Evaluation of the efficacy in a biocide dossier for a disinfectant within MG1

Lucilla Baldassarri

Centro Nazionale Sostanze Chimiche, Prodotti Cosmetici e Protezione del Consumatore – Istituto Superiore di Sanità – Rome - Italy

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Available infos and where to find them

- A documents providing all the necessary informations to evaluate the active substance
- B documents providing the informations regarding the representative product based on the active substance under evaluation

DOC IVA and IVB – Literature search

- The applicant has to provide the data and information required. If they are of adequate quality, unpublished test and study reports available to the applicant, other non published data or published data may be used to fulfil the data requirements.

- The applicant should conduct a detailed literature search to ensure that all relevant data and information can be provided with the dossier. It is recommended to append copies of the profile and the results of such literature searches to Document IV-A and IV-B. This can avoid duplication of work by the competent authorities of the Rapporteur Member State, who can then limit their own literature search to specific data gaps, if appropriate.

- **DOCUMENT IV-A** (for the active substance) and **DOCUMENT IV-B** (for biocidal products) should contain copies of all original test and study reports and of any other information compiled and summarized in the entire dossier.

- Confidential data and information
  - An applicant may indicate commercially sensitive information as confidential. This information should be included as Appendices to Document III-A and/or III-B. Information accepted by the receiving Rapporteur as being confidential will be treated as such by the competent authorities and the European Commission.

Doc III study summaries

- to **evaluate the data** provided by the applicant as to their validity, i.e. acceptability of the quality, compliance with standard test guidelines and, where relevant, GLP or, in the case of tests not conducted according to accepted guidelines, the suitability of test methods

- to **provide evaluated data summaries** based on the key study concept

A key study is a study regarded as sufficient and adequate to use and must be summarized.

The STUDY SUMMARIES submitted by the applicant provide the general basis to the RMS (and other Member States) for their critical evaluation and assessment of the dossier. The standard formats to provide the study summaries have been designed in such a way that allows the RMS (and other Member States) to:

- **annotate on the applicant's version** and/or to **amend and change** applicant's entries;

- **mark** and **comment on any deficiencies** of tests and studies or of their reporting;

- **comment** on the applicant's summary and conclusion;

- include comments on the evaluation of the individual tests and studies submitted to the Rapporteur Member State by other Member States.

• a separate comment area (shaded column); where the RMS can mark fields, e.g. with an X, in the case of reporting errors, study deficiencies for any other reason;

• a separate part "**Evaluation by Competent Authorities**", in which the RMS can enter a revised version of the applicant's summary and conclusion after considering the marked text in the evaluation box. In the fields “Guidelines and Quality Assurance”, "Materials and methods" and "Results and discussion" the RMS can indicate any errors found in the applicant's study summaries or discuss relevant discrepancies and deficiencies referring to the corresponding (sub)heading number(s) in a similar manner.

In this way, the duplication of work should be minimized, as the RMS has to annotate only in the case of discrepancies with the applicant's entries. The lay-out of these standard formats guarantees a high transparency of the comments and evaluation carried out by the Rapporteur Member State and should facilitate the harmonization process between the Member States.

Documents II

Based on the evaluation of the studies and informations provided by the applicant, the RMS prepares the DOCIIA (for the active substance) and IIB (for the representative product) where (for example) evaluation of the efficacy of a substance and of the representative product is done by the RMS based on the critical evaluation of the study summaries, efficacy evaluation provided by the applicant as well as any other relevant technical and scientific information available to the RMS

Assessment report (DOCI of the BPD)

- The AR should provide:

- a **concise but comprehensive overview** of the context in which the dossier was submitted and evaluated, and

- an **overall summary and assessment** including the conclusions derived from the evaluation of the dossier data;

- a **proposal for the active substance approval**, or otherwise a decision for non-approval of the active substance.

Efficacy studies for A.S. approval

- Part A: Efficacy studies on the active substance should be capable of demonstrating the innate activity of the active substance against representatives of the proposed target organisms at the concentration relevant for the risk assessment.
- Part B: Evaluation of the efficacy of the formulated product
  - efficacy is evaluated in relation to the envisaged use
  - include some relevant target species (or representative species)
  - Fulfil a minimum requirements
  - The submitted data should allow the definition of an effective concentration that can be used for the risk assessment.

