years or more and concluded that there is a correlation between C-8 exposure levels and the level of C-8 in human blood.

RESPONSE: DuPont objects to this Request for Admission on the grounds that it is deliberately incomplete and calculated to lead to a false conclusion, and that it sets forth more than one matter to be admitted or denied in derogation of W.Va. R. Civ. P. 36(a). Subject to and without waiving these objections, DuPont denies this Request for Admission, except as follows: DuPont admits that in a March 19, 1990 memorandum from H. A. Smith to J. G. Loschiavo, R. D. Lanyon and W. E. Crawley (hereinafter referred to as the "March 19 Memorandum"), H. A. Smith reviewed personnel air modeling data taken over the period April 1988 through September 1989 and all personnel C-8 blood data going back to 1979-80.

DuPont admits that in the March 19 Memorandum, H.A. Smith noted that the blood data base only included those employees who had been in the indicated job for years, had not moved all over the Fluoropolymers area, and are still in the jobs, and also that interpretation of the data was complicated by the fact that the air monitoring data was recent while the blood data essentially reflected exposure dating back to the "early days." DuPont admits that in the March 19 Memorandum, H.A. Smith concluded from his review of the blood and air monitoring data that, among other things, there was a correlation between C-8 personnel air levels and C-8 in blood levels, and between skin contact and C-8 in blood levels. DuPont admits that in the March 19 Memorandum, H.A. Smith concluded from his review of the blood and air monitoring data that, among other things, the drop-off rate for C-8 in the blood is a half life of about 4-5 years or more, based on a very small amount of data on pensioners and on the observation that there is a slight perceived decline in workers in the various jobs.

REQUEST FOR ADMISSION NO. 24. Attached hereto as Exhibit H is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 25. In October of 1991, W.P. Anderson, Jr. of DuPont's Polymer Products and Gerald F. Kennedy of DuPont's Haskell Laboratory requested the authority to conduct a cross-sectional study of liver enzymes among DuPont Washington Works employees with potential exposure to C-8 to determine whether occupational exposure to C-8 adversely affects the liver, as measured by blood levels of SGOT, LDH, AP, and bilirubin (the "1991 Liver Study Update"), recognizing that it had been 10 years since the 1981 DuPont Liver Study.

RESPONSE: DuPont objects to this Request for Admission on the ground that it sets forth more than one matter to be admitted or denied in derogation of W.Va. R. Civ. P. 36(a). Subject to and without waiving this objection, DuPont denies this Request for Admission, except it is admitted that in October of 1991, W. P. Anderson, Jr. of DuPont's Polymer Products and Gerald L. Kennedy of DuPont's Haskell Laboratory requested the authority to conduct a cross-sectional study of liver enzymes among DuPont Washington Works employees with potential exposure to C-8 to determine whether occupational exposure to C-8 adversely affects the liver, as measured by blood levels of SGOT, LDH, AP, and bilirubin (the "1991 Liver Study Update").

REQUEST FOR ADMISSION NO. 26. Attached hereto as Exhibit I is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted, except denied as to marginalia.

REQUEST FOR ADMISSION NO. 27. During a meeting in October of 1991, Mr. Anderson's and Mr. Kennedy's request for the 1991 Liver Study Update was rejected by DuPont.

RESPONSE: Denied, except admitted that during a meeting held in October of 1991, Mr. Anderson's and Mr. Kennedy's request for the 1991 Liver Study Update was reviewed by Karrh and Ligo, and it was decided that the 1991 Liver Study Update would not be pursued at the time, but that the need for a study would be looked at again in 1993.

REQUEST FOR ADMISSION NO. 28. Attached hereto as Exhibit J is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 29. In November of 1993, Dr. Younger L. Power of DuPont's Washington Works recommended to Dr. Benjamin Ramirez with DuPont in Wilmington, Delaware that DuPont perform liver function tests of its Washington Works employees to discover any potentially unknown liver toxicity among those employees exposed to C-8.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 30. Attached hereto as Exhibit K is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted, except denied as to marginalia.

REQUEST FOR ADMISSION NO. 31. Attached hereto at Exhibit L is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 32. In February of 1995, William J. Brock, Ph.D., Toxicology Consultant to DuPont, contacted Dr. Lance L. Simpson of the Jefferson Clinical Center in Environmental Medicine, Jefferson Medical College, to pursue discussions relating to establishing a corporate policy on medical surveillance for DuPont employees, particularly for the blood monitoring of telomeric acid fluorides, including C-8, mentioning concern about the potential long-term human health effects of these materials, and requesting Dr. Simpson's assistance in designing, conducting, and interpreting a monitoring program for DuPont's employees, including a blood monitoring program design which includes relevant test batteries.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 33. Attached hereto at Exhibit M is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 34. DuPont representatives, including Gerry Kennedy, Judy Walrath, Charles Reinhardt, and William Brock, met with Dr. Lance L. Simpson and E. Mercer of Jefferson Medical College on August 14, 1995 to discuss approaches for developing a medical surveillance program for C-8 and/or HFPO among DuPont's workers, during which DuPont representatives were requested to submit additional data to Jefferson Medical College, which was to then come back with a proposal and guidelines for developing a research and surveillance program.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 35. Attached hereto as Exhibit N is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted, except denied as to marginalia.

REQUEST FOR ADMISSION NO. 36. Upon review of DuPont's 1995 C-8 blood sampling of DuPont's Washington Works employees and pensioners, DuPont noted that the results from the C-8 blood testing indicated an average half-life for C-8 in human blood of approximately 4 years.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without

waiving this objection, DuPont denies this Request for Admission, except as follows: DuPont admits that upon review of DuPont's 1995 C-8 blood sampling of a limited number DuPont's Washington Works employees and pensioners, Anthony Playtis noted the serious limitations on the usefulness of the data, including the small size of most of the data sets, the frequent transfer of site employees from one job to another, and the slow rate at which C-8 blood levels decrease after exposure stopped. DuPont also admits that given these limitations, he concluded that results from the sampled pensioners indicated an average half life for C-8 in blood of about four years.

REQUEST FOR ADMISSION NO. 37. Attached hereto as Exhibit O is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted, except denied as to marginalia.

REQUEST FOR ADMISSION NO. 38. On May 16, 1996, DuPont employees, including William J. Brock, Ph.D., Benjamin Ramirez, and Anthony Playtis, participated in a meeting to discuss a proposed medical surveillance program for DuPont's fluoroproducts employees during which an objective was to obtain agreement by participants that a program needs to be established to gain an understanding of the health risks to employees potentially exposed at fluoroproducts plant sites and to develop a program that best allows DuPont to evaluate these potential health risks in a cost-effective way, with a proposed medical surveillance program for discussion that included aliquots used for liver and kidney function tests, hematology and other parameters.

RESPONSE: Denied.

REQUEST FOR ADMISSION NO. 39. Attached hereto as Exhibit P is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 40. In August of 1996, Dr. Younger Power of DuPont's Washington Works reviewed data developed from medical records on 51 DuPont Washington Works employees with the highest measured levels of C-8 in their blood and found several employees with frequent elevations of blood tests (SGOT-7, Alkaline Phosphatase-10, LDH-7), two cases of kidney disease, and one case of thrombocytopenia/leukopenia.

RESPONSE: DuPont objects to this Request for Admission on the grounds that it is deliberately incomplete and calculated to lead to a false conclusion, and that it sets forth more than one matter to be admitted or denied in derogation of W. Va. R. Civ. P. 36(a). Subject to and without waiving these objections, this Request for Admission is denied, except as follows: It is admitted that in a memorandum to William J. Volger dated August 5, 1996, Dr. Younger L. Power stated that he reviewed medical records on 51 DuPont Washington Works employees with the highest measured levels of C-8 in their blood, and found, in his opinion, very little evidence of disease due to C-8. Dr. Power also stated that while there were several employees with frequent elevations of blood tests (SGOT-7, Alkaline Phosphatase – 10, LDH – 7), there was no evidence of liver disease, and that there were also 2 cases of kidney disease and one case of thrombocytopenia/leukopenia that could not be attributable to some other cause.

REQUEST FOR ADMISSION NO. 41. Attached hereto as Exhibit Q is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 42. In September of 1996, Dr. Benjamin Ramirez, Associate Medical Director for DuPont, received information from 3M regarding the medical surveillance that 3M had performed in connection with employees working in the manufacture of C-8, which 3M medical surveillance included a medical questionnaire, pulmonary function test, chemistry test (P12), hematology test (CBC), urinalysis, and serum fluorine test.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 43. Attached hereto as Exhibit R is an authentic and accurate copy of a document received from 3M in or about September of 1996.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 44. In November of 1996, Dr. Benjamin Ramirez, Associate Medical Director for DuPont, and Charles F. Reinhardt, Director of DuPont's Haskell Laboratory, recommended to J.M. Smith of DuPont fluoroproducts that DuPont perform pre-assignment and post-assignment examinations of its fluoroproducts employees, including: (1) medical history questionnaire, including smoking history; and (2) blood tests (complete blood count, SMA-12, and fluorine-in-blood test).

