Addi-Tec

HARKE GROUP

GUIDE TO BPR TREATED ARTICLES

A Guide for those selling a product that has been treated to impart an antimicrobial effect, such as: antibacterial, insecticidal or mould resistant. The Biocidal Products Regulation affects your products and you must ensure you are BPR compliant. We tell you all you need to know in this guide.

Contents

About This eBook

This eBook has been written by Addi-Tec to help explain the BPR to those in the EU who sell products which make a biocidal claim, this includes any and all articles or products treated with a biocide or a chemical and/or those products that claim any type of biocidal effect that their product has.

The guide is intended for use by product, marketing and technical teams, so we have written the eBook to be accessible to all of these specialist areas, and we've linked to more in-depth articles where appropriate.

The BPR is an EU regulation that will affect many products across a wide range of industries. It has been in-force since 2013 but increasingly Authorities are focusing on enforcement as more active substances are approved and products require authorisation under the scope of the legislation. That's why we're releasing this eBook now.

The aim of this eBook is to help you prepare for any necessary BPR changes, including providing a level of reformulation advice, regulatory advice and marketing advice.

Addi-Tec's team are always available to you should you wish to discuss reformulation or regulatory challenges, you can find our contact details on pg.30.

Addi-Tec also work alongside the regulatory experts from ERM, a leading global provider of environmental, health, safety, risk, and social consulting services you can find their contact details on pg.30.

What Is The BPR?

BPR stands for Biocidal Products Regulation, which is an EU regulation that was introduced in 2012 and came into force in September 2013.

You'd be forgiven for not hearing much about it, unless biocides are your business, but it's going to affect a wide variety of industries and products now that it's being more closely regulated by EU Member States (see pg.23).

Preceding the BPR was another EU regulation called the Biocidal Products Directive, however the BPD did not deal specifically with articles treated with biocides, whereas the BPR includes articles treated with biocides, as well as the biocides themselves. The introduction of a **treated article** (see pg.6) into the scope of the BPR means that any substance, mixture or article that has been treated with or intentionally incorporates one or more a biocidal products now has greater regulatory scrutiny. As a result, the BPR has scope to affect many more businesses across the EU than the BPD has done in the past.

While many EU member states have, of course, had regulations that product manufacturers and marketers must follow regarding biocidal claims on treated products, the BPR was introduced with an aim to unify these regulations across the EU and in doing so aim to create a level market for these types of products.

> "The purpose of this Regulation is to improve the functioning of the internal market through the harmonisation of the rules on the making available on the market and the use of biocidal products, whilst ensuring a high level of protection of both human and animal health and the environment. The provisions of this Regulation are underpinned by the precautionary principle, the aim of which is to safeguard the health of humans, the health of animals and the environment. Particular attention shall be paid to the protection of vulnerable groups."

In addition, the BPR promotes the reduction of testing on animals by introducing the obligation to share data relating to animal testing, and to prohibit duplicate testing to minimise animal testing as much as possible, instead encouraging alternative testing methods.

BPR came into effect back in September 2013, but as you'll see from reading this eBook, most brands are not compliant and many don't even know what the BPR is.

The BPR consolidated document itself is currently 163 pages long, you'll find a link to it on page pg.30 of this eBook.

How The BPR Works

The BPR is governed by the EU and managed by Member States of the EU.

There are legal obligations which the biocide manufacturers and the treated product retailers must adhere to.

For Biocidal Products

- The product must contain active substance sourced from a supply that can be linked to an authorised supplier for that substance (product must be Article 95 compliant)
- The active substance used must be approved under the BPR, or be under review for approval, for the intended use of the product (product must be active substance and product type compliant)
- The biocidal product must be correctly registered or authorised for the intended use according to either national rules or BPR rules depending on the approval status of the active substance (product must be legally compliant)

For Treated Articles

Manufacturers and importers who place treated articles on the market are required to label treated articles when:

- they make a claim that the treated article has biocidal properties
- the conditions of the approval of the active substance(s) use to treat the article require specific labelling provisions to protect public health or the environment

Approval of biocidal active substances is an EU level process. Authorisation of biocidal products is conducted at the Member State level, or can be achieved for certain categories of products at EU level (Union Authorisation). Many substances and products are now approved under the BPR but the process is continuing with new approvals occurring on a regular basis.

The list of approved active substances which is continually updated is available online; **you can find it here.**

The BPR also controls the source(s) of biocidal active substances, through a list of authorised suppliers – the so-called Article 95 list. The list is available online; **you can find it here.** However, please always refer to the latest PDF on this link because suppliers and substances are under continual review and are subject to change.

