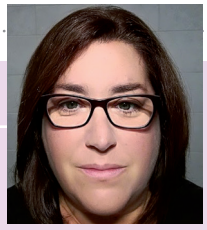
Antimicrobials and their testing



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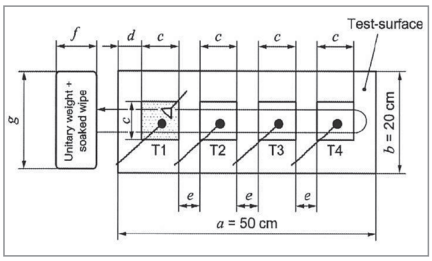
After her Ph.D. in Biophysics and a Post Doc position in medical research, **Daniela Romano** has been working with Eurofins, mainly on Biocides. Since 2013 she manages projects for Biocidal Products authorisation supporting the customers:
- with the data gap analyses
- building the Biocidal Product Families
- following all experimental studies and rearranging priorities according to the scientific data obtained

Antimicrobials products used in house care are Biocidal Products (BPs) and their placing on the market is disciplined by a European regulation, namely the Biocidal Product Regulation (EU)528/2012.
Once an active ingredient is approved, all the products containing it need to be authorized. The substances approval has proceeded at a slow pace for about 15 years, but since 2013 there has been significative increase in the number of approvals with the goal to reach the number of 50 approved active substances per year.
The speed up in the approval procedure requires a great attention from the stakeholders interested in placing those BPs on the market. It is important to monitor the Biocidal Products Committee Agenda to check when the active substance of interest will be discussed and to check the ECHA website to monitor the approval date, because it is mandatory to submit a dossier, on the BPs containing it, within that date.



Among the active substances most commonly used for house care disinfection, that will be approved as PT2 (Disinfectants and algaecides not intended for direct application to humans or animals) and PT4 (Food and feed area) in the next two years, we find: Calcium Hypochlorite, Sodium Hypochlorite, Ampholyt 20, Slaked lime, Dolomitic lime (hydrated and not), Chlorocresol, Citric acid, Lactic acid, in situ generated Peracetic Acid and 1-Propanol.
To obtain the authorisation, the first step is to test the BPs according to the requirements of Annex III of (EU)528/2012. The submission of the dossier will allow to keep on the market the products already present. If a product is not already marketed in the Country of interest, it will have to wait until its authorization before being sold (it may require several years). For this reason it is important to be present on the market of the Country of interest fulfilling the national authorization requirements. In Italy, for instance, the national authorisation for Antimicrobials is disciplined by the decree relative to Presidio Medico Chirurgico (PMC). All PMCs need to be tested for efficacy and stability. The tests performed on PMCs can be used as part of the BP dossier.
The best approach is to test the product efficacy first because in case the product fails the tests, a change in the formulation might be necessary.
The tests to be performed on antimicrobials are described on the ECHA "Guidance on the BPR: Volume II Efficacy, Assessment + Evaluation (Parts B+C)" (December 2017).

Here below you can find, as examples, two case studies: the first one on an antimicrobial wipe and the second one on a laundry antimicrobial.

Disinfectant towelettes/wipes. For disinfectant wipes, the suspension tests (phase 2, step 1: EN1276 bactericidal and EN1650 yeasticidal and fungicidal) should be performed preferably on the liquid extracted from the wipes, or if difficult to extract, it could be used the liquid as it is, before it is added to the wipes. Surface tests (Phase 2, step 2: EN16615) should be performed, on the wipes, with a mechanical action. These tests are available for bacteria and yeasts.

For testing other organisms, surface tests can be done (without mechanical action: e.g. EN13697 fungicidal, EN16777 virucidal) with the liquid extracted from the wipes (not the original liquid), with a definition of the volume that is applied per square centimetre. In addition, a test must be performed that shows that either the wipe will still disinfect after the wipe dries out or that the wipe stays wet long enough to disinfect according to the claim.

Biocides used to treat textiles and fabrics in hospitals, health care facilities, industry, institutions or private homes. They can be laundry products (combining detergent and biocide) or can be laundry additives (added to the wash cycle or as finishing products) added in the last rinsing step or as pre-treatment. Typically contaminated textiles are treated in an appropriate washing machine. The BP is added in concentrated form and diluted in the machine with water, according to the specification of the manufacturer, to get a defined concentration in the machine. The automated chemical-thermal process normally comprises an (optional) initial pre-treatment step for heavily soiled laundry, followed by the main washing step (at a defined temperature and defined contact time) and 3 to 4 rinsing steps with cold water (full-scale laundry machine test according to EN 16616). In some cases textiles can be treated through a hand-wash process using a diluted BP, which can be a pre-soak (after which, machine washing is used), a hand wash only, or through soaking to disinfect textiles before they are destroyed (ASTM E4206 or ASTM E2274).
These are just 2 examples of the efficacy tests that are supposed to be performed on BPs. Such tests are mandatory and depend on the claim and the mode of use of the BPs. They should be performed by experienced laboratories in order to reduce their intrinsic variability.