RESPONSE: DuPont objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without waiving this objection, DuPont admits this Request for Admission as phrased.

REQUEST FOR ADMISSION NO. 45. Attached hereto as Exhibit S is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted, except denied as to marginalia.

REQUEST FOR ADMISSION NO. 46. In February of 1997, Dr. Benjamin Ramirez, Associate Medical Director for DuPont, and R.W. Rickard, Director of DuPont's Haskell Laboratory, recommended to J.M. Smith of DuPont fluoroproducts that DuPont perform pre-assignment and post-assignment examinations of its fluoroproducts employees, including: (1) medical history questionnaire, including smoking history; and (2) blood tests (complete blood count, SMA-12, and fluorine-in-blood test).

RESPONSE: DuPont objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without waiving this objection, DuPont admits this Request for Admission as phrased.

REQUEST FOR ADMISSION NO. 47. Attached hereto as Exhibit T is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 48. By January of 1999, employees at DuPont's Chambers Works Facility in New Jersey (the "Chambers Works") learned that Chambers Works might be cleaning some C-8 materials for DuPont's Washington Works plant and had contacted Anthony Playtis and Dr. Younger Power at DuPont's Washington Works plant, who recommended a pre- and post- (or annual) campaign medical surveillance program for workers

who would be involved with the C-8 materials and commented that DuPont's Washington Works had been looking at worker blood for C-8 levels and had done liver function studies.

RESPONSE: DuPont objects to this Request for Admission on the ground that it sets forth more than one matter to be admitted or denied in derogation of W.Va. R. Civ. P. 36(a). Subject to and without waiving this objection, DuPont denies this Request for Admission, except as follows: DuPont admits that John J. Plum, an employee at DuPont's Chambers Works Facility in New Jersey (the "Chambers Works"), learned that Chambers Works might be cleaning some C-8 materials for DuPont's Washington Works plant, and in January 1999, contacted Anthony Playtis, who forwarded John Plum's letter to Dr. Younger Power at DuPont's Washington Works plant. DuPont also admits that based upon the January 1999 letter from John Plum, Dr. Power recommended that Chambers Works establish a baseline for industrial hygiene purposes, and therefore recommended a pre- and post- (or annual) campaign surveillance program for operators, mechanics and laboratory technicians who would be involved with the C-8 materials, and also stated that DuPont's Washington Works had been looking at worker blood for C-8 levels and had done liver function studies.

REQUEST FOR ADMISSION NO. 49. Attached hereto as Exhibit U is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 50. By March of 1999, Robin C. Leonard of DuPont had forwarded to Barbara J. Dawson at DuPont's Chambers Works a draft proposal for the surveillance for exposure, biopersistence, and potential liver affects from workplace exposures to C-8. (Hereinafter "C-8 Medical Surveillance Proposal").

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 51. Attached hereto as Exhibit V is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 52. DuPont's Medical Surveillance Proposal indicated that changes in liver function may be a means of detecting human biological response to C-8 and set forth a proposed project that included among its objectives correlating data on biomarkers of effect (referenced as serum liver enzymes levels) with the biomarkers of exposure (referenced as fluoride ion in blood and blood perfluorooctanoate level).

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 53. DuPont's C-8 Medical Surveillance Proposal suggested a protocol to prescribe data collection at monthly intervals for liver enzyme measurements and area or personal monitoring at either weekly or biweekly intervals, for a period of one year.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 54. In May of 1999, DuPont's Chambers Works prepared a "C-8 Hazard Communication."

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 55. Attached hereto at Exhibit W is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted, except DuPont notes that this document was redacted prior to production to Plaintiffs.

REQUEST FOR ADMISSION NO. 56. In 1999, DuPont's Chambers Works conducted baseline medical surveillance exams on DuPont employees who DuPont had identified as workers who might be involved in work to recover C-8 salt from a solution from material delivered to DuPont Chambers Works from DuPont's Washington Works facility (the "Chambers Works C-8 Workers").

RESPONSE: Denied, except admitted that in 1999, DuPont's Chambers Works conducted a baseline medical surveillance program on DuPont's Chambers Works employees who were identified as working in jobs with potential for accidental exposure to C-8.

REQUEST FOR ADMISSION NO. 57. The baseline medical surveillance exams conducted by DuPont for its Chambers Works C-8 Workers included: (1) medical history questionnaire; (2) automated chemistry profile (including SMA-12 (including HDL, cholesterol, glucose, uric acid, BUN, calcium, phosphorus, total protein, albumin, bilirubin, alkaline phosphatase, LDH, AST (SGOT), total cholesterol, creatinine, and ALT (SGPT))); (3) complete blood count; (4) perfluorooctanoic acid (PFOA) in blood; and (5) total fluorine in blood.

RESPONSE: Denied, except admitted that the baseline medical surveillance program conducted by DuPont for its Chambers Works C-8 Workers included the following three elements typical of all DuPont medical surveillance: medical history questionnaire, automated chemistry profile (including SMA-12 (including HDL, cholesterol, glucose, uric acid, BUN, calcium, phosphorus, total protein, albumin, bilirubin, alkaline phosphatase, LDH, AST (SGOT), total cholesterol, creatinine, and ALT (SGPT)) and complete blood count, as well as

two elements related to C-8: perfluorooctanoic acid (PFOA) in blood and total fluorine in blood. DuPont notes that the medical history questionnaire, automated chemistry profile and complete blood counts were standard elements of DuPont's annual physical examinations which were conducted until the early 1990's of all DuPont employees.

REQUEST FOR ADMISSION NO. 58. DuPont's Chambers Works C-8 Workers were advised that C-8 was to be handled as a "no contact" chemical.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 59. In May of 1999, DuPont's Chambers Works identified human health effects of overexposure to C-8 (ammonium perfluorooctanoate (salt)) by inhalation, ingestion, or skin or eye contact as including skin irritation with discomfort or rash; eye irritation with discomfort, tearing, or blurring of vision; irritation of the upper respiratory passages; abnormal blood forming system function with anemia; or abnormal liver function as detected by laboratory tests.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 60. In May of 1999, DuPont's Chambers Works stated that human health effects of overexposure to C-8 (ammonium perfluorooctanoic acid) by inhalation includes irritation of the upper respiratory tract, that contact with the skin may result in severe irritation and burns of the skin on direct contact, that the material causes severe eye burns upon contact with liquid vapors and/or mists, and that the material can cause gastric burns on ingestion.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 61. DuPont's Chambers Works facility began its baseline medical surveillance exams of the Chambers Works C-8 Workers in June of 1999.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 62. Attached hereto at Exhibit X is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted, except DuPont notes that this document was redacted prior to production to Plaintiffs.

REQUEST FOR ADMISSION NO. 63. In 1999, DuPont's Chambers Works facility identified liver disorders as the primary concern with respect to pre-existing conditions that would put DuPont Chambers Works C-8 Workers at risk for working with C-8.

RESPONSE: Denied, except admitted that a liver disorder would have been one of the preexisting conditions that would have resulted in disapproval of a DuPont Chambers Works C-8 Worker for working with C-8.

REQUEST FOR ADMISSION NO. 64. Attached hereto at Exhibit Y is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 65. In connection with the baseline medical surveillance exams of the DuPont Chambers Works C-8 Workers in 1999, those DuPont employees who participated in such exams and were determined to have abnormal liver test results through such exams were advised by DuPont that they were not approved for work with C-8.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 66. Attached hereto at Exhibit Z is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 67. In June of 1999, DuPont's Chambers Works determined that at least three of the workers who participated in the baseline medical surveillance exams for C-8 were not approved for work with C-8 at that time based upon the results of the tests conducted in connection with the baseline medical surveillance exams.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 68. Attached hereto at Exhibit AA is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted, except DuPont notes that this document was redacted prior to production to Plaintiffs.

REQUEST FOR ADMISSION NO. 69. Attached hereto at Exhibit BB is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 70. Attached hereto at Exhibit CC is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 71. In February of 2000, Barbara J. Dawson of DuPont's Chambers Works recommended that DuPont implement a medical surveillance program consisting of medical/work histories and blood chemistry profile (including AST and ALT) for the DuPont Chambers Works employees who worked with any fluorine-based chemicals, not just C-8.

RESPONSE: Denied, except admitted that on February 29, 2000, Barbara J. Dawson of DuPont's Chambers Works inquired of Raymond Strocko and Robert Ibbetson whether it would be appropriate for DuPont to implement a medical surveillance program consisting of medical/work histories and blood chemistry profile (including AST and ALT) for the DuPont Chambers Works employees who work with any fluorine-based chemicals, not just C-8.

REQUEST FOR ADMISSION NO. 72. Attached hereto at Exhibit DD is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 73. Attached hereto at Exhibit EE is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Denied, except admitted that each page is a separate business record of Dupont prepared and kept in the regular course of business of DuPont.