Now that many active substances and biocidal products are approved, attention is turning more towards to compliance. We've seen compliance activity increasing since the start of 2018 with the regulatory authorities in each EU member state making plans for enforcing the BPR, so brands need to act now to ensure compliance for the biocidal products and treated articles they market in the EU.

Definition Of A Biocide

The EU Biocides Regulation defines a biocide as:

> *"any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action: or any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action. A treated article that has a primary biocidal function shall be considered a biocidal product."*

A biocide is an agent that acts against...

Microorganisms:

- Bacteria
- Mould
- Viruses
- Algae
- Fungi

Pests:

- Insects
- Rodents
- Arachnids
- And other pests

Definition of A Treated Article & Biocidal Product

In all of the official documentation you'll see that the term **'Treated Article'** is used. A treated article is any physical product that has been treated with a biocidal product to provide some sort of action against a microorganism or pest. So in this text, as our main focus is on treated articles and our audience are manufacturers and marketers, we'll refer to them as **treated products** to remove any ambiguity over what counts as an 'article'.

A '**Biocidal Product**', on the other hand, is a product that contains and 'active substance' that provides an intentional biocidal action as the primary function. One or more 'Biocidal Products' may be added to your 'treated article' to achieve the desired results. Our eBook is not intended for those looking for detailed information about biocides, so if you're a biocide manufacturer you may not find all of the information you're looking for in the eBook.

For this eBook our primary concern is to inform you about products that have been treated with biocides.

Examples of a treated product include:

- A tent which is made from fabric that is mould resistant
- A door handle that uses a chemical to make it antibacterial
- 'Anti-odour' Socks which use a substance to prevent bacteria that cause odour
- Latex gloves that incorporate a substance to make them anti-viral
- A mattress that uses a substance in the fabric to make it hypoallergenic (eg: anti-dust mite)

In all cases, the definition between biocidal product and treated products depends on the function of the product and intention of having the biocide active substance in the product and in many respects, this is determined on a case-by-case basis. Remembering that it is the responsibility of the person placing the product on the market to justify their intent and ensure the product meets the necessary regulatory obligations.

The following useful examples are provided by the HSE in their information for placing treated products on the market in the UK.

Type of Product	Treated Product or Biocidal Product
Product treated with/incorporates a biocide (e.g. a wooden bench painted with wood preservative) with the sole intention of controlling organisms harmful to the treated product/material itself	Treated Product - must comply requirements in Article 58 of EU Biocides Regulation 528/2012
Product is treated with/incorporates a biocide and the primary function of the product is not as a biocide (e.g. odour free/ stay fresh antibacterial sock)	Treated product - must comply requirements in Article 58 of EU Biocides Regulation 528/2012
Product is treated with /incorporates a biocide and the primary function of the product is as a biocide (e.g. antibacterial wipe)	Biocidal product which requires authorisation

Article 58

Article 58 is the topic you'll find has been the most talked about by brands regarding the BPR. In fact, it's so important for brands to know that we're going to include the whole text on the following page.

Article 58 states that you may only place on the market a treated product which complies with BPR, and that these products must be clearly labelled to detail the biocidal product(s) that have been used.

Article 58

Placing on the market of treated articles

1. *This Article shall apply exclusively to treated articles that are not biocidal products. It shall not apply to treated articles where the sole treatment undertaken was the fumigation or disinfection of premises or containers used for storage or transport and where no residues are expected to remain from such treatment.*

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2. *A treated article shall not be placed on the market unless all active substances contained in the biocidal products that it was treated with or incorporates are included in the list drawn up in accordance with Article 9(2), for the relevant product-type and use, or in Annex I, and any conditions or restrictions specified therein are met.*

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3. *The person responsible for the placing on the market of a treated article shall ensure that the label provides the information listed in the second subparagraph, where:*

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— in the case of a treated article containing a biocidal product, a claim is made by the manufacturer of that treated article regarding the biocidal properties of the article, or

— in relation to the active substance(s) concerned, having particular regard to the possibility of contact with humans or the release into the environment, the conditions associated with the approval of the active substance(s) so require. The label referred to in the first subparagraph shall provide the following information:

(a) a statement that the treated article incorporates biocidal products;

(b) where substantiated, the biocidal property attributed to the treated article;

(c) without prejudice to Article 24 of Regulation (EC) No 1272/2008, the name of all active substances contained in the biocidal products;

(d) the name of all nanomaterials contained in the biocidal products, followed by the word 'nano' in brackets;

(e) any relevant instructions for use, including any precautions to be taken because of the biocidal products with which a treated article was treated or which it incorporates.

