DuPont Specialty Chemicals
1007 Market Street
Wilmington, DE 19898

TECHNICAL FILE

C-2624

DuPont Specialty Chemicals

February 2, 1995

CERTIFIED MAIL--RETURN RECEIPT REQUESTED.

Document Processing Center (7407)
Attention: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
401 M Street SW
Washington, DC 20460-0001

BCC: T. A. Bartolec
P. E. Beach - Chambers Works
B. J. Dawson - Chambers Works
E. A. O'Neal - Chambers Works
C. F. Reinhardt - Haskell
A. M. Kaplan - Haskell
M. H. Christman - Legal
J. E. Leemann/File

Dear Coordinator:

8EHQ-93-12761

This letter is in response to EPA's request of December 8, 1994, addressed to Dr. C. F. Reinhardt, MD, Haskell Laboratory, DuPont, asking for information on voluntary actions taken as a consequence of our TSCA section 8(e) filing of November 12, 1993 on o-Toluidine (CAS #95-53-4).

The following actions have been completed or are underway:

1. Based on all available toxicity data, including the new findings, the existing worker exposure limit (Acceptable Exposure Limit, AEL) was reviewed and its validity at 5 ppm, 8- and 12-hr. time weighted average, confirmed. The Unscheduled DNA Synthesis (UDS) assay showed a statistically significant elevation in nuclear grain count over corresponding controls in rat bladder epithelial cells only at the highest dose tested (6000ppm). While this finding triggered the 8(e) notification, no UDS effects were observed at the two lower doses studied (500 and 3000 ppm). Therefore, the existing AEL of 5 ppm, 8- and 12-hr time weighted average, was considered to be sufficiently protective against the potential for this type of genetic damage in humans.

2. The MSDS was updated. It now states that o-Toluidine has caused genetic damage in animals. A copy is attached.

3. Following receipt of additional test results an employee communication was developed for workers at Chambers Works, DuPont's only producing and handling site for o-Toluidine. Site-wide notification was initiated on January 13, 1994 and completed by January 17, 1994. DuPont has since ceased manufacture of o-Toluidine and now only imports the chemical to manufacture 2-Aminotoluene-5-sulfonic acid and for resale into merchant markets.

4. Prior to the conclusion of the UDS assay a biomonitor to measure

DPW 0278

o-Toluidine in urine was developed. This involved extensive pharmacokinetic and analytical chemistry development. Under TSCA 8(d) EPA was notified of the initiation of this work and provided a copy of the final report. However, because DuPont ceased manufacture of o-Toluidine before the method could be validated and lacking a large enough internal cohort to permit validation, the method was offered to a major customer (Goodyear) and to a co-producer (First Chemical Company) for validation studies. A technical paper describing the method has been accepted for publication in "Analytical Toxicology".

5. A 14-day feeding study designed to determine urinary bladder toxicity was completed. A copy of the final report was submitted to EPA under TSCA 8(d) on June 21, 1994.

6. A case-control epidemiology study, comparing bladder cancer incidence rates between DuPont workers exposed to the compound against those who did not handle it and the general population, is in progress. EPA was notified on August 6, 1990, under TSCA 8(d), of the initiation of this study. A copy of the final report will be submitted when it issues.

You may contact me on 302/774-6467 if there are any questions.

Yours truly,

K. D. Dastur
Manager, Product Toxicology
and Chemical Regulations