REQUEST FOR ADMISSION NO. 74. DuPont has recognized that DuPont's Chambers Works employees have an increased risk for bladder cancer.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without waiving this objection, DuPont admits this Request for Admission as phrased.

REQUEST FOR ADMISSION NO. 75. Attached hereto at Exhibit FF is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 76. DuPont has recognized that DuPont's Chambers Works employees have an increased risk for lung cancer.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without waiving this objection, DuPont denies this Request for Admission, except admitted that an increased risk for lung cancer was identified in male salaried Chambers Works employees in 1987, but no workplace exposures could be linked to the disease, and some cases were attributed to smoking and/or asbestos exposure.

REQUEST FOR ADMISSION NO. 77. DuPont has recognized that DuPont's Washington Works employees have an increased risk for buccal cavity and pharyngeal cancer.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without waiving this objection, DuPont denies this Request for Admission, except admitted that there appears to have been an increased risk for buccal cavity and pharyngeal cancer in Washington Works employees between the years 1956 and 1983, and such increase appears to have been related to the use of tobacco.

REQUEST FOR ADMISSION NO. 78. Although DuPont had received by June of 1999 the results of the testing of the Chambers Works C-8 Workers for C-8 in their blood, DuPont did not include those test results in its June 23, 2000 Voluntary Use and Exposure Information Profile for C-8 that it submitted to the United States Environmental Protection Agency.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without waiving this objection, DuPont admits that it had received by June of 1999 the results of the baseline testing of the Chambers Works employees prior to their being exposed to C-8 in the workplace at Chambers Works, and DuPont did not include those baseline test results in its June 23, 2000 Voluntary Use and Exposure Information Profile for C-8 that it submitted to the United States Environmental Protection Agency because the Chambers Works C-8 Workers were not yet being exposed to C-8 in the workplace at that time.

REQUEST FOR ADMISSION NO. 79. Attached hereto at Exhibit GG is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 80. In August of 2000, Anthony J. Playtis of DuPont's Washington Works estimated, based on test results of C-8 in blood of DuPont Washington Works pensioners tested in 1995 and 2000, that the half-life for C-8 in human blood was approximately four years.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without

waiving this objection, this Request for Admission is denied, except as follows: DuPont admits that based on test results of C-8 in blood of DuPont Washington Works pensioners tested in 1995 and 2000, and given the serious limitations on the accuracy of the data, including the small size of most of the data sets, the frequent transfer of site employees from one job to another, and the slow rate at which C-8 blood levels decrease after exposure stops, Anthony Playtis estimated that results from pensioners indicated an average half life for C-8 in blood of about four years.

REQUEST FOR ADMISSION NO. 81. Attached hereto at Exhibit HH is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 82. In August of 2000, DuPont was prepared to offer testing for C-8 in blood of citizens residing of the area of the DuPont Washington Works plant, with collection of blood at the Washington Works plant and use of the same laboratory that DuPont used for analysis of DuPont's Washington Works employees' blood for C-8.

RESPONSE: Denied.

REQUEST FOR ADMISSION NO. 83. Attached hereto at Exhibit II is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 84. Attached hereto at Exhibit JJ is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 85. In 2000, DuPont's Chambers Works commenced follow-up medical surveillance for the DuPont Chambers Works employees who had participated in the baseline medical surveillance exams for C-8 at DuPont's Chambers Works in 1999 (the "Chambers Works Follow-Up Exams").

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 86. Attached hereto at Exhibit KK is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted, except DuPont notes that this document was redacted prior to production to Plaintiffs.

REQUEST FOR ADMISSION NO. 87. The DuPont Chambers Works Follow-up Exams included: medical history questionnaire; automated chemistry profile (SMA-12 (including HDL, cholesterol, glucose, uric acid, BUN, calcium, phosphorus, total protein, bilirubin, alkaline phosphatase, LDH, AST(SGOT), total cholesterol, creatinine, and ALT (SGPT)); complete blood count; perfluorooctanoic acid (PFOA) in blood; and total fluorine in blood.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 88. In 2001, DuPont's Chambers Works received the results of C-8 blood testing done during the Chambers Works Follow-Up Exams.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 89. Attached hereto at Exhibit LL is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 90. Attached hereto at Exhibit MM is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 91. Attached hereto at Exhibit NN is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 92. DuPont's current community exposure guideline for C-8 in community water is 1 ppb, if the community at issue also is exposed to C-8 in air.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 93. DuPont's current community exposure guideline for C-8 in community water is 3 ppb, if the community at issue is not exposed to C-8 in air.

RESPONSE: Denied, except admitted that DuPont established a "community exposure guideline" for water of 3 parts per billion based on the assumption that 100% of an individual's exposure would come from water.

REQUEST FOR ADMISSION NO. 94. DuPont's current community exposure guideline for C-8 in community air is 0.3 ug/m3.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 95. The levels of C-8 in air exceeded 0.3 ug/m3 at the fenceline of DuPont's Washington Works plant according to calculations made by DuPont in 1987 using data from 1984 and 1986.

RESPONSE: DuPont objects to this Request for Admission on the grounds that it is deliberately incomplete and calculated to lead to a false conclusion and that it is vague and ambiguous. Subject to and without waiving these objections, DuPont admits this Request for Admission as phrased.

REQUEST FOR ADMISSION NO. 96. According to DuPont's air emissions modeling calculations, the level of C-8 in air of some residents living near DuPont's Washington Works plant exceeded 0.3 ug/m3 prior to DuPont's installation of new scrubber equipment at the Washington Works plant during 2002.

RESPONSE: DuPont objects to this Request for Admission on the grounds that it is deliberately incomplete and calculated to lead to a false conclusion and that it is vague and ambiguous. Subject to and without waiving these objections, DuPont admits this Request for Admission as phrased.

REQUEST FOR ADMISSION NO. 97. Attached hereto at Exhibit OO is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Denied.

REQUEST FOR ADMISSION NO. 98. According to DuPont's air emissions modeling calculations, the level of C-8 in the air of some residents serviced by the Little Hocking Water Association exceeded 0.3 ug/m3, based on DuPont's year 2000 modeled emission levels from DuPont's Washington Works plant.

RESPONSE: DuPont lacks sufficient information to admit or deny this Request for Admission; therefore DuPont denies this Request for Admission.

REQUEST FOR ADMISSION NO. 99. According to DuPont's air emissions modeling calculations, the level of C-8 in the air of some residents serviced by the Little Hocking Water Association exceeded 0.3 ug/m3 prior to installation of new scrubber equipment at DuPont's Washington Works plant during 2002.

RESPONSE: DuPont lacks sufficient information to admit or deny this Request for Admission; therefore DuPont denies this Request for Admission.

REQUEST FOR ADMISSION NO. 100. C-8 has in the past been present in the Lubeck Public Service District's public drinking water at a concentration above 1 ppb.

RESPONSE: DuPont objects on the ground that this Request for Admission is vague and ambiguous. Subject to and without waiving this objection, DuPont denies this Request for Admission, except it is admitted that samples of the Lubeck Public Service District's public drinking water have been analyzed for C-8 content, and some of those analysis results have indicated a concentration of C-8 of greater than one part per billion.

REQUEST FOR ADMISSION NO. 101. Attached hereto at Exhibit PP is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 102. C-8 is present in Lubeck Public Service District's drinking water at a concentration above 1 ppb.

RESPONSE: DuPont objects on the ground that this Request for Admission is vague and ambiguous. Subject to and without waiving this objection, DuPont denies this Request for Admission as phrased.

REQUEST FOR ADMISSION NO. 103. Some residents obtaining drinking water from the Lubeck Public Service District are potentially exposed to air emissions of C-8 from DuPont's Washington Works plant.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 104. C-8 has in the past been present in the Little Hocking Water Association's drinking water at a concentration above 1 ppb.

RESPONSE: DuPont objects on the ground that this Request for Admission is vague and ambiguous. Subject to and without waiving this objection, DuPont admits this Request for Admission as phrased.

REQUEST FOR ADMISSION NO. 105. C-8 is present in Little Hocking Water Association's drinking water at a concentration above 1 ppb.

RESPONSE: DuPont objects on the ground that this Request for Admission is vague and ambiguous. Subject to and without waiving this objection, DuPont admits this Request for Admission as phrased.

REQUEST FOR ADMISSION NO. 106. C-8 has in the past been present in the Little Hocking Water Association's drinking water at a concentration above 3 ppb.

RESPONSE: DuPont objects on the ground that this Request for Admission is vague and ambiguous. Subject to and without waiving this objection, DuPont denies this Request for

Admission, except it is admitted that water sampling performed in October 2002 indicated that at that time, the water system point had a concentration of C-8 of 4.29 ppb.

REQUEST FOR ADMISSION NO. 107. C-8 is present in the Little Hocking Water Association's drinking water at a concentration above 3 ppb.