This paragraph shall not apply where at least equivalent labelling requirements already exist under sector-specific legislation for biocidal products in treated articles to meet information requirements concerning those active substances.

4. *Notwithstanding the labelling requirements set out in paragraph 3, the person responsible for the placing on the market of a treated article shall label it with any relevant instructions for use, including any precautions to be taken, if this is necessary to protect humans, animals and the environment.*

5. *Notwithstanding the labelling requirements set out in paragraph 3, the supplier of a treated article shall, where a consumer so requests, provide that consumer, within 45 days, free of charge, with information on the biocidal treatment of the treated article.*

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6. *The labelling shall be clearly visible, easily legible and appropriately durable. Where necessary because of the size or the function of the treated article, the labelling shall be printed on the packaging, on the instructions for use or on the warranty in the official language or languages of the Member State of introduction, unless that Member State provides otherwise. In the case of treated articles that are not produced as part of a series but rather designed and manufactured to meet a specific order, the manufacturer may agree other methods of providing the customer with the relevant information.*

7. *The Commission may adopt implementing acts for the application of paragraph 2 of this Article, including appropriate notification procedures, possibly involving the Agency, and further specifying the labelling requirements under paragraphs 3, 4 and 6 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).*

8. *Where there are significant indications that an active substance contained in a biocidal product with which a treated article is treated or which it incorporates does not meet the conditions laid down in Article 4(1), Article 5(2) or Article 25, the Commission shall review the approval of that active substance or its inclusion in Annex I in accordance with Article 15(1) or Article 28(2).*

How To Comply

Before you place a treated product on the EU market, you will need to ensure that:

- The active substance used is either Approved for that Product Type, or is under review for that Product Type (learn about Product Types on pg:15)
- Correctly labelled according to the BPR Article 58 guidelines (see pg:13)
- And that you have necessary additional information about the biocidal products used in your product on request

Of course, products made outside the EU for sale only outside the EU do not have to comply with BPR, but again, you should check local regulatory authorities in the sale destination country.

Many worldwide authorities look to the EU's updates and follow suit, so product manufacturers worldwide would be wise to learn as much as possible about BPR and act in advance, should any other countries decide to implement a similar level of restriction to match the BPR.

NB: Products made outside the EU for sale inside the EU must comply with the BPR, but do not have to use an approved supplier, only an approved active substance. This has caused controversy amongst biocide producers and brands that use biocides in the EU, as there is now a distinct advantage to manufacturing your biocide treated products outside the EU.

What About Brexit?

Unfortunately we don't currently, at the time of writing, have a definitive answer for you on this point regarding the BPR specifically. But it is reasonable to assume that as the UK was involved in setting up the BPR that similar if not identical regulations will be adopted for the UK from 30th March 2019.

The Health and Safety Executive (HSE) have released the following information regarding chemical regulations, in general, post Brexit.

> *"The UK is strongly committed to the effective and safe management of chemicals. That will not change when we leave the EU.*
>
> *The Government fully recognises the importance of the chemicals sector to the UK economy and its contribution to other sectors, such as automotive, aerospace and life sciences.*
>
> *Our priorities are to ensure the continued effective and safe management of chemicals to safeguard human health and the environment, respond to emerging risks and allow trade with the EU that is as frictionless as possible."*

And have stated that the following will apply even if an EU agreement is not in-place:

During the implementation period, and subject to finalisation of the Withdrawal Agreement:

- *Registrations, approvals, authorisations and classifications in place before March 2019 will continue to be valid during the implementation period in the same way that they are now.*
- *REACH will continue to apply to the UK during the implementation period.*
- *The process for registering new chemicals under REACH during the implementation period will remain the same as it is now, which will require UK companies to register with the European Chemicals Agency (ECHA).*
- *During the implementation period, the UK will recognise all new registrations, approvals, authorisations and classifications granted by the EU.*
- *During the implementation period, we expect that HSE will not be able to act as a 'leading authority' to conduct certain assessments under the Plant Protection Products, Biocides and REACH regulations. We will work with affected businesses to minimise disruption and delay to their ongoing assessments.*
- *UK-based businesses will have the same rights during the implementation period as EU-based businesses to have their cases accepted and processed by 'leading authorities' based in other EU member states.*
- *HSE will continue to process product applications under the Biocidal and Plant Protection Products Regulation for the UK market under the national authorisation route during the implementation period. Any applications will be considered against the current rules and standards.*

Read the full statement here.

