

TSCA NON-CONFIDENTIAL BUSINESS INFORMATION

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October 30, 2009

VIA COURIER

TSCA Confidential Business Information Center (7407M)

EPA East - Room 6428

Attn: Section 8(e)

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue, NW

Washington, DC 20460-0001



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RE: TSCA 8(e) Submission: Tetrapropenyl Phenol (TPP; CAS # 74499-35-7)



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Dear TSCA 8(e) Coordinator:

Pursuant to Section 8(e) of the Toxic Substances Control Act (TSCA), the Lubricant Additives Alkyl Phenol Panel (Panel) of the American Chemistry Council hereby submits this letter on behalf of its member companies that produce tetrapropenyl phenol (TPP; CAS # 74499-35-7).

The letter is intended to inform EPA of certain preliminary findings from "A Dietary Two Generation Reproductive Toxicity Study of Tetrapropenyl Phenol in Rats" that is in progress at WIL Research Laboratories LLC in Ashland, Ohio. Although the information is being submitted in accordance with the Agency's interpretation of relevant TSCA 8(e) requirements, the Panel has not made a determination as to whether a significant risk or injury to health or the environment is actually presented by the findings. However, the Panel is aware that EPA could consider this information to constitute a substantial risk. For this reason, it is being submitted to EPA under 8(e) out of an abundance of caution. This submission, therefore, should discharge any 8(e) responsibilities that might exist, and should be processed in accordance with EPA's "substantial risk" procedures.

CONTAINS NO CBI

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The dietary two-generation reproductive toxicity study with TPP in rats is being conducted in accordance with OECD TG 416. The dose levels are 0, 1.5, 15 and 75 mg/kg/day. The concentration of TPP in the diet is being adjusted each week to ensure a constant dose in mg/kg/day to both males and females. To date, no adverse effects on reproduction parameters have been observed in the F0 parents.

The study is continuing as designed, and the pups selected to become the F1 parents are being treated with TPP. When the endpoints listed below, which measure time to onset of sexual maturation, were collected and analyzed statistically, the results indicate that the time to onset of sexual maturation in females was decreased, and the time to onset of sexual maturation in males was increased. The relevance of these findings to the ability of the F1 parents to reproduce will be evaluated as the study continues to conclusion.

The following table summarizes the results:

Summary of Animal Development Parameters (F1 Generation):

Males		0 mg/kg/day	1.5 mg/kg/day	15 mg/kg/day	75 mg/kg/day
Balanopreputial Separation (PND)					
Mean		45.1	42.5	45.8	47.1* [↑4.0%]
[% Δ vs. Control]					
Females		0 mg/kg/day	1.5 mg/kg/day	15 mg/kg/day	75 mg/kg/day
Vaginal Patency (PND)					
Mean		32.4	32.2	32.4	27.4** [↓15.4%]
[% Δ vs. Control]					

Summary of Body Weight Changes (F1 Generation):

Males		0 mg/kg/day	1.5 mg/kg/day	15 mg/kg/day	75 mg/kg/day
Cumulative Body Weight Changes (g)					
Mean	Weeks 17-23	352.0	360.0	331.0* [↓6.0%]	295.0** [↓16.2%]
[% Δ vs. Control]					

Females		0 mg/kg/day	1.5 mg/kg/day	15 mg/kg/day	75 mg/kg/day
Cumulative Body Weight Changes (g) Mean [% Δ vs. Control]	Weeks 17-23	195.0	192.0	191.0	178.0* [↓8.7%]

The results presented in the table above have not been fully audited. When available, a copy of the audited, final study report will be provided by the Panel to EPA as a follow-up to this letter

If you have any questions regarding this submission, please contact me at (703) 741-5614, or at Kristy_morrison@americanchemistry.com

Sincerely yours,

Kristy L. Morrison
 Manager, Lubricant Additives Alkyl Phenol Panel
 Chemical Products & Technology Division