Evaluation report on the Vitrolife-Skin™, a 3-dimensional cultured skin model for skin corrosivity testing

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Summary

We evaluated the utility of a test method using Vitrolife-Skin™, a 3D human skin model, as an alternative to skin-corrosion testing using live rabbits. Validations in the U.S.A. and EU of a skin-corrosion test using the Japan-developed 3D human skin model EpiDerm™ yielded results that conform to OECD guidelines. Vitrolife-Skin is a skin model similar to EpiDerm and comprises a multi-layered structure, in which skin cells derived from a mixture of collagen and fibroblast cells lie beneath a stratum corneum. In this case, EpiDerm and Vitrolife-Skin were both evaluated simultaneously using a minimal number of test substances in a catch-up validation. Assessment of the Vitrolife-Skin test method and results was essentially the same at that of EpiDerm and involved processing with the test substances, after which the specimens were stained and measured for absorbance to determine cell viability as an indicator of corrosion potency. The twelve substances used in the test have all exhibited corrosion potency in vivo and were identified only by code numbers to the six participating laboratories. The tests were performed by trained technicians following a standard operating procedure. Each substance was tested twice, unless differing results were obtained, in which case a third test was performed, so that determinations were based on multiple results. Measured values for all test substances were substantially the same, indicating good intra-laboratory reproducibility. The assessed results of tests performed on EpiDerm were identical at all laboratories except for one, which determined a different assessment for one of the twelve test substances. In contrast, the assessed results of tests performed on Vitrolife-Skin were identical for all test substances at all laboratories. Also, substances that were difficult to assess proved to be the same for both EpiDerm and Vitrolife-Skin, indicating extremely good inter-laboratory reproducibility. Based on the above, we have determined that this skin corrosion [test method] using Vitrolife-Skin demonstrates specificity, sensitivity, and reproducibility equal to or better than EpiDerm for the identification [of skin-corrosion potency]. There are, however, other issues that have been noted, including difficulties in assessment of strong alkaline or similar substances that affect the collagen cells comprising the model's supporting tissue as well as the need for a means of ensuring quality control and verifying comparability after changes in manufacturing methods during mass production. Nevertheless, just like Epi-Derm, the use of Vitrolife-Skin obviates the need for laboratory animals and provides results in a relatively short time. Moreover, Vitrolife-Skin has the benefit of being less expensive than EpiDerm and of being readily available, since it is manufactured and sold in Japan. In conclusion, it is our opinion that this skin-corrosion test method using VitroLife Skin is useful as an alternative to animal testing.

***Keywords**: corrosion , human skin model, alternative*