

8EHQ-0197-13866



**Chevron**

January 23, 1997

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Attention: TSCA 8(e) Coordinator  
Office of Pollution Prevention and Toxics  
U. S. Environmental Protection Agency  
401 M Street S. W.  
Washington, DC 20460



8EHQ-97-13866

**TSCA 8(e) Submission for Tertiary Amyl Methyl Ether (TAME)**

Dear Sir or Madam:

This notice is submitted pursuant to Section 8(e) of the Toxic Substances Control Act on behalf of Amerada Hess Corporation, Chevron Products Company, CITGO Petroleum, Exxon Company USA, Marathon Oil Company, Sun Refining and Marketing, and Texaco Refining and Marketing. This notice is based on test results obtained under the Enforceable Consent Agreement (54 FR 14910 - March 21, 1995) for Tertiary Amyl Methyl Ether (CAS No. 994-05-8). The required studies are being coordinated by staff from the American Petroleum Institute.

We are advising the EPA of results from an ongoing 2-Generation Reproduction Study in Rats conducted at 3000, 1500, and 250 ppm TAME (OPPTS Guidelines 870.3800). The F1 females were examined once a day beginning postnatal day 22 for vaginal patency until the event occurred. The F1 females showed a dose-dependent delay in vaginal opening that was statistically significant at all dose levels. The F1 males were examined once a day beginning postnatal day 35 for preputial separation until the event occurred. The F1 males showed a dose-dependent delay in preputial separation that was statistically significant at 1500 and 3000 ppm.



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The results are summarized in the Table below.

|   | 0 PPM                             | 250 PPM                | 1500 PPM               | 3000 PPM                |
|---|-----------------------------------|------------------------|------------------------|-------------------------|
| Mean Day of Vaginal Opening <sup>1</sup>      | 32.5 ± 0.4 $\Phi \zeta$<br>n = 30 | 32.7 ± 0.3 *<br>n = 30 | 33.3 ± 0.3 *<br>n = 30 | 36.0 ± 0.6 **<br>n = 29 |
| Median Day of Vaginal Opening                 | 32                                | 33                     | 33                     | 35                      |
| Mean Day of Preputial Separation <sup>2</sup> | 43.6 ± 0.4 $\Phi \xi$<br>n = 30   | 43.9 ± 0.4<br>n = 30   | 45.3 ± 0.5 *<br>n = 30 | 47.8 ± 0.4 **<br>n = 29 |
| Median Day of Preputial Separation            | 44                                | 44                     | 45                     | 48                      |

<sup>1</sup>Because Bartlett's test was significant (p<0.001) nonparametric statistics were used in analysis of data from the F1 females.

<sup>2</sup>Parametric statistics were used in analysis of data from the F1 males.

- $\Phi$  p< 0.001; Kruskal-Wallis Test or ANOVA
- $\xi$  p <0.001; Jonckheere's Test or Test for Linear Trend
- \* p< 0.05; Mann Whitney U Test or Dunnett's Test
- \*\* p<0.001; Mann Whitney U Test or Dunnett's Test

Considering previous Agency guidance for reporting of reproductive effects, we are notifying the EPA of these statistically significant findings. Because of the delayed developmental landmarks in the F1 animals, the study design will be modified to measure anogenital distance on the F2 pups of both sexes at birth.

There is no confirmed mechanism for causing the observed developmental delays in both sexes. However, the body weight of treated animals is being investigated as a possible confounder of these observations. A covariant analysis of body weight with day of event will be appended to the final report.

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Results of this study will be forwarded to EPA under the conditions of the Enforceable Consent Agreement, Docket Number OPPTS-4205Q. If you have any questions about this submission, please contact Dr. Richard Rhoden at the American Petroleum Institute (202) 682-8480.

Very truly yours,



Richard D. Cavalli  
Manager, Toxicology & Health Risk Assessment

cc. Mr. Gary Timm  
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