



ANTIBACTERIAL
AND ANTIVIRAL
EFFICACY TESTS

TEXTILES

How are biocides regulated?



Biocides are regulated at EU Level by the Biocidal Products Regulation (BPR, Regulation (EU) 528/2012) - & ulterior amendments such as the Regulation (EU) No 334/2014 of the European Parliament and Council amending the BPR with regard to certain conditions for access to the market [Article 95].

BIOCIDES

This regulation concerns the placing on the market and use of **biocidal products**, which are used to protect humans, animals, materials or articles **against harmful organisms like pests or bacteria**, by the action of the active substances contained in the biocidal product. This regulation aims to improve the functioning of the biocidal products market in the EU, while ensuring a high level of protection for humans and the environment.

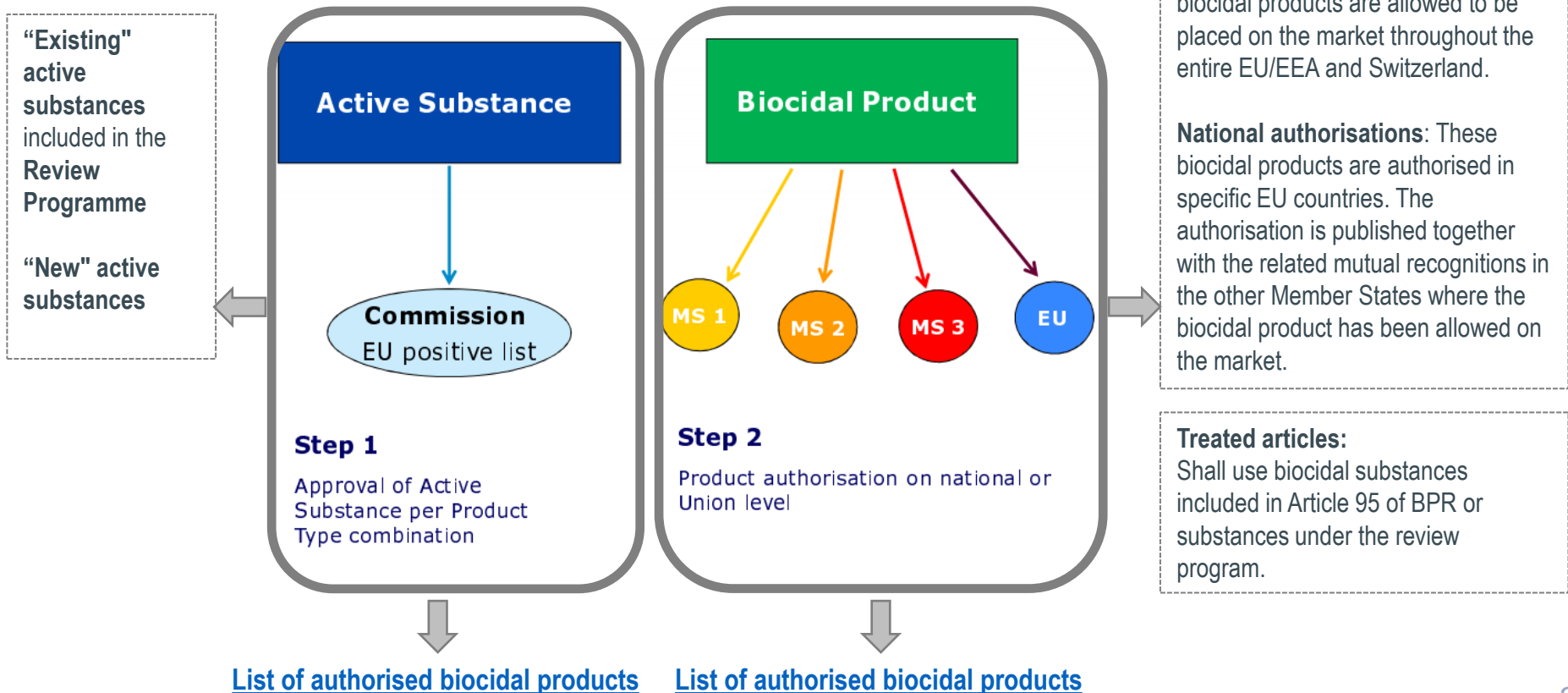
All **biocidal products** containing **approved active substances** are evaluated for **safety and efficacy in relation to the label claims made for the product** before they are allowed to be sold in the EU. However, products that were on the market before 2000 can continue to be sold * while the authorities are evaluating the active substances they contain.

* Before the active substance is approved in the ECHA positive list, the national legislation holds.

TREATED ARTICLE:

Are articles treated with biocidal substances or formulations intended to protect the article itself from biological deterioration.

How are biocides regulated?





