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EU Biocidal Products Regulation 528/2012

Biocidal products manufactured in or imported into the EU or European Economic Area must be authorised for compliance with the requirements of the EU Biocidal Products Regulation (BPR) and any relevant national legislation before being placed on the market.

Biocidal products have been regulated in the European Union (EU) by the EU Biocidal Product Regulation 528/2012 (BPR) since 1 September 2013.

After Brexit, when the United Kingdom left the EU, there has been a "copy-paste" of EU BPR into a GB legislation, the GB Biocidal Products Regulation (GB BPR). This came into force on 1st Jan 2021 and applies to England / Scotland and Wales. Northern Ireland will still be governed by the EU BPR legistlation.

Aim of the legislation

The aim of the BPR is to improve the consistency of the biocidal products available in the EU and Great Britain and ensure a high level of protection for humans and the environment via a two-stage process of active substance approval followed by biocidal product authorisation.

The current authorisation process for hard surface disinfectants varies from country to country. From the simple, a Safety Data Sheet (SDS) being sent to the poison centre or time consuming and expensive requiring full microbiological, stability and safety information.

The provisions of the BPR set out to harmonise the market at EU level by simplifing the approval of active substances and authorisation of biocidal products.

It also introduces timelines for Member State evaluations, opinion-forming and decision- making.In addition, the BPR promotes the reduction of animal testing by introducing mandatory data sharing obligations and encouraging the use of alternative testing methods. The EU Biocides Regulation covers a diverse group of products.

As a regulation, the BPR acts directly in all EU Member States, meaning that local legislation does not need to be created to implement the requirements, however, due to transitional measures provided for in the Regulation, national Member State legislation, which pre- dates the introduction of the BPR will still apply to some biocidal products.

Companies placing biocidal products on the market will need to take these transitional measures into consideration until December 2024, when the Review Programme for the evaluation of active substances is due to end. In addition, the Regulation has been fully implemented in Norway and Switzerland.

Biocidal product authorisation process

There are two consecutive steps required to gain EU BPR biocidal product authorisation:

1. The active substance(s) in the biocidal product must be approved under the appropriate product-type. This process takes place at EU-level.
2. Each biocidal product consisting of, containing or generating the approved active substance(s) must then be authorised under the appropriate product-type at country level.

What is a biocidal product?

Article 3 (1) (a) of the BPR defines a biocidal product as "any substance or mixture ... consisting of, containing or generating one or more active substances, with the intention of destroying, rendering harmless preventing the action of .... any harmful organism by means other that mere physical or mechanical action."

So the BPR covers disinfectants, bleach, insect repellents, preservatives, insecticides but not fly paper or fly swats. In cleanrooms it covers all microbial products whether they come in a trigger spray bottle, presaturated wipe, fogging or gassing system, ready-to-use or concentrate.

A key part of the definition is "any substance with the intention of ... destroying .. harmful organisms." This means if the intended use of the product is for surface disinfection regardless of whether the manufacturer is selling the product with no biocidal claims the product is still classified as a biocidal product according to the BPR. A good example of this is 70% IPA presaturated wipes, many of which are sold in the EU without claims. If they are being used for disinfection of surfaces the product needs to be authorised under the BPR under Product Type 2.

As IPA was approved as an active substance on 11 March 2015, all products containing IPA should have had a BPR dossier submitted by 1 July 2016 to remain on the market during dossier evaluation. Most biocidal products take 2 - 4 years to go through the authorisation process meaning all products containing 70% IPA should now be BPR authorised or they should be removed from the market until authorisation is gained.

Active substances

Information and data requirements for active substance approval and biocidal product authorisation are outlined in Annex II and Annex III of the BPR.

When active substances are approved, they are listed on EU BPR Article 9 Union List of Approved Active substances: echa.europa.eu/information-on-chemicals/biocidal-active-substances. The list needs to be filtered to approved substances only.

The EU BPR consists of four product groups including 22 different biocidal product types covering: disinfectants, preservatives, pest control and specialty biocides. The group relevant to life science cleanroom users is Main Group 1 Disinfectants:

- PT1 — human hygiene products such as hand gels and hand rubs
- PT2 — disinfectants and algaecides not intended for direct application to humans or animals. This includes products used for the disinfection of surfaces, materials and equipment, which do not come into contact with food
- PT3 — veterinary hygiene products, used to disinfect materials associated with the housing or transportation of animals.