RESPONSE: DuPont objects on the ground that this Request for Admission is vague and ambiguous. Subject to and without waiving this objection, DuPont denies this Request for Admission, except it is admitted that water sampling performed in October 2002 indicated that at that time, the water system point had a concentration of C-8 of 4.29 ppb.

REQUEST FOR ADMISSION NO. 108. C-8 is present in the Little Hocking Water Association's drinking water at a concentration above 4 ppb.

RESPONSE: DuPont objects on the ground that this Request for Admission is vague and ambiguous. Subject to and without waiving this objection, DuPont denies this Request for Admission, except it is admitted that water sampling performed in October 2002 indicated that at that time, the water system point had a concentration of C-8 of 4.29 ppb.

REQUEST FOR ADMISSION NO. 109. Some individuals obtaining drinking water from the Little Hocking Water Association are potentially exposed to air emissions of C-8 from DuPont's Washington Works plant.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 110. DuPont's operations have resulted in the presence of C-8 in private drinking water wells near DuPont's Washington Works plant.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 111. Attached hereto at Exhibit QQ is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Denied.

REQUEST FOR ADMISSION NO. 112. Attached hereto at Exhibit RR is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 113. DuPont's operations have resulted in the presence of C-8 in drinking water supplied by the Lubeck Public Service District in West Virginia.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 114. DuPont's operations have resulted in the presence of C-8 in drinking water supplied by Little Hocking Water Association of Ohio.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 115. DuPont's operations have resulted in the presence of C-8 in drinking water supplied by the City of Belpre, Ohio.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is vague and ambiguous. Subject to and without waiving this objection, DuPont denies this Request for Admission, except DuPont admits that in February, March and April 2002, C-8 was detected at levels from 0.0818 ppb to 0.12 ppb in drinking water supplied by the City of Belpre, Ohio, and at this time, DuPont is unable to identify any alternative sources of C-8 that have resulted in the presence of C-8 in drinking water supplied by the City of Belpre, Ohio.

REQUEST FOR ADMISSION NO. 116. DuPont's operations have resulted in the presence of C-8 in drinking water supplied by Blennerhassett Island.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is vague and ambiguous. Subject to and without waiving this objection, DuPont denies this Request for Admission, except DuPont admits that in January 2002, C-8 was detected at a level of 0.165 ppb in drinking water supplied by Blennerhassett Island, and at this time, DuPont is unable to identify any alternative sources of C-8 that have resulted in the presence of C-8 in drinking water supplied by Blennerhassett Island.

REQUEST FOR ADMISSION NO. 117. DuPont's operations have resulted in the presence of C-8 in drinking water supplied by the General Electric Plastics plant in Wood County, West Virginia.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is vague and ambiguous. Subject to and without waiving this objection, DuPont admits this Request for Admission as phrased.

REQUEST FOR ADMISSION NO. 118. DuPont's operations have resulted in the presence of C-8 in drinking water supplied by DuPont's Washington Works plant.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is vague and ambiguous. Subject to and without waiving this objection, DuPont admits this Request for Admission as phrased.

REQUEST FOR ADMISSION NO. 119. DuPont's operations have resulted in the presence of C-8 in drinking water supplied by the Tupper Plains Public Service District in Ohio.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is vague and ambiguous. Subject to and without waiving this objection, DuPont denies this Request for Admission, except DuPont admits that in February, March, April, August and October 2002, C-8 was detected at levels from 0.246 ppb to 0.363 ppb in drinking water supplied by the Tupper Plains Public Service District in Ohio, and at this time, DuPont is unable to identify any alternative sources of C-8 that have resulted in the presence of C-8 in drinking water supplied by the Tupper Plains Public Service District in Ohio.

REQUEST FOR ADMISSION NO. 120. DuPont's operations have resulted in the presence of C-8 in drinking water supplied by the Mason County Public Service District in West Virginia.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is vague and ambiguous. Subject to and without waiving this objection, DuPont denies this Request for Admission, except DuPont admits that in January, March and April 2002, C-8 was detected at levels from non-quantifiable (below 0.050 ppb) to 0.102 ppb in drinking water supplied by the Mason County Public Service District in West Virginia, and at this time, DuPont is unable to identify any alternative sources of C-8 that have resulted in the presence of C-8 in drinking water supplied by the Mason County Public Service District in West Virginia.

REQUEST FOR ADMISSION NO. 121. DuPont's operations have resulted in the presence of C-8 in drinking water supplied by the Village of Syracuse, Ohio.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is vague and ambiguous. Subject to and without waiving this objection, DuPont denies this Request for Admission as phrased.

REQUEST FOR ADMISSION NO. 122. DuPont's operations have resulted in the presence of C-8 in drinking water supplied by the Village of Pomeroy, Ohio.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is vague and ambiguous. Subject to and without waiving this objection, DuPont denies this Request for Admission, except DuPont admits that in March and April 2002, C-8 was detected at levels from 0.0628 ppb to 0.0659 ppb in drinking water supplied by the Mason County Public Service District in West Virginia, and at this time, DuPont is unable to identify any alternative sources of C-8 that have resulted in the presence of C-8 in drinking water supplied by the Mason County Public Service District in West Virginia.

REQUEST FOR ADMISSION NO. 123. In 2001, DuPont's Haskell Laboratory developed a simple, conservative compartmental model (hereinafter "Compartmental C-8 Model") to relate ammonium perfluorooctanoate (APFO) exposure to estimates of perfluorooctanoate (PFO) blood levels in humans.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without waiving this objection, DuPont admits this Request for Admission, except DuPont notes that, for accuracy, the Compartmental C-8 Model and its corresponding tables must be read in accordance with the assumptions and caveats set forth in the Model itself, namely that (1) the Model is not unique to PFOA, but could be used unchanged for any chemical with a half-life of one year; (2) the Model is intended to be overly simplified for ease of use and therefore is more theoretical and less realistic and practical; (3) the Model is constructed to be conservative and theoretical, and not as a substitute for a more complex and realistic model more closely approximating the physiology and function of the human body; (4) although the Model is constructed as a two-

compartment model, i.e., a human blood compartment and a human body compartment, only the blood compartment is “run” to compute the simulated results; (5) the Model is based on general kinetic principles, but it does not simulate actual body mechanisms or functions; (6) the Model is based on standard estimates of volumes of daily water and air consumption, and PFOA exposures are considered by the Model to occur daily; (7) the Model is constructed to simulate the highest possible intake of PFOA through ingestion and inhalation (i.e., it does not diffuse, and is completely and instantly absorbed); and (8) the Model is constructed to provide a conservative, i.e., highly theoretical estimates of possible concentrations of PFOA in the blood.

REQUEST FOR ADMISSION NO. 124. Attached hereto at Exhibit SS is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Denied that the exhibit as attached at Exhibit SS, EID166599 - EID166608, is an accurate copy, because page EID166603 is illegible. However, DuPont has appended herein at Exhibit 1 a complete and legible copy of the same document, EID166599 - EID166608, and as to Exhibit 1, this Request for Admission is admitted, except denied as to marginalia.

REQUEST FOR ADMISSION NO. 125. DuPont used its Compartmental C-8 Model to create a table relating APFO exposures through air and drinking water to estimated steady-state PFO blood concentrations.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without waiving this objection, this Request for Admission is denied, except it is admitted that DuPont’s Haskell Laboratory ran a series of model simulations pursuant to its Compartmental

C-8 Model to estimate the steady-state human PFO blood levels resulting from drinking water containing APFO, breathing air containing APFO or combinations of the two, and created a table (hereinafter referred to as the "Compartmental Model Table") reflecting these results, and DuPont notes that, for accuracy, the Compartmental C-8 Model and its corresponding tables must be read in accordance with the assumptions and caveats set forth in the Model itself, namely that (1) the Model is not unique to PFOA, but could be used unchanged for any chemical with a half-life of one year; (2) the Model is intended to be overly simplified for ease of use and therefore is more theoretical and less realistic and practical; (3) the Model is constructed to be conservative and theoretical, and not as a substitute for a more complex and realistic model more closely approximating the physiology and function of the human body; (4) although the Model is constructed as a two-compartment model, i.e., a human blood compartment and a human body compartment, only the blood compartment is "run" to compute the simulated results; (5) the Model is based on general kinetic principles, but it does not simulate actual body mechanisms or functions; (6) the Model is based on standard estimates of volumes of daily water and air consumption, and PFOA exposures are considered by the Model to occur daily; (7) the Model is constructed to simulate the highest possible intake of PFOA through ingestion and inhalation (i.e., it does not diffuse, and is completely and instantly absorbed); and (8) the Model is constructed to provide a conservative, i.e., highly theoretical estimates of possible concentrations of PFOA in the blood.

REQUEST FOR ADMISSION NO. 126. According to DuPont's Compartmental C-8 Model, those consuming drinking water containing 1 ppb APFO with no APFO in their inhaled air would be estimated to have resulting steady-state PFO concentration in their blood of 0.30 parts per million (ppm).

