

COMPARISON OF CORROSITEX AND EPIDERM™ *IN VITRO* SKIN CORROSION SCREENING ASSAYS TO *IN VIVO* CORROSIVITY RESULTS.

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A battery of chemicals was objectively compared in the EpiDerm™ (MatTek Corp., Ashland, MA) and Corrositex (InVitro International, Irvine, CA) *In vitro* corrosivity screens to existing *in vivo* data. EpiDerm™ consists of cultured, normal human epidermal keratinocytes in a differentiated epidermal model with organized basal, spinous and granular layers, and a stratum corneum containing intercellular lamellar lipid layers analogous to those found *in vivo*. Corrosivity is assessed as relative cytotoxicity at 3-min and 1-hr as the mitochondrial reduction of a tetrazolium salt. Corrositex uses a bio-barrier membrane comprised of a hydrated collagen matrix and supporting filter membrane on top of a vial filled with a chemical indicator dye, with corrosivity assessed according to breakthrough time. A panel of 12 reference chemicals recommended in OECD Guideline 431 for laboratory validation procedures was used [six corrosive: 1,2-diaminopropane; acrylic acid; 2-tert-butylphenol; potassium hydroxide; sulfuric acid; octanoic acid; and six non-corrosive: 4-amino-1,2,4-triazole; eugenol; phenethyl bromide; tetrachloroethylene; isostearic acid; and 4-methylthio-benzaldehyde], as well as 15 proprietary chemicals [nine corrosives and six non-corrosives *in vivo*, comprised of one alcohol, three organic acids, seven amines, two acrylic acid derivatives, and two halogenated herbicides]. EpiDerm™ exhibited 96% *in vivo* concordance (26 of 27), with 1 of 27 giving a borderline false negative for an organic acid. Corrositex exhibited 70% (19 of 27) *in vivo* concordance; with 3 of 27 false negatives (two organic acids and one halogenated herbicide), 2 of 27 false positives (both were amines), and 3 of 27 that didn't qualify due to lack of reactivity with the indicator dye. Erroneous results weren't restricted to false negatives, positives or by chemical class. One organic acid was a false negative for both *in vitro* assays, with the borderline EpiDerm™ result suggesting potential corrosivity *in vivo*. In conclusion, EpiDerm™ gave near-perfect concordance with *in vivo* corrosivity data.

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