1. Were the submitted test method and supporting validation data subjected to a transparent and independent peer review process?

The test method was published in an academic paper and has excellent transparency. The validation data has been subjected to a transparent and independent peer review process.

2. Does the data generated by the test method adequately measure or predict the end point of interest? For replacement test methods, does the data show a linkage between the proposed test method and an existing test method, and/or the proposed test method and effects in the target or model species?

An in vivo/in vitro agreement of 83.3% was observed. Nevertheless, neither lactic acid nor a 5% aqueous solution of potassium hydroxide were in agreement.
The comment was made that some of the in vivo data for substances that were not in agreement were not necessarily suitable and will require further investigation.
We consider the test capable of predicting corrosive potency on humans.

This test method was considered to have the same basic mode of action and equivalent functionality as the existing EpiDermTM test method given in OECD guideline 431.[3] The suitability of this method for predicting corrosive potency based on cytotoxicity is based on the premise that corrosive substances are absorbed by and penetrate the stratum corneum, thereby damaging the underlying cells, after which the viability of epidermal cells are considered an indicator of corrosive potency.

3. Does the test method generate data useful for hazard/risk assessment purposes?

This test method is useful for hazard assessment.

4. Do the submitted test method and supporting validation data adequately cover a spectrum of chemicals and products representative of those administered by the regulatory program or agency for which the test method is proposed? Are the applicability and limitations of the test method clearly described?

This validation uses test substances and acceptance criteria substances that are subject to the provisions of the Poisonous and Deleterious Substances Control Act.
Obtained the minimum data necessary to ascertain a mode of action for corrosive potency.
Test substances with strong alkalinity dissolved the collagen matrix for cell culture. Difficult to use with stained substances or those with strong adsorptive properties.

5. Is the test method sufficiently robust (relatively insensitive to minor changes in protocol) and transferable among properly-equipped laboratories with adequately-trained staff?

We see no major issues with transferability. Neither is there any special technology required for implementation. There is little potential to modify the protocol, however, since the test comes as a measuring kit.

6. Is the test method both time and cost effective as well as likely to be used in a regulatory context?

We consider the method to be effective.

7. Can scientific, ethical, and economic justification be provided for the new or updated test method in light of existing test methods?

We consider this test method to be justifiable.

8. Is this test method acceptable for use in regulatory documentation on safety assessment?

This test method is capable of assaying the direct corrosive potency of chemical substances. We consider it suitable for regulatory use in that context.

We consider this test method to be useful in assaying corrosive potency of cosmetics and quasi drugs as well as in classifying poisonous or deleterious substances under the Poisonous and Deleterious Substances Control Act.

Based on the above, the JaCVAM Regulatory Acceptance Board has concluded that correct application of test methods for determining corrosive potency using Vitrolife-Skin™ as an alternative to animal testing are a scientifically-valid means of assaying the corrosive potency of chemical substances.