RESPONSE: DuPont objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without waiving this objection, DuPont admits this Request for Admission, except DuPont notes that, for accuracy, the Compartmental C-8 Model and its corresponding tables must be read in accordance with the assumptions and caveats set forth in the Model itself, namely that (1) the Model is not unique to PFOA, but could be used unchanged for any chemical with a half-life of one year; (2) the Model is intended to be overly simplified for ease of use and therefore is more theoretical and less realistic and practical; (3) the Model is constructed to be conservative and theoretical, and not as a substitute for a more complex and realistic model more closely approximating the physiology and function of the human body; (4) although the Model is constructed as a two-compartment model, i.e., a human blood compartment and a human body compartment, only the blood compartment is “run” to compute the simulated results; (5) the Model is based on general kinetic principles, but it does not simulate actual body mechanisms or functions; (6) the Model is based on standard estimates of volumes of daily water and air consumption, and PFOA exposures are considered by the Model to occur daily; (7) the Model is constructed to simulate the highest possible intake of PFOA through ingestion and inhalation (i.e., it does not diffuse, and is completely and instantly absorbed); and (8) the Model is constructed to provide a conservative, i.e., highly theoretical estimates of possible concentrations of PFOA in the blood.

REQUEST FOR ADMISSION NO. 127. According to DuPont’s Compartmental C-8 Model, those consuming drinking water containing 1 ppb APFO with 0.30 ug/m³ APFO in their inhaled air would be estimated to have a resulting steady-state PFO concentration in their blood of 1.20 ppm.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without waiving this objection, DuPont admits this Request for Admission, except DuPont notes that, for accuracy, the Compartmental C-8 Model and its corresponding tables must be read in accordance with the assumptions and caveats set forth in the Model itself, namely that (1) the Model is not unique to PFOA, but could be used unchanged for any chemical with a half-life of one year; (2) the Model is intended to be overly simplified for ease of use and therefore is more theoretical and less realistic and practical; (3) the Model is constructed to be conservative and theoretical, and not as a substitute for a more complex and realistic model more closely approximating the physiology and function of the human body; (4) although the Model is constructed as a two-compartment model, i.e., a human blood compartment and a human body compartment, only the blood compartment is "run" to compute the simulated results; (5) the Model is based on general kinetic principles, but it does not simulate actual body mechanisms or functions; (6) the Model is based on standard estimates of volumes of daily water and air consumption, and PFOA exposures are considered by the Model to occur daily; (7) the Model is constructed to simulate the highest possible intake of PFOA through ingestion and inhalation (i.e., it does not diffuse, and is completely and instantly absorbed); and (8) the Model is constructed to provide a conservative, i.e., highly theoretical estimates of possible concentrations of PFOA in the blood.

REQUEST FOR ADMISSION NO. 128. According to DuPont's Compartmental C-8 Model, those consuming drinking water containing 1 ppb APFO with 0.20 ug/m³ APFO in their inhaled air would be estimated to have a resulting steady-state PFO concentration in their blood of 0.90 ppm.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without waiving this objection, DuPont admits this Request for Admission, except DuPont notes that, for accuracy, the Compartmental C-8 Model and its corresponding tables must be read in accordance with the assumptions and caveats set forth in the Model itself, namely that (1) the Model is not unique to PFOA, but could be used unchanged for any chemical with a half-life of one year; (2) the Model is intended to be overly simplified for ease of use and therefore is more theoretical and less realistic and practical; (3) the Model is constructed to be conservative and theoretical, and not as a substitute for a more complex and realistic model more closely approximating the physiology and function of the human body; (4) although the Model is constructed as a two-compartment model, i.e., a human blood compartment and a human body compartment, only the blood compartment is “run” to compute the simulated results; (5) the Model is based on general kinetic principles, but it does not simulate actual body mechanisms or functions; (6) the Model is based on standard estimates of volumes of daily water and air consumption, and PFOA exposures are considered by the Model to occur daily; (7) the Model is constructed to simulate the highest possible intake of PFOA through ingestion and inhalation (i.e., it does not diffuse, and is completely and instantly absorbed); and (8) the Model is constructed to provide a conservative, i.e., highly theoretical estimates of possible concentrations of PFOA in the blood.

REQUEST FOR ADMISSION NO. 129. According to DuPont’s Compartmental C-8 Model, those consuming drinking water containing 3 ppb APFO with no APFO in their inhaled air would be estimated to have a resulting steady-state PFO concentration in their blood of 0.90 ppm.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without waiving this objection, DuPont admits this Request for Admission, except DuPont notes that, for accuracy, the Compartmental C-8 Model and its corresponding tables must be read in accordance with the assumptions and caveats set forth in the Model itself, namely that (1) the Model is not unique to PFOA, but could be used unchanged for any chemical with a half-life of one year; (2) the Model is intended to be overly simplified for ease of use and therefore is more theoretical and less realistic and practical; (3) the Model is constructed to be conservative and theoretical, and not as a substitute for a more complex and realistic model more closely approximating the physiology and function of the human body; (4) although the Model is constructed as a two-compartment model, i.e., a human blood compartment and a human body compartment, only the blood compartment is “run” to compute the simulated results; (5) the Model is based on general kinetic principles, but it does not simulate actual body mechanisms or functions; (6) the Model is based on standard estimates of volumes of daily water and air consumption, and PFOA exposures are considered by the Model to occur daily; (7) the Model is constructed to simulate the highest possible intake of PFOA through ingestion and inhalation (i.e., it does not diffuse, and is completely and instantly absorbed); and (8) the Model is constructed to provide a conservative, i.e., highly theoretical estimates of possible concentrations of PFOA in the blood.

REQUEST FOR ADMISSION NO. 130. According to DuPont’s Compartmental C-8 Model, those consuming drinking water containing 3 ppb APFO with 0.20 ug/m³ APFO in their inhaled air would be estimated to have a resulting steady-state PFO concentration in their blood of 1.80 ppm.

RESPONSE: Denied.

REQUEST FOR ADMISSION NO. 131. According to DuPont's Compartmental C-8 Model, those consuming drinking water containing 4 ppb APFO with no APFO present in their inhaled air would be estimated to have a resulting steady-state PFO concentration in their blood of 1.20 ppm.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without waiving this objection, DuPont admits this Request for Admission, except DuPont notes that, for accuracy, the Compartmental C-8 Model and its corresponding tables must be read in accordance with the assumptions and caveats set forth in the Model itself, namely that (1) the Model is not unique to PFOA, but could be used unchanged for any chemical with a half-life of one year; (2) the Model is intended to be overly simplified for ease of use and therefore is more theoretical and less realistic and practical; (3) the Model is constructed to be conservative and theoretical, and not as a substitute for a more complex and realistic model more closely approximating the physiology and function of the human body; (4) although the Model is constructed as a two-compartment model, i.e., a human blood compartment and a human body compartment, only the blood compartment is "run" to compute the simulated results; (5) the Model is based on general kinetic principles, but it does not simulate actual body mechanisms or functions; (6) the Model is based on standard estimates of volumes of daily water and air consumption, and PFOA exposures are considered by the Model to occur daily; (7) the Model is constructed to simulate the highest possible intake of PFOA through ingestion and inhalation (i.e., it does not diffuse, and is completely and instantly absorbed); and (8) the Model is

constructed to provide a conservative, i.e., highly theoretical estimates of possible concentrations of PFOA in the blood.

REQUEST FOR ADMISSION NO. 132. According to DuPont's Compartmental C-8 Model, those consuming drinking water containing 4 ppb APFO with 0.20 ug/m³ APFO in their inhaled air would be estimated to have a resulting steady-state PFO concentration in their blood of 1.80 ppm.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without waiving this objection, DuPont admits this Request for Admission, except DuPont notes that, for accuracy, the Compartmental C-8 Model and its corresponding tables must be read in accordance with the assumptions and caveats set forth in the Model itself, namely that (1) the Model is not unique to PFOA, but could be used unchanged for any chemical with a half-life of one year; (2) the Model is intended to be overly simplified for ease of use and therefore is more theoretical and less realistic and practical; (3) the Model is constructed to be conservative and theoretical, and not as a substitute for a more complex and realistic model more closely approximating the physiology and function of the human body; (4) although the Model is constructed as a two-compartment model, i.e., a human blood compartment and a human body compartment, only the blood compartment is "run" to compute the simulated results; (5) the Model is based on general kinetic principles, but it does not simulate actual body mechanisms or functions; (6) the Model is based on standard estimates of volumes of daily water and air consumption, and PFOA exposures are considered by the Model to occur daily; (7) the Model is constructed to simulate the highest possible intake of PFOA through ingestion and inhalation (i.e., it does not diffuse, and is completely and instantly absorbed); and (8) the Model is

constructed to provide a conservative, i.e., highly theoretical estimates of possible concentrations of PFOA in the blood.