How To Market Your Product To Comply With The BPR

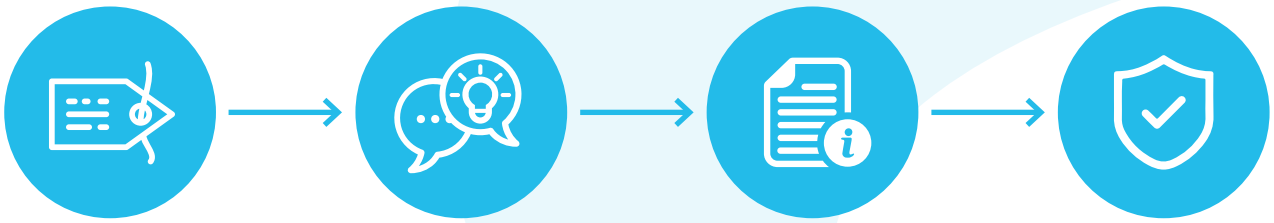
One of the requirements clearly stated in Article 58 is that you must label products containing a biocide. Of course, adding a clear label stating the biocidal products have been used to provide the biocidal qualities of your product can present a marketing challenge.

The BPR is not widely known in the public, and it's unlikely to make the headlines, so knowledge about the regulation will be limited. It won't be obvious to your customers why you have added additional labelling information. What will be highlighted is the use of a chemical substance, but to many consumers 'chemicals' are something to be avoided due to the common misconception that all chemicals are bad.

So our advice is, be as transparent as possible. Follow the advice on the next page to provide fully compliant labelling and information. State that you are adding the additional labelling as part of your necessary compliance with BPR and give your customers the tools they need to learn more about the biocides you use, why you use them and general information about what the BPR is.

You can do this many ways, you can encourage any concerned customers to consult a page on your website detailing more about BPR and the biocidal products you have chosen to use. Provide a leaflet inside your packaging, or you can offer additional information by phone/post. Be sure to educate your marketing and customer service teams so that they feel confident to answer all questions about biocides and the BPR correctly.

You can use BPR compliance to your advantage, the best way is to talk about it. Consider creating a campaign announcing what biocide you're using, why you're updating your packaging to reflect this and why BPR compliance is an important step for your company as well as human, animal and environmental safety. You may well have competitors who aren't as quick off the mark to promote this important USP, so take advantage while you can.



Examples Of Compliant Product Labelling

In case of a labelling requirement, the tag or the packaging must include the following information:

1. A statement that the treated article incorporates biocidal products;
2. Where this is substantiated, the biocidal property attributed to the treated article;
3. The name of all active substances, which are contained in the biocidal products;
4. The names of all nano materials contained in the biocidal products, if applicable, followed by the word “nano” in parentheses.

The label must be clearly visible, easily read and in that or those official languages of the respective country.

Here is an example from one of our suppliers, SANITIZED AG.

Label or packaging contains the following information:

1. A statement that the treated article incorporates biocidal products;
   = Contains a biocidal substance
2. Where this is substantiated, the biocidal property attributed to the treated article;
   = Claim: Feel the difference of Sanitized® treated odor-resistant articles
3. The name of all active substances, which are contained in the biocidal products;
   = Contains biocidal substance: silver glass phosphate
4. The names of all nano materials contained in the biocidal products, if applicable, followed by the word “nano” in parentheses.
   = SANITIZED has no products with nano material

The QR code provides additional proactive information about the effect for consumers on a mobile website and at www.sanitized.com.

And here is a great example of a product manufacturer/retailer working together with a biocide supplier to ensure that they are meeting BPR compliance:

