In Vitro Corrosivity and Irritation Models

Assessment of the corrosivity and irritation potential of chemicals from multiple product sectors is a key element in their safety evaluation. Traditionally, these tests have been conducted in rodents and rabbits and can result in discomfort to the animals that are treated. The in vitro methods presented can offer an alternative testing strategy that can be used in a tiered approach to identify corrosive and irritating substances prior to animal exposure. For cosmetics, these tests are replacements for in vivo animal testing.

The endpoint of all three assays is an assessment of cell viability, determined by measuring the rate of conversion of MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide) to its formazan salt by mitochondrial reductase enzymes. The formazan salt is blue in color and can be extracted from the tissues and quantified by spectrophotometry. The dermal corrosivity and irritation assays are conducted in identical test systems; however, in the corrosivity assay damage is assessed after acute exposure, whereas in the irritation assay, longer exposure and recovery periods are included.

**Assay Details**

**SkinEthic EpiSkin® Skin Corrosivity Assay (OECD 431):**
EpiSkin® is a 3D cell-culture-based model of human epidermis, reconstructed from cells derived from donated human skin. In the corrosivity assay, test item is applied to the upper surface of the epidermis for two exposure periods (3 minutes and 1 hour) and then rinsed off. This assay can classify substances as corrosive or non-corrosive.

**SkinEthic EpiSkin® Skin Irritation Assay (OECD 439):**
In this irritation assay, test item is applied to the upper surface of the epidermis for 15 minutes, then rinsed off and cells are incubated for 42 hours to allow recovery or development of damage. This assay can classify substances as irritants in accordance with GHS Category 2.

**MatTek EpiOcular™ and SkinEthic HCE Eye Irritation Assays (ECVAM Prevalidation):**
These are reconstructed models of human corneal epithelium. In the HCE eye irritation assay, test item is applied to the upper surface of the epithelium for 3 minutes, then rinsed off and cells are incubated for 16 hours to allow recovery or development of damage. A very similar method is used for the EpiOcular™ assay. This assay is designed to classify substances as irritant (EU R41 or R36) or non-irritant.

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