REQUEST FOR ADMISSION NO. 133. According to DuPont's Compartmental C-8 Model, those consuming drinking water containing 4 ppb APFO with 0.30 ug/m³ APFO in their inhaled air would be estimated to have a resulting steady-state PFO concentration in their blood of 2.10 ppm.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is deliberately incomplete and calculated to lead to a false conclusion. Subject to and without waiving this objection, DuPont admits this Request for Admission, except DuPont notes that, for accuracy, the Compartmental C-8 Model and its corresponding tables must be read in accordance with the assumptions and caveats set forth in the Model itself, namely that (1) the Model is not unique to PFOA, but could be used unchanged for any chemical with a half-life of one year; (2) the Model is intended to be overly simplified for ease of use and therefore is more theoretical and less realistic and practical; (3) the Model is constructed to be conservative and theoretical, and not as a substitute for a more complex and realistic model more closely approximating the physiology and function of the human body; (4) although the Model is constructed as a two-compartment model, i.e., a human blood compartment and a human body compartment, only the blood compartment is "run" to compute the simulated results; (5) the Model is based on general kinetic principles, but it does not simulate actual body mechanisms or functions; (6) the Model is based on standard estimates of volumes of daily water and air consumption, and PFOA exposures are considered by the Model to occur daily; (7) the Model is constructed to simulate the highest possible intake of PFOA through ingestion and inhalation (i.e., it does not diffuse, and is completely and instantly absorbed); and (8) the Model is

constructed to provide a conservative, i.e., highly theoretical estimates of possible concentrations of PFOA in the blood.

REQUEST FOR ADMISSION NO. 134. DuPont has estimated the mean concentration of APFO in the blood of its employees in jobs with potential for APFO exposure who had their blood tested in 1989-90 to be 1.96 ppm.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 135. Attached hereto at Exhibit TT is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 136. DuPont estimated the mean concentration of APFO in the blood of its employees in jobs with potential for APFO exposure who had their blood tested in 1995 to be 1.56 ppm.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 137. DuPont estimated the mean concentration of APFO in the blood of its employees in jobs with potential for APFO exposure who had their blood tested in 2000 to be 1.53 ppm.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 138. Attached hereto at Exhibit UU is an authentic and accurate copy of a business record of DuPont prepared and kept in the regular course of business of DuPont.

RESPONSE: Admitted.

REQUEST FOR ADMISSION NO. 139. 3M has reported to the United States Environmental Protection Agency that it detected a median concentration of 5.1 parts per billion (“PPB”) PFOA in human sera from pooled samples drawn in 1995 from 599 individuals from 23 different states in the United States in the age span of 2-12 years old.

RESPONSE: DuPont objects to this Request for Admission on the grounds that it is vague and ambiguous, and that it apparently refers to a third-party document not prepared by DuPont, which speaks for itself.

REQUEST FOR ADMISSION NO. 140. 3M has reported to the United States Environmental Protection that it detected a median concentration of 4.7 ppb PFOA in human sera from pooled samples drawn in 2000 from over 600 individuals from 6 blood banks from across the United States, focusing in the age span 20-69 years old.

RESPONSE: DuPont objects to this Request for Admission on the grounds that it is vague and ambiguous, and that it apparently refers to a third-party document not prepared by DuPont, which speaks for itself.

REQUEST FOR ADMISSION NO. 141. In May of 1999, 3M reported to the United States Environmental Protection Agency that it had detected an average concentration of 3 ppb PFOA in over 35 lots of individual pooled human sera samples purchased from chemical or biological supply companies.

RESPONSE: DuPont objects to this Request for Admission on the grounds that it is vague and ambiguous, and that it apparently refers to a third-party document not prepared by DuPont, which speaks for itself.

REQUEST FOR ADMISSION NO. 142. Individuals who were exposed to C-8 in drinking water supplied by the Lubeck Public Service District have been significantly exposed

to C-8 in comparison to the levels of C-8 to which the general population of the United States is exposed.

RESPONSE: Denied.

REQUEST FOR ADMISSION NO. 143. Those individuals who are exposed to C-8 in drinking water supplied by the Lubeck Public Service District have been significantly exposed to C-8 in comparison to the levels of C-8 to which the general population of the United States is exposed.

RESPONSE: Denied.

REQUEST FOR ADMISSION NO. 144. Individuals who have been exposed to C-8 in drinking water supplied by the Little Hocking Water Association have been significantly exposed to C-8 in comparison to the levels of C-8 to which the general population of the United States is exposed.

RESPONSE: Denied.

REQUEST FOR ADMISSION NO. 145. Those individuals who are exposed to C-8 in drinking water supplied by the Little Hocking Water Association have been significantly exposed to C-8 in comparison to the levels of C-8 to which the general population of the United States is exposed.

RESPONSE: Denied.

REQUEST FOR ADMISSION NO. 146. Those individuals whose air and drinking water have been contaminated with C-8 from DuPont's Washington Works plant have been significantly exposed to C-8 in comparison to the levels of C-8 to which the general population of the United States is exposed.

RESPONSE: Denied.

REQUEST FOR ADMISSION NO. 147. Overexposure to C-8 is toxic to humans.

RESPONSE: DuPont objects on the ground that this Request for Admission is vague and ambiguous. Subject to and without waiving this objection, DuPont denies this Request for Admission, except to the extent that it admits that any substance can have some degree of adverse consequence in humans at a sufficiently high dose.

REQUEST FOR ADMISSION NO. 148. Overexposure to C-8 is hazardous to humans.

RESPONSE: DuPont objects on the ground that this Request for Admission is vague and ambiguous. Subject to and without waiving this objection, DuPont denies this Request for Admission, except to the extent that it admits that any substance can have some degree of adverse consequence in humans at a sufficiently high dose.

REQUEST FOR ADMISSION NO. 149. Physicians employed by or on behalf of DuPont have recommended that testing be performed of those exposed to C-8 to determine, among other things, whether there are health effects from such C-8 exposure.

RESPONSE: DuPont objects on the ground that this Request for Admission is vague and ambiguous. Subject to and without waiving this objection, DuPont denies this Request for Admission, except it admits that certain physicians employed by or on behalf of DuPont have recommended that testing be performed on employees exposed to C-8.

REQUEST FOR ADMISSION NO. 150. DuPont is aware of C-8 having been detected at levels exceeding 10 ppb in the blood of individuals living in Wood County, West Virginia, who had never worked for DuPont.

RESPONSE: DuPont admits that it is aware of certain information relating to blood testing for C-8 of certain individuals living in Wood County, West Virginia to which a

confidentiality agreement applies, but this information does not provide DuPont with sufficient information to admit or deny this Request for Admission as phrased; therefore, DuPont denies this request for admission.

REQUEST FOR ADMISSION NO. 151. DuPont is providing medical monitoring to persons residing in West Virginia and Ohio who are non-DuPont employees who claim to have been exposed to C-8.

RESPONSE: DuPont objects to this Request for Admission on the ground that it is vague and ambiguous. Subject to and without waiving this objection, DuPont denies this Request for Admission, except it admits that DuPont has conducted blood testing for the presence of C-8 for certain non-DuPont employees in West Virginia and Ohio.

Respectfully submitted,

E. I. DU PONT DE NEMOURS AND COMPANY

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**A Simple, Conservative Compartmental Model to Relate
Ammonium Perfluorooctanoate (APFO) Exposure to
Estimates of Perfluorooctanoate (PFO) Blood Levels in
Humans**

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Gary W. Jepson, Ph.D.

**Biochemical Toxicology
DuPont Haskell Laboratory for Health and Environmental Sciences**

10 October, 2001

DRAFT

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Abstract

A simple and conservative compartmental model was developed to relate ammonium perfluorooctanoate (APFO) exposures to estimates of perfluorooctanoate (PFO) concentrations in human blood. The model was based on kinetic principles, but it did not include mechanistic or physiological descriptions. Further, the model was not intended to replace the need for more robust models that include mechanistic and appropriate physiological descriptions. The model included zero-order mathematical descriptions of oral and inhalation input and a first order elimination description. Standard estimates of the volumes of daily water consumption and air breathed were used to relate daily intake of APFO to concentrations of APFO in air and drinking water. The model was exercised under a variety of exposure conditions and used to create a table relating APFO intake via drinking water and/or air to PFO blood concentrations. The simplicity and utility of this model provide decision-makers with an easily applied tool to relate APFO exposures to estimates of resulting PFO concentrations in human blood.

Introduction

A simple compartmental model was developed and used to estimate the concentration of perfluorooctanoate (PFO) in blood following inhalation or ingestion of ammonium perfluorooctanoate (APFO). The model presented is intended to complement various consequence analysis and planning activities and is not intended to be a substitute for a robust, mechanism based physiological model. In order to realize both the strengths and limitations of the model, it is important to carefully consider the assumptions and caveats relevant to the model development and application.