2. Where this is substantiated, the biocidal property attributed to the treated article

1. A statement that the treated article incorporates biocidal products

3. The name of all active substances, which are contained in the biocidal products

The Right Product For The Right Purpose

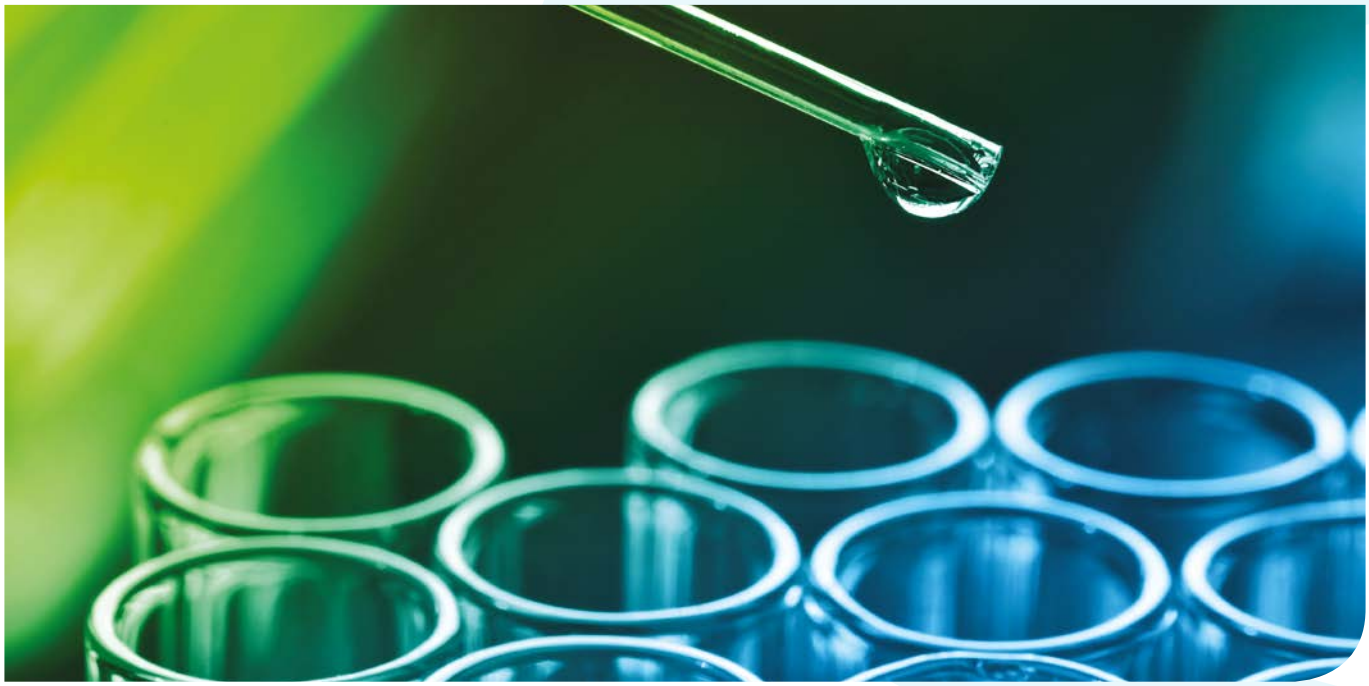
The list of BPR approved active substances (biocides) is also a little complex. Not all biocides are created equally, some have efficacy against certain microbes, some may be more suitable for contact with human skin, some may need to have less environmental impact dependant upon their intended end use. For this reason, the BPR approves certain biocides to be used for certain categories of product (see pg.16-18).

The biocial claim your product makes must be supported by using a biocide that belongs to the correct Product Type in the BPR list. So not only do you need to ensure your supplier and biocide are approved by the BPR, you also need to ensure that the biocide you're using is appropriate for the category your product belongs to.

Similarly, you must ensure that the biocidal claim you're making, eg: antibacterial, is supported by the Product Type category. For example, you cannot claim antibacterial using a biocidal product that's listed under the 'Preservative' category of the BPR.

So what if you know your biocidal product does have an antibacterial application which you'd like to advertise along with its anti-algae capabilities, but it's only listed as a preservative on the BPR? You'll have to either change your biocidal claim, use an additional approved biocide from the 'Disinfectant' list, or find a biocide that has been approved for both the 'Disinfectant' and the 'Preservative' list.

And if you're wondering why your biocidal product which you know has preservative and disinfectant qualities has not been included on both lists, that's simply because it's costing manufacturers a significant amount of money to register a product on a single list. This is particularly unfair to smaller manufacturers, unfortunately, and has caused a huge shakeup in the biocide industry. But the rules are the rules, you can only claim it if the category allows for it.