AS proposed for approval for PT1-PT5

- EN1040
- EN1275
- EN1276
- EN1650
- EN13704
- EN13697

Group of test organisms	Typical conditions for effective disinfection
Bacteria	36 – 720 mg/L, 20 °C, 5 min
Bacteria (spores)	500 mg/L, 20 °C, 60 min
Mycobacteria	5000 mg/L, pH 11.2, 1 min
Fungi	360 - 3600 mg/L, 20 °C, 5 min
Viruses	360 mg/L, 25 °C, 60 min
Prions	13000 mg/L, > 30 min

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The efficacy data package will have to be implemented at product authorization stage, and more information should be provided to demonstrate full efficacy against all claimed target organisms of the products.

Example:

- For a PT2 product based on the AS
- To clean floors/hard surfaces by wiping with mop/cloth/bucket
- Bactericidal/fungicidal/sporicidal

The following test should be carried out to authorize a product

- EN1276; EN1650, EN13704
- EN13697

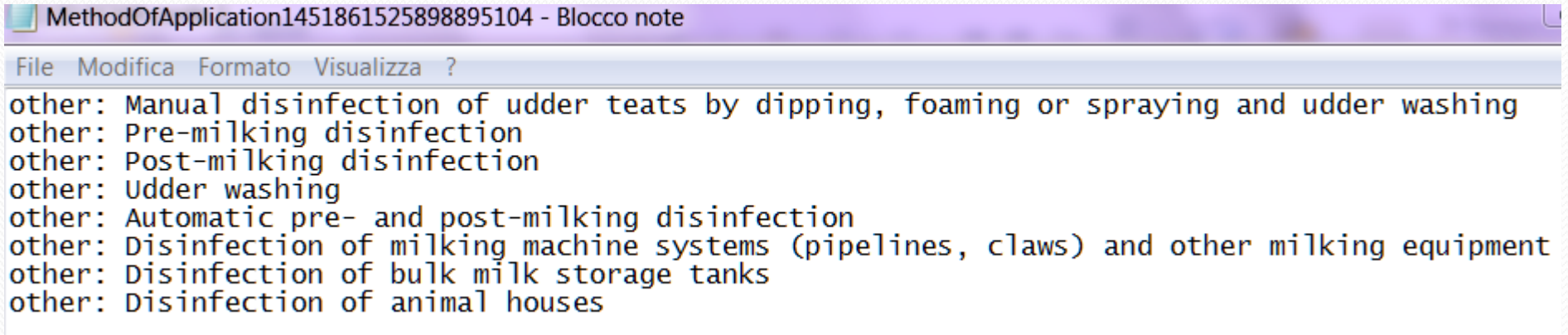
Example:

- For a PT5 product
- To be used in a water distribution system
- Bactericidal/Virucidal

- The following test should be carried out to authorize a product
  - EN1276 modified
  - EN14476 adapted
  - Simulated use test
  - Challenge test to ensure secondary disinfection

Product authorization – PT3 (Vet area)

Field of application-Target organism(s) – mode of use/instructions- user(s)-resistance data

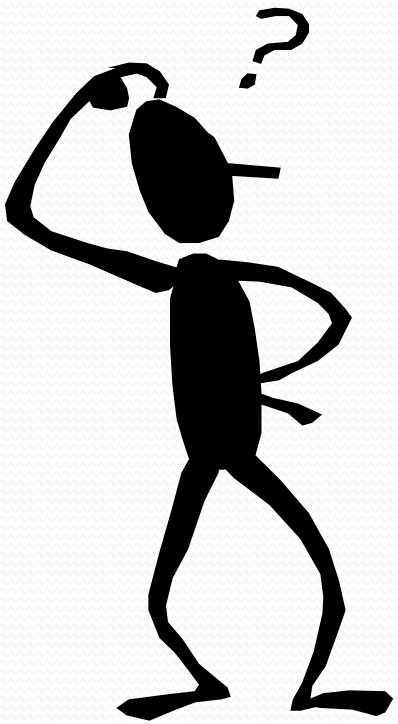


Tests applied

EN1040
EN1275
EN1276
EN13697
EN1656

Also a phase2/step2 test should have been used for evaluation: the EN16437 for porous surface is now available, which is not exactly designed for teat disinfection products but may provide interesting informations anyhow

For this dossier, instead of the complete report for each standard applied, only tables with a summary of the data were provided. This does not allow an appropriate evaluation of the efficacy data



Thanks for your attention!