Approach

Model Development:

The model developed for this application was a two-compartment open model with one compartment defined as the blood compartment and the other as the body compartment. While the model is constructed as a two-compartment model, transfer of PFO is confined to only one compartment (blood compartment) in order to provide a conservative estimate of PFO concentrations in blood following APFO exposure. Functionally, this reduces to a one-compartment open model with two zero-order-input processes and one first-order elimination process. In other words, PFO is confined to the blood compartment and the PFO concentration in blood cannot be reduced by the distribution of PFO into other body tissues. In order to contribute to the conservative estimates produced by this model, any APFO that is ingested or inhaled is not subject to diffusional resistance and is assumed to be completely and instantly absorbed into the blood compartment. Since PFO is not metabolized, elimination from the blood is via renal excretion. In this model the elimination is described as a pseudo first-order process. A schematic of the model is shown in Figure 1.

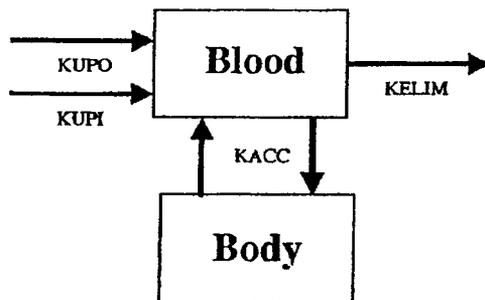


Figure 1. Schematic of PFO Compartmental Model.

In Figure 1, KACC is the distribution coefficient for transfer of PFO between the blood and body compartments. It has the units of day^{-1} , but as discussed earlier, it is set to zero

in order to create a conservative one-compartment model. KUPO is a zero-order term to describe PFO input into the blood compartment (ug/day) via the oral route. KUPI is a zero-order term to describe PFO input into the blood compartment (ug/day) via the inhalation route. KELIM is a pseudo first-order elimination coefficient (day⁻¹) that describes removal of PFO from the blood compartment via renal excretion. Differential rate equations were developed from the schematic in Figure 1 and the equations were solved using Advanced Continuous Simulation Language (ACSL, Aegis Corp.). The mathematical equations used to describe the concentration of PFO in the blood compartment (CBLOOD) are shown in the series of equations below.

$$\frac{dAB}{dt} = KUPO + KUPI - KELIM * CBLOOD * VOL - RAF \quad (1)$$

$$dAB = (KUPO + KUPI - KELIM * CBLOOD * VOL - RAF) dt \quad (2)$$

$$\int_{AB=0}^{AB} dAB = \int_{t=0}^t (KUPO + KUPI - KELIM * CBLOOD * VOL - RAF) dt \quad (3)$$

$$AB = \int_{t=0}^t (KUPO + KUPI - KELIM * CBLOOD * VOL - RAF) dt \quad (4)$$

$$CBLOOD = AB / VOL \quad (5)$$

In the equations above, AB is the amount (ug) of PFO in blood, t is time (days), VOL is the volume (ml) of the blood compartment and RAF (ug/day) is the rate of PFO movement between the blood and body compartments (RAF=0 in this model). The ACSL coding of the above equations is given immediately below and in Appendix 1. The corresponding ACSL command file is provided in Appendix 2.

$$RA = KUPO + KUPI - KELIM * CBLOOD * VOL - RAF \quad (6)$$

$$CBLOOD = INTEG(RA, 0.) / VOL \quad (7)$$

Model Input Assumptions/Descriptions:

Blood Compartment Volume: The blood volume of 3.5 L used in the model was that of a 50-Kg human (average human female weight). The female weight was selected to maintain the conservative approach desired for this model. Obviously, blood volume is a function of body weight so larger body weights will equate to larger blood volumes. PFO concentrations in blood will therefore decrease for a given APFO exposure as body weights increase.

Elimination Rate Constant: The elimination rate constant, KELIM, was assigned a value of 0.0019/day. This was derived assuming a PFO half-life (t_{1/2}) in humans of 365 days and that first order kinetics apply. While current human half-life estimates are placed in the 200-300 day range, the 365-day half-life is a conservative value for initial model conditions. The actual value for KELIM was derived using the relationship between the half-life and the elimination rate constant where first order kinetics are obeyed.

$$KELIM = \frac{\ln 2}{t_{1/2}} \quad (8)$$

Input of APFO via Drinking Water: Drinking water concentrations of APFO were converted to micrograms (ug) of APFO ingested per day using the assumption that approximately 2L of the water are consumed per day. An example follows where drinking water containing 1 part per billion (ppb) APFO was consumed:

$$1 \text{ ppb} = \frac{1\text{ug}}{L} \quad \text{so} \quad \frac{1\text{ug}}{L} \times \frac{2L}{\text{day}} = \frac{2\text{ug}}{\text{day}} \quad (9)$$

Input of APFO via Inhalation: Inhaled concentrations of APFO were converted to micrograms of APFO absorbed into the blood using the assumption that approximately 20 m³ of air are breathed per day. An example follows where air containing 1 ug/m³ APFO was inhaled.

$$\frac{1\text{ug}}{\text{m}^3} \times \frac{20\text{m}^3}{\text{day}} = \frac{20\text{ug}}{\text{day}} \quad (10)$$

General Assumptions:

The simple model described here is designed to be conservative and is not intended to be a substitute for a more robust, mechanism based physiological model. Consistent with the design of this model, several general assumptions have been made.

- ~~No~~ (1) The PFO is distributed only in the human blood compartment. *Conservative*
- ~~No~~ (2) There is no metabolism of PFO.
- ~~No~~ (3) No binding or mechanistic descriptions are included in the model. *Conservative*
- ~~ok~~ (4) Elimination occurs by a single first-order pathway. It is likely that elimination actually displays biphasic elimination with an initial rapid elimination phase followed by a slower or terminal phase elimination. In order to be consistent with the conservative nature of the model, only the slow (terminal) phase *terminal* elimination is included in the model. *Conservative*
- probably in* ? (5) All APFO inhaled or ingested in drinking water is instantly and completely absorbed into the blood compartment. *Conservative*
- read in* ? (6) APFO exposures occur every day throughout the exposure period modeled.

Results

The simulated PFO levels in human blood resulting from repeated ingestion of 6 ug/day APFO are shown in Figure 2. As would be expected based on the estimated half-life of PFO in the human body, the simulation illustrates that steady-state PFO blood levels are reached only after repeated exposure for over 6 years. Figure 3 is a simulation of the elimination of PFO from the blood once PFO levels are at steady state and PFO exposure is terminated.

Figure 2. Simulated PFO Concentration in Human Blood Following Continuous Intake of 6 ug/day

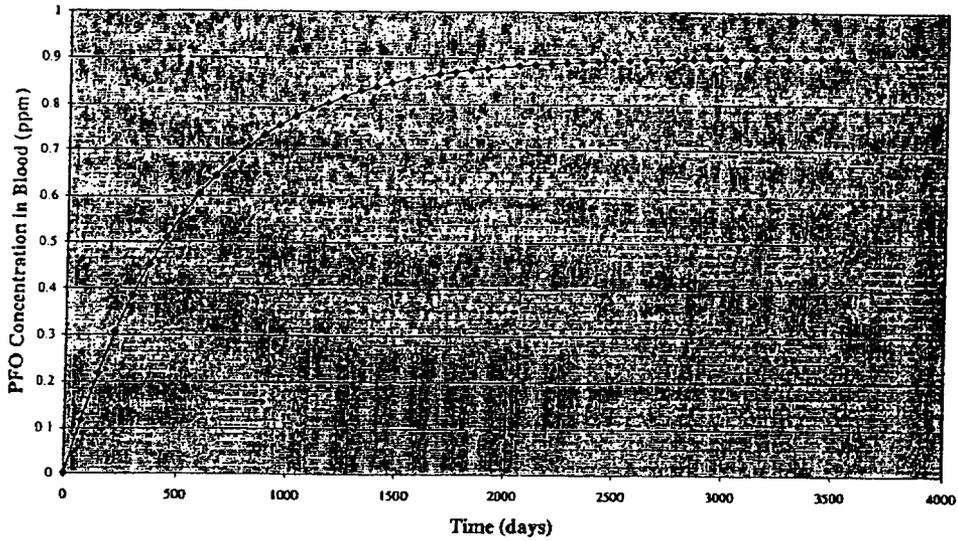
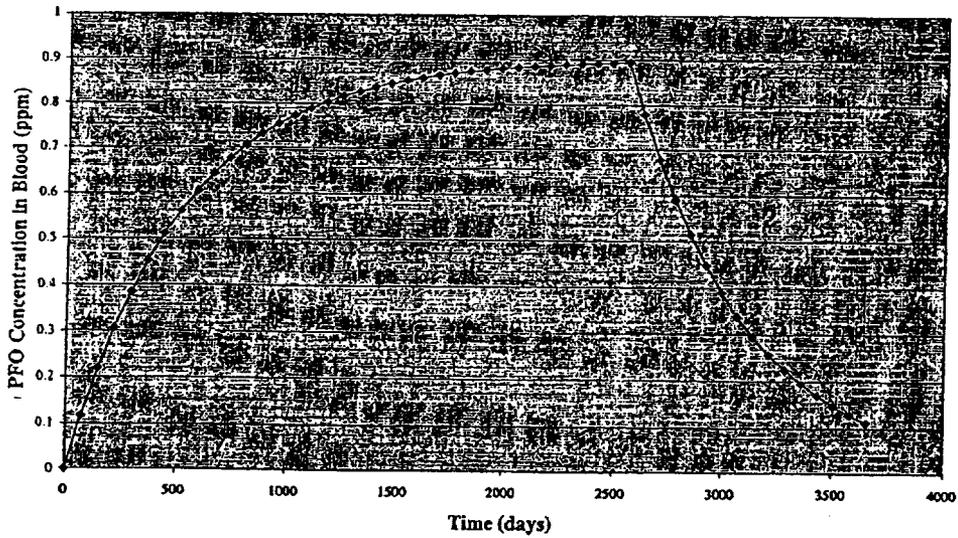


