

## ANNEX

### Inventory of validated Alternatives to Animal Testing applicable for cosmetic products and their ingredients in all ICCR Regions<sup>1</sup>

|   |                      |
|---|----------------------|
| <b>Date of Preparation:</b><br>26 November 2013 | <b>Status:</b> FINAL |
|---|----------------------|

#### Table with Internationally Accepted Alternative Test Methods for Cosmetic Products/Ingredients Safety Testing, successfully worked upon by ICATM

The present document is an annex to the ICCR Report on the Inventory of validated Alternatives to Animal Testing applicable for cosmetic products and their ingredients in all ICCR Regions (Document reference: Alternatives to animal testing/Report (text)/Final-2013-11-26), and provides an inventory of methods that are recognised by ICCR as validated alternative methods applicable to cosmetics in the four ICCR regions.

This table will be updated regularly by the ICCR Industry Committee on the basis of the "Status report on current alternative test method validation and regulatory acceptance status report", issued bi-annually for ICCR by the International Cooperation on Alternative Test Methods (ICATM), hereafter referred to as "ICATM bi-annual report to ICCR".

The version of the ICATM bi-annual report to ICCR, taken as the basis for the last update of this document, is indicated below. It is however important to notice that this table is not exhaustive, as there are additional validated methods available via OECD, which have not been worked upon by ICATM partners. The reader is referred to the OECD website for additional updates<sup>2</sup>.

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| <b>Basis for last update:</b> ICATM bi-annual report to ICCR of June 17, 2013 <sup>3</sup> |
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<sup>1</sup> The inventory is based on the report issued bi-annually to ICCR by the International Cooperation on Alternatives to Animal Testing (ICATM) and is not necessarily exhaustive.

<sup>2</sup> OECD Guidelines for testing of chemicals, at [http://www.oecd-ilibrary.org/content/package/chem\\_guide\\_pkg-en](http://www.oecd-ilibrary.org/content/package/chem_guide_pkg-en)

<sup>3</sup> JRC Technical Report N° JRC82925, European Commission Joint Research Centre, Ispra, Italy, 2013, available at [http://ihcp.jrc.ec.europa.eu/our\\_activities/alt-animal-testing-safety-assessment-chemicals/alt\\_test\\_cosmetics](http://ihcp.jrc.ec.europa.eu/our_activities/alt-animal-testing-safety-assessment-chemicals/alt_test_cosmetics)

| <b>Method</b>  | <b>International Acceptance</b>   |
|--|-----------------------------------|
| <b><i>Dermal Corrosivity Test Methods</i></b>  |                                   |
| CORROSITEX Skin Corrosivity Test   | OECD TG 435 (2006)                |
| <i>In vitro</i> reconstructed human epidermis (RhE) test methods for skin corosivity:<br>EpiSkin, EpiDerm™, SkinEthic™, EpiCS® <sup>4</sup>  | OECD TG 431 (2004) <sup>5</sup>   |
| Rat TER Skin Corrosivity Test  | OECD TG 430 (2004) <sup>6</sup>   |
| <b><i>Dermal Irritation Test Methods</i></b>   |                                   |
| <i>In vitro</i> reconstructed human epidermis (RhE) test methods: EpiDerm™; EpiSkin™; SkinEthic™ and LabCyte EPI-Model24SIT  | OECD TG 439 ( 2010) <sup>7</sup>  |
| <b><i>Phototoxicity Test Methods</i></b>   |                                   |
| 3T3 NRU Phototoxicity Test   | OECD TG 432 (2004)                |
| <b><i>Ocular Toxicity Test Methods</i></b>   |                                   |
| Bovine Corneal Opacity and Permeability Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage | OECD TG 437 (2013)                |
| Isolated Chicken Eye Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage                    | OECD TG 438 (2013)                |
| Fluorescein Leakage Test Method for Identifying Ocular Corrosives and Severe Irritants   | OECD TG 460 (2012)                |
| Use of histopathology as an additional endpoint in Ocular safety testing   | OECD Guidance Document 160 (2011) |
| <b><i>Acute Toxicity Tests</i></b>   |                                   |
| <i>In Vitro</i> cytotoxicity test methods for estimating starting doses for acute oral systemic toxicity tests   | OECD Guidance document 129 (2010) |
| <b><i>Endocrine Disruptor Test Methods</i></b>   |                                   |
| Stably Transfected Human Estrogen Receptor-α Transcriptional Activation Assay for Detection of Estrogenic Agonist-Activity of Chemicals  | OECD TG 455 (2012)                |

<sup>4</sup> Formerly known under the name EST-1000

<sup>5</sup> Updated in 2013 to include Performance Standards and division of corrosivity into two categories

<sup>6</sup> Updated in 2013 to include Performance Standards

<sup>7</sup> Updated in 2013 to include the LabCyte EPI-Model24SIT

|   |                    |
|---|--------------------|
| BG1Luc Estrogen Receptor Transactivation Test<br>Method for Identifying Estrogen Receptor Agonists and<br>Antagonists | OECD TG 457 (2012) |
| <b>Genetic Toxicity Test Methods</b>  |                    |
| <i>In Vitro</i> micronucleus Test   | OECD TG 487 (2010) |