European Cosmetics Responsible Person Association

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Minimum Information to be Included in Test Report

ERPA POSITION PAPER

DATE : 7/3/2014 Version 1.0

PUBLISHED BY : ERPA
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A. *Current legislation – References*

1. Regulation 1223/2009/EC, Annex I, Part A – Cosmetic product safety information

- Point 2 – Physical/chemical characteristics and stability of the cosmetic product
  - *"The stability of the cosmetics product under reasonably foreseeable storage conditions"*
- Point 3 – Microbiological quality
  - *"Results of preservation challenge test"*

2. Regulation 1223/2009/EC, Annex I Guidelines

- Point 3.2 – Physical/chemical characteristic and stability of the cosmetic product
  - *"That section of the cosmetic product safety report also requires an assessment of the stability of the cosmetic product, under reasonably foreseeable storage conditions. The aim is to evaluate if the stability of the cosmetic product affects the safety and quality of the product, and to use the information to determine its minimum durability and period-after-opening (PAO)."*
  - *"The methodology used to determine the product's minimum durability should be described. Any specific preservation precautions should be mentioned."*
  - *"All available data used to justify the indicated minimum durability should be listed in the safety report. In order to determine the coherence of the stability study conducted, and to check the relevance of the date of minimum durability chosen for the product, the description of the tests specific to the stability study and the results of those tests should be included in the cosmetic product safety report. In addition, the following should also be provided:*
    (1) evidence that the composition of the product used for stability testing corresponds to the product actually placed on the market;
    (2) the results of the preservative efficacy study, e.g. challenge test, if applicable (1);
    (3) when applicable, the period-after-opening (PAO) (2) and its justification."
  - *"The SCCS has recommended that 'relevant stability tests, adapted to the type of cosmetic product and its intended use, should be carried out. To make sure that no stability problems are induced by the type of container and packaging used, physical stability tests are currently carried out with inert containers and those intended to be used on the market.'"*

3. ISO:11930, 5.8 Test Report

4. Regulation 655/2013 – Laying down common criteria for the justification of claims used in relation to cosmetic products

- Art. 2
  - *"The responsible person referred to in Article 4 of Regulation (EC) No 1223/2009 shall ensure that the wording of the claim in relation to cosmetic products is in compliance with the common criteria set out in the Annex and is consistent with the documentation proving the effect claimed for the cosmetic product in the product information file referred to in Article 11 of Regulation 1223/2009."*

B. *Issues arising from the above articles*

Though various protocols to run the Microbiological, Challenge, Efficacy, Safety, Stability or Compatibility tests between the formulation and the primary packaging are acceptable based on the type of the product and its characteristics, there are no general acceptance criteria on the information to be presented in the report.

This leads to well run protocols with reports lacking the details necessary for the Responsible Person and the Safety Assessor to consider them for the Product Information File or the Safety Assessment report.

As per Good Manufacturing Practices (GMP 22716:2007) many of the tests are run internally by the laboratories / producers developing the product. Given the lack of specific minimum elements to be reported, the documentation provided is often incomplete and the information necessary not recorded leading to the necessity of re-running the tests.

C. *Proposal for adding information on the minimum information in a test report in the Annex I guidelines*

1. Report Identification

- Report title
- Report number/code, which enables the clear and unique identification of the test report and respective versions
- Test beginning date
- Test conclusion date
- Report date
- History of the document and version control, which enables to record amendments to the original test report, respective version numbers and dates.

2. Identification of the Test and Reference items

- Identification of test items, including at least the name of the test product(s) and batch number(s)
- Identification of reference items, including at least the name of the substance, CAS number (where applicable) and batch number

3. Identification of the Study Personal, Test facilities and Sponsor

- Sponsor identification, including at least the name and address
- Test facilities identification, including at least the name and address (if more than one test facility was used for the test all of them should be mentioned)
- Identification and signature of the person(s) responsible for preparing/changing the report (e.g.,: laboratory technician(s), researcher(s)) and of the person(s) responsible for approving it (e.g.,: technical director, quality manager)

4. Study Report

- Description of the methods/ protocols used in the study (if in accordance with relevant harmonized standards or internal standard operating procedures their reference should be given)
- Results, including at least mean and standard deviations calculations and statistical significance (complete raw data should also be provided)
- Results discussion
- Conclusion(s)

5. Archiving

In this section the location(s) where the study plan, raw data and the final report are to be stored, and the time of storage should be given.

About ERPA

ERPA is the European Cosmetics Responsible Persons Association.
More information:
http://www.erpacosmetics.com/