



## **Irritation Screening of Vaginal-Care Products Using EpiVaginal, a Human Vaginal-Ectocervical Tissue Model**

Seyoum Ayeahunie, Chris Cannon, Jeff Gimondo, Mitchell Klausner, Helena Kandarova  
MatTek Corporation, Ashland, MA.

The utility of an organotypic vaginal-ectocervical (VEC) tissue model, composed on normal human cells, to test the irritation potential of vaginally-applied chemicals and their formulations was examined. Histologically, the VEC tissues have nucleated basal and parabasal cell layer and glycogenated intermediate and superficial layers. To insure tissue reproducibility, standardized quality control (QC) tests utilized the MTT assay to determine the exposure time necessary to decrease the tissue viability to 50% (ET50). ET50 results for the positive control (1% Triton X-100) showed the tissues to be highly reproducible; the average intra-lot coefficient of variation (CV) was less than 10% and ET-50s averaged 1.40 hr  $\pm$  0.26 (n=55 lots). Endpoints including MTT ET50, histology, RT-PCR, and cytokine release patterns were used to evaluate 20 commercially available test articles. Upon exposure to test articles, the tissue model was able to discriminate between the mildness of test articles. The ET50 values ranged between 3.5-7.0 hr for contraceptives, between 6.9->18 hr for anti-itch creams, and between 1.7-2.7 hr for feminine washes. Released cytokines and gene expression levels showed that IL-1 $\alpha$ , IL-1 $\beta$ , IL-6, and IL-8 were associated with toxicity of test materials. In conclusion, the VEC tissue model will serve as a useful, highly reproducible, non-animal test method to assess the irritation potential of vaginally applied chemicals and their formulations. Models such as the EpiVaginal tissue which mimic the vaginal microenvironment could provide essential data set for early identification of the biological/toxicological property of chemicals/products intended for vaginal use. Development of such in vitro test model for risk-assessment and management of chemicals is in line with the new European Union chemicals policy known as REACH.

**Keywords:** EpiVaginal, organotypic vaginal tissue model, irritation, women's care products

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