RTI Prominent Publications Summary

Two-Generation Reproduction Study with *Para*-Tert-Octylphenol in Rats


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Tyl, R.W., Myers, C.B., Marr, M.C., Brine, D.R., Fail. P.A., Seely, J.C., & Van Miller, J.P. (1999). Two-generation reproduction study with *para*-tert-octylphenol in rats. *Regulatory Toxicology and Pharmacology* 30 (2):81-95.

Octylphenol (OP) is used primarily for production of octylphenol polyethoxylate surfactants. To determine potential reproductive toxicity of OP, a two-generation reproductive toxicity study was conducted under US EPA OPPTS Guideline 870.3800 (1996), with additional assessments of retained F2 offspring. OP was administered ad libitum to five groups of rats (30/sex/group), at dietary concentrations of 0, 0.2, 20, 200 and 2000 ppm; the 0.2 ppm concentration was included to assess any low dose effects. Adverse systemic effects were observed only at 2,000 ppm, including decreased body weights in adults and in offspring in late lactation (when they began to self feed), and minor body weight-related delays in acquisition of vaginal patency in F1 females and preputial separation in F1 males. There were no effects on reproductive parameters, testes, prostate or ovarian weights or morphology, on sperm counts, motility, morphology or production, or on estrous cyclicity. No estrogen-like effects were observed. The NOAELs (no observed adverse effect levels) for systemic and postnatal (developmental) toxicity were 200 ppm, and at or above 2,000 ppm for reproductive toxicity.

This study supports the increasing evidence that screening assays for estrogenic activity or studies with limited numbers of animals and/or unrealistic dose regimens are inappropriate for use in assessment of human health and environmental risks. Our work does not support previous preliminary data on low dose OP effects. It provides a thorough, guideline-compliant, large study which indicates toxicity only at the highest dose (2,000 ppm) for systemic and postnatal developmental toxicity and at above the highest dose for reproductive toxicity. There were no low-dose effects observed (doses down to 0.2 ppm) in either sex in adults or offspring in this study.

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