



HSIA

halogenated
solvents
industry
alliance, inc.

November 14, 2018

Contact: Faye Graul
fgraul@hsia.org
703-875-0683

Charles River Laboratory (CRL) Study Shows Animals Exposed In-Utero to Trichloroethylene (TCE) in Drinking Water do not Show Increase in Congenital Heart Defects

Since 2011, EPA has based its reference concentration/reference dose for TCE primarily on a single study of rats exposed to TCE in drinking water (Johnson, P; Goldberg, S; Mays, M; Dawson, B., Threshold of trichloroethylene contamination in maternal drinking water affecting fetal heart development in the rat, *Environ Health Perspect* 111:289-292 (2003)). HSIA sponsored an effort to replicate this study as other studies, conducted according to EPA test guidelines, but by different routes of exposure, had shown no effect on fetal heart development.

The HSIA-sponsored study was similar in design to Johnson et. al. (2003) study; but the protocol was enhanced to meet the EPA test guidelines and data quality standards. Since TCE is a highly volatile chemical, methods were developed to ensure that there was minimal loss of TCE during the preparation of the drinking water formulations and that the animals had consistent exposures over the course of the study.

The draft audited study results which have been shared with EPA showed that exposure to TCE in drinking water did not increase the incidence of congenital heart defects in the offspring of the treated animals.

We believe that this new study will be invaluable for addressing the criticisms raised in the published literature and by many regulatory agencies of Johnson et.al. With these results, there are now EPA guideline studies by all three potential exposure routes that have found no relationship between *in-utero* TCE exposure and cardiac malformations.