The BPR Product Type (PT) Groups

Number	Product Type	Description
Group 1: Disinfectants **These product types exclude cleaning products that are not intended to have a biocidal effect, including washing liquids, powders and similar products.**		
PT1	Human Hygiene	Products in this group are biocidal products used for human hygiene purposes, applied on or in contact with human skin or scalps for the primary purpose of disinfecting the skin or scalp.
PT2	Disinfectants and algaecides not intended for direct application to humans or animals	Used for the disinfection of surfaces, materials, equipment and furniture which are not used for direct contact with food or feeding stuffs. Usage areas include, inter alia, swimming pools, aquariums, bathing and other waters; air conditioning systems; and walls and floors in private, public, and industrial areas and in other areas for professional activities. Used for disinfection of air, water not used for human or animal consumption, chemical toilets, waste water, hospital waste and soil. Used as algaecides for treatment of swimming pools, aquariums and other waters and for remedial treatment of construction materials. Used to be incorporated in textiles, tissues, masks, paints and other articles or materials with the purpose of producing treated articles with disinfecting properties.
PT3	Veterinary hygiene	Used for veterinary hygiene purposes such as disinfectants, disinfecting soaps, oral or corporal hygiene products or with anti-microbial function. Used to disinfect the materials and surfaces associated with the housing or transportation of animals.
PT4	Food and feed area	Used for the disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage or consumption of food or feed (including drinking water) for humans and animals. Used to impregnate materials which may enter into contact with food.
PT5	Drinking water	Used for the disinfection of drinking water for both humans and animals.

Number	Product Type	Description
Group 2: Preservatives **Unless otherwise stated these product-types include only products to prevent microbial and algal development.**		
PT6	Preservatives for products during storage	Used for the preservation of manufactured products, other than foodstuffs, feeding stuffs, cosmetics or medicinal products or medical devices by the control of microbial deterioration to ensure their shelf life. Used as preservatives for the storage or use of rodenticide, insecticide or other baits.
PT7	Film preservatives	Used for the preservation of films or coatings by the control of microbial deterioration or algal growth in order to protect the initial properties of the surface of materials or objects such as paints, plastics, sealants, wall adhesives, binders, papers, art works.
PT8	Wood preservatives	Used for the preservation of wood, from and including the saw-mill stage, or wood products by the control of wood-destroying or wood-disfiguring organisms, including insects. This product type includes both preventive and curative products.
PT9	Fibre, leather, rubber and polymerised materials preservatives	Used for the preservation of fibrous or polymerised materials, such as leather, rubber or paper or textile products by the control of microbiological deterioration. This product-type includes biocidal products which antagonise the settlement of micro-organisms on the surface of materials and therefore hamper or prevent the development of odour and/or offer other kinds of benefits.
PT10	Construction material preservatives	Used for the preservation of masonry, composite materials, or other construction materials other than wood by the control of microbiological and algal attack.
PT11	Preservatives for liquid-cooling and processing systems	Used for the preservation of water or other liquids used in cooling and processing systems by the control of harmful organisms such as microbes, algae and mussels. Products used for the disinfection of drinking water or of water for swimming pools are not included in this product-type.
PT12	Slimicides	Used for the prevention or control of slime growth on materials, equipment and structures, used in industrial processes, e.g. on wood and paper pulp, porous sand strata in oil extraction.
PT13	Working or cutting fluid preservatives	Products to control microbial deterioration in fluids used for working or cutting metal, glass or other materials.

Number	Product Type	Description
Group 3: Pest control		
PT14	Rodenticides	Used for the control of mice, rats or other rodents, by means other than repulsion or attraction.
PT15	Avicides	Used for the control of birds, by means other than repulsion or attraction.
PT16	Molluscicides, vermicides and products to control other invertebrates	Used for the control of molluscs, worms and invertebrates not covered by other product types, by means other than repulsion or attraction.
PT17	Piscicides	Used for the control of fish, by means other than repulsion or attraction.
PT18	Insecticides, acaricides and products to control other arthropods	Used for the control of arthropods (e.g. insects, arachnids and crustaceans), by means other than repulsion or attraction.
PT19	Repellents and attractants	Used to control harmful organisms (invertebrates such as fleas, vertebrates such as birds, fish, rodents), by repelling or attracting, including those that are used for human or veterinary hygiene either directly on the skin or indirectly in the environment of humans or animals.
PT20	Control of other vertebrates	Used for the control of vertebrates other than those already covered by the other product types of this main group, by means other than repulsion or attraction.
Group 4: Other biocidal products		
PT21	Antifouling products	Used to control the growth and settlement of fouling organisms (microbes and higher forms of plant or animal species) on vessels, aquaculture equipment or other structures used in water.
PT22	Embalming and taxidermist fluids	Used for the disinfection and preservation of human or animal corpses, or parts thereof.

Table and contents from ECHA website

Products Likely To Require An Update Or Reformulation To Comply

Currently, at the time of writing (Sept 2018), 36 out of around 800 active substances submitted have not been approved, and this number is likely to rise as substances currently under review (486 out of the 800) will either be fully approved, not approved, or unsupported by the manufacturers or importers, to name only a few possible reasons.

