Title: A study to support regulatory submission assessing effects of Tri(2-ethylhexyl) trimellitate (TEHTM) upon pre and post-natal development in the rat, with a comparative group receiving Di(2-ethyl hexyl) phthalate (DEHP) included.

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PII: S0890-6238(16)30368-9
DOI: http://dx.doi.org/10.1016/j.reprotox.2017.08.020
Reference: RTX 7574

To appear in: *Reproductive Toxicology*

Received date: 27-10-2016
Revised date: 14-8-2017
Accepted date: 29-8-2017

Please cite this article as: Renaut Steven D, Whiteley Michele.A study to support regulatory submission assessing effects of Tri(2-ethylhexyl) trimellitate (TEHTM) upon pre and post-natal development in the rat, with a comparative group receiving Di(2-ethyl hexyl) phthalate (DEHP) included.*Reproductive Toxicology* http://dx.doi.org/10.1016/j.reprotox.2017.08.020

A study to support regulatory submission assessing effects of Tri(2-ethylhexyl) trimellitate (TEHTM) upon pre and post-natal development in the rat, with a comparative group receiving Di(2-ethyl hexyl) phthalate (DEHP) included.

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Highlights

- A regulatory toxicity study with TEHTM is described.
- The study included one dose level of DEHP, another plasticizer, as a comparative group
- The study demonstrated differences between TEHTM and DEHP

Abstract

Oral exposure of rodents to the plasticizer, Di(2-ethyl hexyl) phthalate (DEHP), elicits birth defects and effects upon the reproductive tract. There is currently limited published information regarding potential developmental effects in rodents of another phthalate ester, TEHTM.

To support regulatory submission, a study assessing of the effects of administration of Tri(2-ethylhexyl) trimellitate (TEHTM) upon embryo-fetal and post-natal development in Sprague Dawley rats was performed. This study included a group of animals receiving DEHP to provide a concurrent comparative reference.

TEHTM elicited no definitive biologically significant effects on the mother, or on fetal or offspring development at dose levels up to 1050 mg/kg/day whereas DEHP, administered at a dosage equimolar with the highest level of TEHTM, elicited adverse effects on the dam and fetus and impaired development of the male reproductive system, demonstrating some differences between TEHTM and DEHP at the highest dose level of TEHTM investigated.

1. Introduction

A regulatory toxicity study was performed to assess the effects of oral gavage administration of TEHTM (tri(2-ethylhexyl) trimellitate), also known as tri octyl trimellitate (TOTM), on embryo-fetal