



ProEconomy Biocidal Products Regulations

The EU Biocidal Products Regulation (EU No. 528/2012¹ - EU BPR) concerns the making available on the market and use of biocidal products, that are used to protect humans, animals, materials, or articles against harmful organisms like pests or bacteria, by the action of the active substance(s) contained in the biocidal product.

The purpose of the EU-BPR is to improve the free movement of biocidal products within the EU while ensuring a high level of protection of both human and animal health and the environment.

As of 1 September 2015, a biocidal product consisting of, containing, or generating an active substance, cannot be made available on the EU market unless either the active substance supplier or the product supplier is included in the EU Article 95 list for the product type(s) to which the product belongs.

The EU Article 95 list is a register of authorised suppliers established in the EU who have submitted to the European Chemicals Agency (ECHA) a complete biocide active substance dossier, a letter of access (LoA) to a complete active substance dossier, or a reference to a complete active substance dossier for which all data protection periods have expired. A complete dossier is one that contains all information required to establish that the active substance will cause no unacceptable effects on human or animal health, or the environment and show that the active substance will be sufficiently effective against target organisms, when used as intended.

As of 1 September 2015, a biocidal product consisting of, containing, or generating an active substance, cannot be made available on the EU market unless either the active substance supplier or the product supplier is included in the EU Article 95 list for the product type(s) to which the product belongs.

ProEconomy is listed as an authorised active substance supplier for both copper and silver in both the EU and GB Article 95 lists, and are allowed to make these active substances available on both the EU and GB markets for the following product types (PTs).

For further specification and pricing contact
sales@proeconomy.com

¹ As amended by Regulation (EU) No 334/2014.

² Great Britain collectively includes England, Scotland and Wales.



The objective of the EU Article 95 list is to ensure the equal treatment of companies placing active substances on the market and the EU-BPR requires all companies to hold a dossier or have a letter of access to a dossier, or to relevant data in a dossier, for each of the active substances they use in the biocidal products they make available on the EU market.

Following Brexit, the EU BPR has been implemented in the UK as the GB BPR, and the EU Article 95 list has its UK equivalent, the GB Article 95 list. The objective of the GB Article 95 list and the requirements placed on companies making biocidal products available on the market in Great Britain² under GB-BPR are the same as EU-BPR.

Biocidal products containing active substances for which a company does not comply with the relevant Article 95 obligations should no longer be made available on the market.

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Copper (CAS No. 7440-50-8):

- PT2 (Disinfectants and algacides not intended for direct application to humans or animals)
- PT5 (Disinfectants for drinking water)
- PT11 (Preservatives for liquid-cooling and processing systems).

Silver (CAS No. 7440-22-4):

- PT2 (Disinfectants and algacides not intended for direct application to humans or animals)
- PT4 (food and feed area)
- PT5 (Disinfectants for drinking water)
- PT11 (Preservatives for liquid-cooling and processing systems).

Active Substance Approval and Biocidal Product Authorisation

All biocidal products require an authorisation before they can be placed on the EU market, and the active substance(s) contained in biocidal products must have been previously approved in the EU.

There are, however, exceptions to this principle, the most important being the transitional provisions in Article 89 of the EU-BPR that allow biocidal products containing an active substance included in the Review Programme to be made available on the

market and used, subject to the national rules concerning biocides that are in force in each of the EU Member States.

The Review Programme noted above is the name commonly used for the programme of work for the examination of existing biocidal active substances contained in biocidal products. The programme was set up by the Commission under the Biocidal Product Directive (BPD) and it continues to date under the EU-BPR. Existing active substances are those substances which were on the market in the EU on 14 May 2000 as an active substance of a biocidal product.

The existing active substances which were accepted to be examined in the Review Programme were those which were identified as such and for which a notification to support the substance in the Review Programme was accepted, as set out in Annex II to Regulation (EC) No 1451/2007.

Similarly, all biocidal products require an authorisation before they can be placed on the market in GB, and the active substance(s) contained in biocidal products must be approved according to GB-BPR.

The 'GB-BPR Active Substance List for GB and NI' contains a list of all the biocidal active substances that have been approved, are being evaluated, or have a non-approval decision under the relevant Biocidal Products Regulation (BPR) for the Great Britain and Northern Ireland³ markets.

GB-BPR has also created a GB Review Programme which like the EU-BPR is the system of evaluating existing biocidal active substances (those on the market on 14 May 2000) in Great Britain. The rules and procedures of the GB Review Programme are provided by the GB Review Regulation.

Copper

A timely notification to support copper as a biocidal active substance was not submitted in the EU under the BPD and consequently copper was not allowed to be used in the EU as a biocide.

Following procedures that allow biocidal products that are considered essential to protect human health to be made available on the market, ProEconomy submitted an essential use derogation application to the EU Commission through the UK Health and Safety Executive (HSE), following which an exemption from the restriction was granted for copper in the EU. ProEconomy's copper is therefore allowed to be used as a biocide in the EU and is listed in the EU Article 95 list for PT2, PT5, and PT11.

³ The EU Biocidal Products Regulation (EU-BPR) is the biocide legal framework for Northern Ireland.

As a condition of granting the derogation, the EU Commission required a complete active substance dossier to be submitted to allow an evaluation to approval copper under the EU-BPR. A copper task force, consisting of suppliers that support copper as a biocide, was formed soon after the derogation was granted. ProEconomy are a founder member of this task force and the required dossiers supporting PT2, PT5, and PT11 have been submitted for evaluation.

The essential use derogation also applies under GB-BPR and the copper dossier supporting PT2, PT5, and PT11 is currently under assessment by the UK HSE. A complete dossier supporting use in PT4 will be submitted to the UK HSE for evaluation in due course.

Silver

A timely notification to support silver as a biocidal active substance for use in PT2, PT4, PT5, and PT11 was submitted in the EU under the BPD and silver is considered an existing active substance in the EU review programme and may be used as a biocide in EU Member States while the evaluation of silver continues. ProEconomy's silver has therefore always been supported for use in PT2, PT4, PT5, and PT11 under the EU BPR and is listed accordingly in the EU Article 95 list.

A silver task force, consisting of suppliers that support silver containing active substances as biocides, was formed to submit and support the required silver active substance dossiers. ProEconomy are a founder member of this task force and are currently the only copper and silver ionisation company remaining as a member.

The active substance dossier supporting approval of silver under EU-BPR is now required to be examined by the UK HSE under GB-BPR. ProEconomy has informed the UK HSE, before the given deadline of the 29th June 2021, that they will support silver for PT2, PT4, PT5, and PT11 under GB-BPR and have submitted the relevant dossier to the HSE.

When the review of silver by the HSE is complete and silver is approved, biocidal products containing silver for use in either PT2, PT4, PT5, or PT11 must be authorised under GB-BPR. The application for authorisation must contain a right to access the active substance dossier evaluated by the HSE.

To our knowledge, no other copper and silver ionisation company has notified to the HSE that they wish to support silver as a biocide in the UK under GB-BPR. It is likely therefore that only ProEconomy's silver active substance dossiers will have been evaluated by HSE, and these dossiers will be the only dossiers to which product authorisations can refer to for data access.

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