Products 'Under Review' may still be used and are considered BPR-compliant, though their status will eventually change to approved or not approved. So if you're using a substance which is 'Under Review' you should keep yourself up to date in regards to it's status.

By now your supplier should have ceased sales on any biocidal product that is not BPR compliant, however if you source chemicals from non-EU countries you may need to be extra cautious.

Commonly used biocides which have not been approved:

- **Triclosan** - Used in the healthcare industry in the US as a hand disinfectant. Healthcare authorities have recently begun phasing out triclosan for an alternative, safer, disinfectant
- **Glutaraldehyde** - An antimicrobial commonly used in engineering and sterilisation has not been approved for human hygiene uses, so in cases where it is likely to come into contact with humans, an alternative now needs to be sourced
- **PHMB** - A preservative and antimicrobial has not been approved for the purpose of in-can preservation and human hygiene, a BPR compliant alternative must now be sourced.

f Your Biocide Is Not On The Approved/Under Review List

You may still have a supply of now non-compliant product on-sale or in your warehouse, so you need to make a decision about what you will do with non-compliant stock. For example, there may be the possibility to sell your left over stock in a non-EU country, but you would need to ensure there could be no re-sale of the product into the EU and always check local regulations first.

To continue to sell your treated product in Europe you will need to reformulate with an approved biocide for your claimed biocidal effect, eg: Approved supplier and product listed under the correct PT.

If Your Biocide Is On The Approved/Under Review List But In The Wrong PT Category

For example, if you use a product listed under PT1 (human hygiene) but are claiming it's an appropriate biocide for veterinary hygiene (PT3) then you have two options available to you:

- Cease the claim that it is an effective biocide for veterinary hygiene and label it correctly as PT1 on your branding materials
- Reformulate with an approved PT3 biocide and label it correctly with the new biocides' information

If You Claim A Biocidal Effect Without Using A Biocide

Companies that claim a biocidal result from a non-biocidal product also need to make changes. For example, some products claim that using herbal oils can prevent dust mites on fabrics, however this is untrue, misleading and definitely not compliant with the BPR. In this case these are the options available to you:

- Update your treated product to use a biocide approved and listed under the correct PT and label it correctly
- Cease the marketing claim that your untreated product has a biocidal effect

If You Claim Your Product Has Natural Biocidal Action Without Using A Biocide

If you claim your product has a biocidal effect without using a biocide, ie: some property of the structure prevents a microbe, you are claiming your product achieves a biocidal effect without the use of any biocide, chemical or substance.

In this case the BPR does not apply to your product as it is not a treated article, however, you are still responsible for your marketing claims so you should:

- Be able to back up your claims with independent testing and make results available to your customers at their request
- Ideally, seek certification, such as Allergy UK to backup your claims.

If your product contains any of the chemicals mentioned on this page or you think your current biocide is not BPR compliant, contact Addi-Tec for regulatory and re-formulation advice as soon as possible.

Products To Help With Compliance

While there are many biocides available which are BPR approved, we've picked out one in particular which we feel is suitable for a wide variety of treated products. It's available in many forms, so can be included in a variety of ways to your product, and it's highly effective against a large variety of microbes.

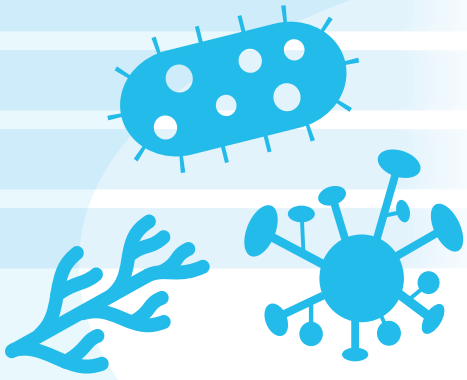
Sanitized®
BPR PT9 Compliant

Sanitized® is a PT9 BPR compliant biocide from a BPR approved supplier based in Switzerland.

PT9 substances act as a preservative for the following materials by antagonising the settlement of microorganisms on the surface.			
Fibre	Leather	Rubber	Polymers

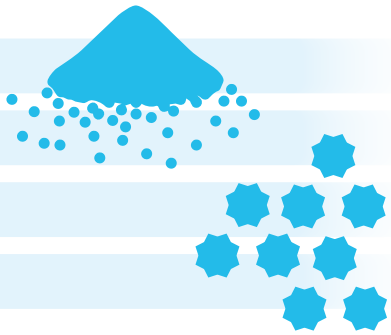
This means Sanitized® is suitable for a wide range of products to prevent:

- Bacteria
- Fungi
- Mould
- Mildew
- Biofilm
- Algae
- Pink stain



Sanitized® can be added to virtually any product, it's available in a variety of formats and requires a relatively low inclusion level of product to be added during the manufacturing process for good efficacy.