When a disinfectant has been authorised under one product-type it cannot be used in another product-type unless authorisation is also granted for the second product-type. For example, a hard surface disinfectant authorised under product-type 2 would need a separate authorisation under product-type 1 to be used as hand sanitiser. For life science cleanrooms, hard surface disinfectants are categorised under product-type 2.

Approved Suppliers - Article 95 of the BPR

As well as the approval process described above, from 1 September 2015, Article 95 of the BPR has applied to active substances placed on the EU market, either on their own or in biocidal products. The provisions of Article 95 aim to make access to the market fairer via sharing of the costs associated with active substance approval.

From 1 September 2015 biocidal products cannot be made available on the EU market unless the active substance is sourced from an approved supplier on the so-called Article 95 list maintained by the European Chemicals Agency (ECHA). The list of approved suppliers and their related active substances can be found here: echa.europa.eu/information-on-chemicals/active-substance-suppliers

For example, if a wipe containing 70% IPA and 30% water is imported from a manufacturer outside of the EU, either the active substance supplier or the product manufacturer or the EU importer must be listed in Article 95. If none of the above are listed in Article 95, the product cannot be sold legally in the EU as a biocidal product. It should be noted that non-EU companies can be included in the Article 95 list alongside an appointed EU representative.

Active substance approvals

The active substance approval process is ongoing and is gradually replacing national regulations. Each biocidal active substance is at a different stage in the regulatory process and keeping track of the status of the active substances in your biocidal products is critical to ensure continuity of supply of the finished biocidal products.

Some key active substances commonly found in cleanroom disinfectants have already been approved and add to the Union List of approved active substances. This means the biocidal product manufacturer then has 2 years in which to submit a BPR product dossier.

Approval Dates

Propan-2-ol (IPA)	1st July 2014
Glutara ldehyde	1st Oct 2014
Peracetic acid	1st Oct 2015
Hydrogen peroxide	1st Feb 2015
Propan-1-ol	1st May 2017
PHMB	1st Nov 2017
Active chlorine released from calcium hypochlorite	1st Jan 2017
Active chlorine released from sodium hypochlorite	1st Jan 2017
PHMB	1st Nov 2017

Biocidal Products

All biocidal products must get an authorisation before they can be made available on the market. Companies can choose between several alternative processes, depending on their product and the number of countries where they wish to sell it. If the product will be placed only in a single market, national authorisation from that country is sufficient. This will have an individual country authorisation number which will look like this DE-0014073-00-0000.

A company who wishes to sell a biocidal product in all EU/EEA countries and Switzerland can apply for a Union authorisation, the number will look like this EU-0027735-0000.

Any biocidal products, which are not going through the authorisation process can no longer be placed on the market from 180 days after the date of approval of the active substance, and they can no longer be used from 365 days after the date of approval. Where the biocidal product contains more than one active substance, the relevant phase- out periods begin on the date of approval of the final active substance to be approved, or not-approved.

For all biocidal products containing only the active substances listed above the deadline for dossier submission has now passed. All products containing these should have a BPR authorisation number or a R4BP Case Number showing proof of submission.

Impact of the BPR on cleanroom disinfectants

Although no financial penalties are necessarily provided for in the BPR in every member state for an end user using an unauthorised product in their cleanrooms, it could still potentially cause problems. An unauthorised biocidal product discovered by regulators could immediately be withdrawn from the market leaving the end user without a validated disinfectant.

As a worst-case scenario, product manufacture could be delayed whilst a replacement disinfectant undergoes months of validation. Any company about to start, or whom has an ongoing disinfectant validation project needs to ensure that the biocidal product under investigation is already, or is intended to be, authorised under the EU BPR by the manufacturer or importer.

The costs to approve active substances and authorise biocidal products are significant due to the cost of generating the required supporting data and dossier preparation, as well as the evaluation fees. In broad terms, the costs to gain approval of an active substance can be several million pounds and a simple disinfectant product could potentially cost €750k to €1m to authorise. We have already seen products being withdrawn from the market as it is not cost effective for a manufacturer to support them through the authorisation process.

If a biocidal product is currently registered as a medical device it will still need to be authorised separately as biocidal product under PT2 to be used as a hard surface disinfectant.

List of authorised biocidal products

It has now become easier to check whether a particular disinfectant is authorised under the BPR. On ECHA's website there is a list of authorised products which can be searched by product type, active ingredient, manufacturer and brand name. This list can be found here: echa.europa.eu/information-on-chemicals/biocidal-products

There is a slight time delay between products being authorised and appearing on the website but a manufacturer would be able to send your their authorisation number and paperwork.