	MAIN GROUP 1: Disinfectants	MAIN GROUP 2.: Preservatives	MAIN GROUP 3: Pest control	MAIN GROUP 4: Other biocidal products
Description	These product types exclude cleaning products that are not intended to have a biocidal effect, including washing liquids, powders and similar products PT 1: Human hygiene	Unless otherwise stated these product-types include only products to prevent microbial and algal development PT 6: Preservatives for products during storage	PT 14: Rodenticides	PT 21: Antifouling products
	PT 2: Disinfectants and algacides not intended for direct application to humans or animals PT 3: Veterinary hygiene	PT 7: Film preservatives	PT 15: Avicides	PT 22: Embalming and taxidermist fluids
Product-type	PT 4: Food and feed area PT 5: Drinking water	PT 8: Wood preservatives PT 9: Fibre, leather, rubber and polymerised materials preservatives PT 10: Construction material preservatives PT 11: Preservatives for liquid-cooling and processing systems PT 12: Slimicides PT 13: Working or cutting fluid preservatives	PT 16: Molluscicides, vermicides and products to control other invertebrates PT 17: Piscicides PT 18: Insecticides, acaricides and products to control other arthropods PT 19: Repellents and attractants PT 20: Control of other vertebrates	

Evaluation of efficacy- biocidal products



- Efficacy of a treated article shall be demonstrated using standard conditions, as described in the ECHA and test guidelines.
- If additional test conditions are claimed, they shall also be demonstrated.
- All the samples batches used in the efficacy tests must have identical composition and should be representative of the finished good.
- Efficacy shall be maintained during the expected life cycle of the good.



Guidance on the Biocidal Products Regulation

Volume II Efficacy - Assessment and Evaluation (Parts B+C)

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As the claimed antimicrobial / antiviral efficacy will encompass a large spectrum of potential target organisms, it is not necessary or indeed feasible to include all possible micro-organisms /viruses in an efficacy test designed to support a claim.

Standard test methods normally specify one or more representative species taking into account their relevance to practical use, susceptibility to biocidal substances and adequacy for laboratory testing.

Efficacy test: methods overview

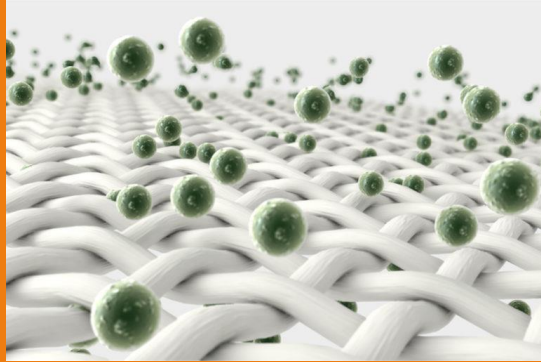
For efficacy testing of treated articles a tiered approach is recommended. The following tiers can be distinguished:

- **TIER 1** tests to support the basic activity of the treated article to define minimum standards for antibacterial, antifungi or antiviral activity. Only **contact times and test organisms** shall be defined
- **TIER 2**
Tests to support the efficacy of the treated article under simulated conditions of use (e.g. soiling, temperature, ageing, leaching...)



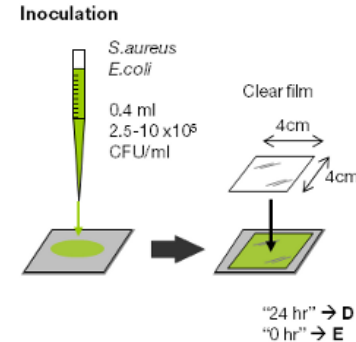
To define the correct test panel the following information must be provided:

- Matrix: fabric, nonwoven, etc...
- Area of application: domestic, medical, food etc...
- Intended use: clothes, masks, filters, etc...
- Active ingredient and application mode (e.g. coating, extrusion, fiber-bonding, etc...)
- Product label or claims to be demonstrated: e.g. antibacterila, antiviral etc..

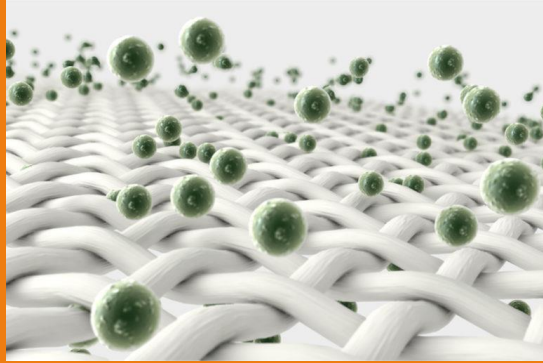


Determination of the antibacterial activities of textiles according to :

- *ISO 20743: Textiles — Determination of antibacterial activity of textile products*