Figure 3. Simulated PFO Concentration in Human Blood During and After 2600 Days of Exposure to 6 ug/day APFO



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A series of model simulations were run to estimate the steady-state human PFO blood levels resulting from drinking water containing APFO, breathing air containing APFO or combinations of the two. The resulting estimates of PFO concentrations in human blood are shown in Table 1. Table 1 can be used under the conditions described in the text, to assign a PFO blood concentration to a particular exposure. Example 1: If drinking water containing 1 ppb APFO was consumed and no APFO was present in the inhaled air, the resulting steady-state PFO concentration estimate in human blood would be 0.30 ppm. Example 2: If no APFO was present in the drinking water and 0.05 $\mu\text{g}/\text{m}^3$ APFO was in the inhaled air, the resulting steady-state PFO concentration estimate in human blood would be 0.15 ppm. Example 3: If APFO was present in the drinking water at 1ppb and in the air at 0.3 $\mu\text{g}/\text{m}^3$, the resulting steady-state PFO concentration estimate in human blood would be 1.20 ppm.

Table 1. Estimated human steady-state PFO blood levels (ppm) following exposure to APFO via air and/or drinking water.*

		Parts per billion APFO in drinking water													
		0	1	2	3	4	5	6	7	8	9	10	15	30	40
$\mu\text{g}/\text{m}^3$ APFO in air	0.00	0.00	0.30	0.60	0.90	1.20	1.50	1.80	2.10	2.40	2.70	3.00	4.50	9.00	12.02
	0.05	0.15	0.45	0.75	1.05	1.35	1.65	1.95	2.25	2.55	2.85	3.16	4.66	9.32	12.17
	0.10	0.30	0.60	0.90	1.20	1.50	1.80	2.10	2.40	2.70	3.00	3.31	4.81	9.62	12.32
	0.15	0.45	0.75	1.05	1.35	1.65	1.95	2.25	2.55	2.85	3.16	3.46	4.96	9.92	12.47
	0.20	0.60	0.90	1.20	1.50	1.80	2.10	2.40	2.70	3.00	3.31	3.61	5.11	10.22	12.62
	0.30	0.90	1.20	1.50	1.80	2.10	2.40	2.70	3.00	3.31	3.61	3.91	5.41	10.82	12.92
	0.40	1.20	1.50	1.80	2.10	2.40	2.70	3.00	3.31	3.61	3.91	4.21	5.71	11.42	13.22
	0.50	1.50	1.80	2.10	2.40	2.70	3.00	3.31	3.61	3.91	4.21	4.51	6.01	12.02	13.52
	1.00	3.00	3.61	4.21	4.81	5.41	6.01	6.61	7.21	7.81	8.41	9.01	12.02	15.02	18.03
	2.00	6.01	7.21	8.41	9.61	10.81	12.01	13.21	14.41	15.61	16.81	18.01	24.02	30.02	36.03
	3.00	9.01	10.81	12.61	14.41	16.21	18.01	19.81	21.61	23.41	25.21	27.01	36.02	48.02	60.03
	4.00	12.02	14.41	16.81	19.21	21.61	24.01	26.41	28.81	31.21	33.61	36.01	48.02	60.02	72.03

 PFO Blood levels less than or equal to 5 ppm
 PFO Blood levels greater than 5 ppm but less than or equal to 10 ppm

* Use of this table requires careful consideration of assumptions and limitations described in the text.

Discussion

A relatively simple and conservative compartmental model was developed and exercised to create an estimate of the PFO concentration in human blood following exposure to APFO in drinking water and/or inhaled air. The model was then used to create a table relating APFO exposures to estimates of steady-state PFO blood concentrations. Within the constraints of the assumptions and descriptions provided in this report, a variety of

exposure combinations could be evaluated using the model. Given a specific PFO concentration in blood, the model could also be used to create a plausible exposure scenario that could produce the observed PFO blood level. For example, if one had a hypothetical steady-state PFO concentration of 5 ppb in blood, the corresponding APFO exposure estimate using the model would be approximately 16 parts per trillion (ppt).

The model and approach presented in this report may be valuable for consequence analysis or planning activities, however, it should not serve as a substitute for more robust mechanistic, physiologically based models as they become available. The model presented here is based on sound compartmental analysis principles and is exclusive of mechanistic or physiological descriptions. As discussed earlier, this model is based on conservative assumptions and therefore is likely to provide high estimates of PFO concentrations in blood following ingestion or inhalation of PFO. Nevertheless, the simplicity and utility of this model provide decision-makers an easily applied tool to relate APFO exposures to estimates of resulting PFO concentrations in human blood.

Appendix 1: ACSL Model Code

```
PROGRAM
!MODEL TO SIMULATE PFO BLOOD LEVELS FOLLOWING ORAL AND
!INHALATION OF APFO
VARIABLE TIME

INITIAL

!CONSTANTS CAN BE GIVEN VALUES TO SIMULATE EXPOSURE AND
!SYSTEM OF INTEREST

CONSTANT KUPI      = 0.    !ZERO ORDER INHALATION UPTAKE (ug/day)
CONSTANT KUPO      = 0.    !ZERO ORDER ORAL UPTAKE (ug/day)
CONSTANT KELIM     = 0.    !FIRST-ORDER ELIMINATION (/day)
CONSTANT KACC      = 0.    !FIRST-ORDER DISTRIBUTION TO BODY (/day)
CONSTANT VOL       = 1.    !BLOOD VOLUME (ml)
CONSTANT VF        = 1.    !BODY VOLUME (ml)

!TIMING COMMANDS

CONSTANT TSTOP     =3650.   !LENGTH OF EXPOSURE (days)
CONSTANT POINTS    =3650.   !NO. OF POINTS IN PLOT
CONSTANT TOFF      =3650.   !END OF EXPOSURE TIME (DAYS)

CINT=TSTOP/POINTS  !COMMUNICATION INTERVAL
END                !END INITIAL

DYNAMIC

ALGORITHM IALG=2

DERIVATIVE
IF (TIME .GT. TOFF) THEN
KUPI = 0.
KUPO = 0.
END

IF TERMT(TIME.GE.TSTOP)

!CONCENTRATION OF PFO IN THE BLOOD COMPARTMENT (ug/day)
RA=KUPO + KUPI - KELIM*CBLOOD*VOL - RAF
CBLOOD=INTEG(RA,0.)/VOL

!CONCENTRATION OF PFO IN THE BODY
RAF = KACC*(CBLOOD*VOL-CF*VF)
CF = INTEG(RAF,0.0)/VF

END !END DERIVATIVE
END !END DYNAMIC
END
```

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Appendix 2: ACSL Command File for Assigning Appropriate
Parameter Values

TSTOP=10*365;
POINTS=50;
TOFF=TSTOP+1;
VOL=3500;

KACC=0.;
KELIM=0.0019;
KUPO=2;
KUPI=6;

keyboard
figure;
!!START
line(_time, _cblood, @linestyle="+");
_cblood(POINTS)

xlabel('Time (Days)');
ylabel('Conc. in blood (ug/mL)');
title('BLOOD CONCENTRATION');

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000325

IN THE CIRCUIT COURT OF WOOD COUNTY, WEST VIRGINIA

JACK W. LEACH, ET AL.,

Plaintiffs,

v.

**CIVIL ACTION NO. 01-C-608
(Judge George W. Hill, Jr.)**

**E. I. DU PONT DE NEMOURS AND COMPANY,
and LUBECK PUBLIC SERVICE DISTRICT,**

Defendants.

CERTIFICATE OF SERVICE

I, Heather Heiskell Jones, do hereby certify that I have served a true and exact copy
"Responses of E. I. du Pont de Nemours and Company to Plaintiffs' Second Set of Requests
for Admissions to DuPont" upon the following counsel of record in the manner indicated
below on this 23rd day of January 2003, addressed as follows:

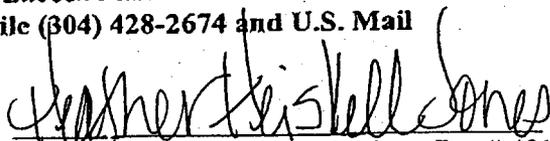
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