Tips for surviving the BPR

Understand your product portfolio – which are in scope of BPR?

List all products being used for microbial control (these might be products not currently supplied with efficacy claims such as IPA presaturated wipes). Review the SDS for these products and note the ingredients.

Check the supplier of the active substance is on Article 95?

Ask your supplier to provide details of the active substance manufacturer's inclusion on the ECHA Article 95 list.

Check if the biocidal product is authorised in your country of use?

Ask your supplier to provide details of the BPR authorisation number confirming it is for Product Type 2 and for the country you are using it in. You can check yourself at: echa.europa.eu/information-on-chemicals/biocidal-products. They may be a time delay between the company being granted the authorisation and it appearing on the website.

The product isn't authorised !

a. This is ok if all the active substances in a formulated product have not yet been approved. The product would need to be registered under the current local / national rules for your country. Ask the manufacturer is they are planning to support the product through the BPR process. This is not possible to check but if a lack of knowledge of the BPR from a manufacturer's standpoint is apparent, it would be prudent to start a revalidation plan to ensure continuity of a legal supply from a different manufacturer.

b. This is ok if the manufacturer has submitted the dossier for authorisation within the correct time period and the authorisation is delayed because of Covid, Brexit etc. Ask for the supplier to prove that they have submitted their dossier, they should have an R4BP Case Number.

c. This is not ok if all the active substances in the product are already approved and your supplier has not submitted a dossier with the correct time period. You are taking a risk that this product For more information on the BPR or to request maybe withdrawn from the market at short notice.

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EU Biocidal Product Regulation
Current status of Contec's Disinfectants

From the 1 Sept 2013, biocidal products manufactured in, or imported into, the European Union (EU) or European Economic Area (EEA) must be authorised in accordance with the EU Biocidal Products Regulation (EU) 528/2012 (BPR), and any relevant national legislation, before they are placed on the market.

All active substances in Contec's biocidal products are approved, or being evaluated for approval, in the relevant product-types in the BPR review programme. For all Contec biocidal products, the active substance or biocidal product suppliers are included in the Article 95 list.

Contec have submitted applications for Union Authorisation for all its biocidal product families to ensure continuity of supply throughout the entire EU/ EA. We will submit separate applications for the new GB BPR.

70% IPA

Contec 70% IPA, PROSATS with 70% IPA, SATWIPEs with 70% IPA

Contec's EU BPR product dossier for all products containing 70% IPA has received **Union Authorisation** from the ECHA Biocidal Products Committee. All Contec's IPA products including presaturated wipes are authorised for sale in all EU countries and the UK. The Authorisation Number for the product family is EU-0020460-0000.

6% Hydrogen Peroxide / Peracetic Acid

Contec PeridoxRTU

Contec's EU BPR product dossier for all Contec PeridoxRTU products has received **Union Authorisation** from the ECHA Biocidal Products Committee. All products are authorised for sale in all EU countries and the UK. The Authorisation Number for the product family is EU-0023658-0000.

6% Hydrogen Peroxide

Contec HydroPure, SATWIPES with HydroPure

Contec's EU BPR product dossier for all products containing 6% Hydrogen Peroxide has received **Union Authorisation** from the ECHA Biocidal Products Committee. All Contec's Hydrogen Peroxide products are authorised for sale in all EU countries. The Authorisation Number for the product family is EU-0027735-0000. Contec's HydroPure dossier for the GB BPR has been submitted, which allows the product to remain on the market in UK, pending authorisation.

Hypochlorous Acid

Contec ProChlor and CyChlor, SATWIPES with ProChlor

Contec's biocidal product dossier for Contec ProChlor and Contec CyChlor was submitted before the BPR deadline of 1 January 2019 and is now under review by the MSCA for the Netherlands [Contec Calcium Hypochlorite Product Family Case number: BC-LY047116-11].

70% Denatured Ethanol

Contec 70% DE, PROSATS with 70% DE, SATWIPEs with 70% DE

Biocidal product authorisation applications will be submitted for all Contec Denatured Ethanol products before the relevant deadline. This will be assigned on completion of the active substance approval. The approval process for ethanol has been ongoing for several years at EU-level and is not expected to be completed before the end of 2023.

For more information on the BPR or to request information on Contec's BPR authorized disinfectants, email us:

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