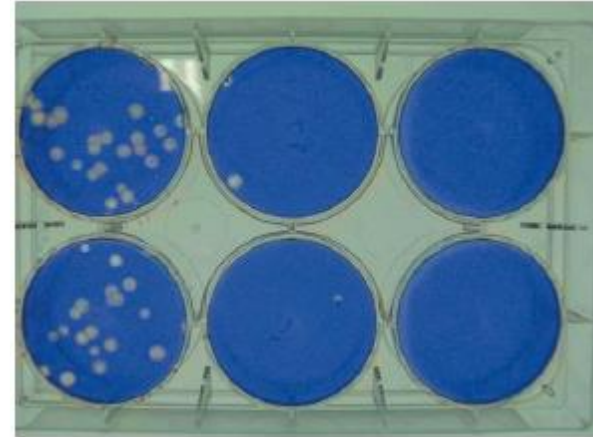
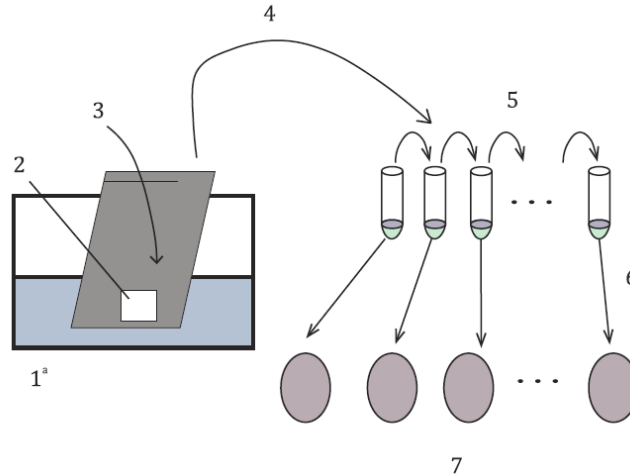


- *ISO 20645 Textiles — Determination of antibacterial activity of textile products for leaching substances*
- *AATCC test methods*
- *ASTM E 2149: Textiles — Determination of antibacterial activity of textile products under dynamic conditions*



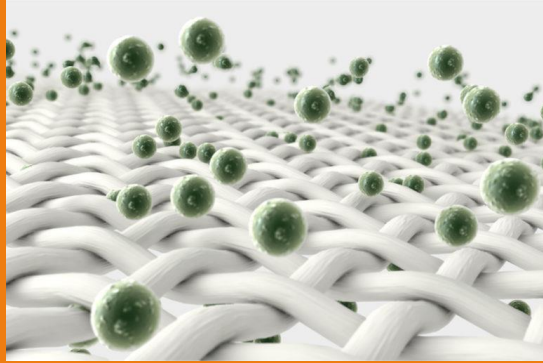
Determination of the antiviral activities of textiles according to :

- *ISO 18184: Textiles — Determination of antiviral activity of textile products⁽¹⁾*



Plaque forming units test performed on Feline calicivirus (ISO 18184)

Additional test conditions using other test strains (i.e. bovine coronavirus may used).

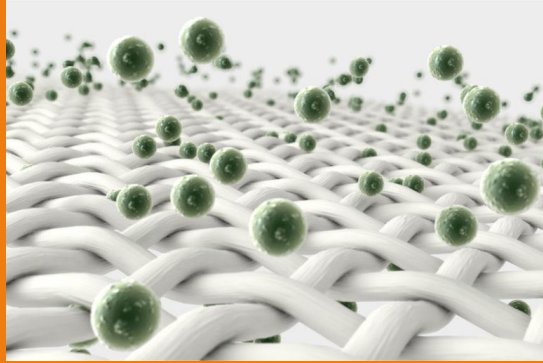


Determination of the antiviral activities of textiles according to :

- *ISO 18184: Textiles — Determination of antiviral activity of textile products*

Main mandatory validation parameters of the norm:

- *Minimum viral recovery from untreated specimen.*
- *Appropriate repeatability of recovery at all contact times from the untreated specimen.*
- *Check of residual toxicity to host cells.*
- *Check of neutralization of the antiviral substance (especially, if leaching from the surface).*



Determination of the antiviral activities of textiles according to :

- ISO 18184: Textiles — Determination of antiviral activity of textile products

Guidance to effective testing:

- expect poor efficacy on non enveloped viruses (such as *Feline calicivirus*).
- Contact times shorter than **2 hours** are normally non effective.
- Do not expect viral titer reduction similar to bacterial reduction (e.g. **99%** reduction is already a success).
- If antibacterial activity is obtained, antiviral, activity may be not comparable (viruses may form **aggregates** on porous materials).
- **Homogenous** dispersion and **density** of the active ingredient as well as its availability on the surface is most important.
- Testid performed at 25°C under **highly humid** conditions: some substances may be less effective under these test conditions.

Testing & compliance
Product expertise

Eurofins BioPharma Product
Testing (IT)

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Useful links



Biocides

European Commission:

- [Biocidal Products Regulation \(BPR, Regulation \(EU\) 528/2012\)](#)
- [General information about Regulation on the supply and use of biocidal products.](#)

ECHA (European Chemical Agency)

[ECHA: Guidance on the Biocidal Products Regulation](#)

[ECHA: the status of the active substance](#)

[ECHA: the list of active substances](#)