



## Biocidal products analysis

*The Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (BPR) concerns:*

- the approval of the active substances: the compilation at Community level of a list of active ingredients which can be used in biocides;
- the authorization for making available on the market and use of biocidal products in the Members States and the mutual recognition of authorizations within the European Union;
- specific provisions for placing on the market of treated articles;
- the introduction of simplified authorisation procedure.

### The Regulation defines 22 biocidal Product-types, divided in 4 Groups:

- **MAIN GROUP 1:** Disinfectants
- **MAIN GROUP 2:** Preservatives
- **MAIN GROUP 3:** Pest control
- **MAIN GROUP 4:** Other biocidal products

### General considerations:

- Biocidal products shall not be made available on the market or used unless authorised in accordance with this Regulation;
- An authorisation may be granted for a single biocidal;
- The applicant for an authorisation shall submit the following documents together with the application: a dossier or letter of access for the biocidal product and a summary of the biocidal product characteristics;
- Depending from commercial purpose of each applicant, the authorization could be: National (for example in Italy we have the D.P.R. 392/98), Simplified National authorization or European Union authorization (Reg. EU 528/2012).



### CONTACTS

[daniela.siconolfi@renolab-glp.com](mailto:daniela.siconolfi@renolab-glp.com)





## Biocidal products analysis

In accordance with Good Laboratory Practice, Renolab can support biocidal producers/importers in the execution of the tests needed for the dossier presentation:

- 5 Batch analysis on the active substance
- Purity and impurity profile
- Physical and chemical properties on both active substances and formulated products
- Stability tests (storage stability test long term at room temperature, CIPAC MT 46.3, CIPAC MT 39.3)
- Efficacy tests (efficacy against viruses, bacteria, moulds, fungi and mycoplasmas)
- Residues studies on surfaces

### SOME OF THE EFFECTIVENESS TESTS WE CAN OFFER

- EN 14476 and EN 16777- Poliovirus type 1, Adenovirus type 5, Murine Norovirus, Vaccinia virus, Human coronaviruses
- EN 1500 - Hygienic handrub
- EN 1499 - Hygienic handwash
- EN 1040
- EN 1276
- EN 13623 - Legionella pneumophila
- EN 13624
- EN 13697
- EN 13704
- EN 13727
- EN 14348 - Mycobactericidal/Tuberculocidal activity
- EN 14349
- EN 14561
- EN 14563 - Mycobactericidal/Tuberculocidal activity
- EN 14675
- EN 16437
- EN 16438
- EN 1650
- EN 1656
- EN 1657
- EN 16615 - Bactericidal and yeasticidal activity employing wipes
- ISO 22196:2011
- ISO 16869:2008
- And more...

#### Useful links:

<http://www.renolab-glp.com/>

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32012R0528>

<https://echa.europa.eu/it/information-on-chemicals/biocidal-active-substances>

[https://echa.europa.eu/documents/10162/23036412/bpr\\_guidance\\_assessment\\_evaluation\\_part\\_vol\\_ii\\_part\\_bc\\_en.pdf/950efefa-f2bf-0b4a-a3fd-41c86daae468](https://echa.europa.eu/documents/10162/23036412/bpr_guidance_assessment_evaluation_part_vol_ii_part_bc_en.pdf/950efefa-f2bf-0b4a-a3fd-41c86daae468)

<https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation>

#### CONTACTS

[daniela.siconolfi@renolab-glp.com](mailto:daniela.siconolfi@renolab-glp.com)