- Powder
- Masterbatch
- Liquid
- Paste



Sanitized® is a trusted global brand, and they offer more than just an amazing product.

- 80 years' expertise
- The best available technology
- Marketing support and tools; including BPR-compliant labelling and additional information
- Technical and regulatory advice
- Antimicrobial testing and lab services
- A recognised and trusted brand to partner with

Penalties For Non Compliance

Member States across the EU are responsible for monitoring biocidal products, treated products and the marketing claims made regarding biocides and treated products. Here is a brief overview of the organisations responsible in Europe:

UK:	Local Trading Standards Offices and the **Health & Safety Executive (HSE)**
France:	**Ministère de la Transition écologique et solidaire**
Germany:	**Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA)**
Spain:	Local Autonomous Communities Authorities and the **Ministerio de Sanidad, Consumo y Bienestar Social**
Sweden:	**Kemikalieinspektionen**

A full list of the regulatory authorities per member state can be found on this link.

Once every 5 years (from Sept 2015), these Member States are to report back to the EU on the use of biocides with regards to the BPR. And in many Member States, more resources are being put towards BPR enforcement in order to facilitate this report due in less than 2 years' time.

The BPR states that penalties for non-compliance with the BPR must be, **"must be effective, proportionate and dissuasive"**, and these penalties are also to be set and enforced by Member States.

In the UK the duty of enforcement and penalties falls between local Trading Standards Offices and HSE, depending the particular situation.

If the incident involves...	It should be reported to...
Advertisement or retail sale of Biocides	Your local trading standards office – which can be found on the Trading Standards Central website
All issues arising from the use of Biocidal products	HSE or your Local Authority. You can find out who is the appropriate enforcing authority from the HSE website

The HSE's compliance strategy is taking two broad approaches:

1. Education, help and promotion. The HSE recognises the need for additional information on the BPR for manufacturers and brands.
2. Proactive and reactive interventions, backed up by formal enforcement where necessary.

Enforcement tools include:

- Formal written advice
- Improvement notice
- Prohibition notice
- Prosecution

And penalties include:

- Summary Conviction
    - Unlimited fine and/or
    - Up to three months imprisonment
- Conviction on Indictment
    - Unlimited fine and/or
    - Up to two years imprisonment

As with all enforcements, the HSE are looking for compliance, not for convictions. So things like attitude to compliance, confession vs complaint, and previous interactions with enforcement bodies can work for or against your case.

Looking for help? Here's a link to the **BPR Helpdesks** for each EU nation.

Accountability & Legal Obligations

Briefly, the biocidal chemical suppliers and manufacturers in the EU are responsible for ensuring the biocides they sell to manufacturers are BPR compliant.

Whoever places the treated product on the market, ie: is selling it, is responsible for ensuring the product is BPR compliant. So care should be taken to investigate each step of the manufacturing process, especially if the product is made from component parts which are manufactured in many countries.

Here's an example from the **Treated Article Q&A Document:**

Q: Does the concept of treated articles cover only treatments made on the finished article, or also treatments made on components further back in the supply chain? If so, how far back in the supply chain have possible treatments to be identified?

For example, a table is manufactured outside the EU from composite wood, and the wood is bound with glue containing an in-can preservative (also manufactured outside the EU) – does the preservative have to be approved if the table is then placed on the EU market? Or, electrical components within a television were treated with a biocidal product to give them protection against the growth of fungi (and no other part of the TV was treated). Does the active substance in the fungicide have to be approved in the EU?

A. In the case of "complex" articles made up of different components and/or materials, it is unlikely that any treatment or incorporation of a biocidal product concerns uniformly all components/materials. Nevertheless, one or several individual components/materials of a complex article may have been treated with or incorporate a biocidal product, and the biocidal property or function conferred to these components/materials may still be beneficial for the finished good as such (e.g. by increasing overall durability of the complex article). Such complex articles are to be regarded as treated articles.

Consequently, in relation to the examples given in the question, the residual presence of an in-can preservative in the glue used to make composite wood would not lead to a classification as a treated article, as this preservative was used to preserve the glue during storage, but not after its use to make the composite wood and the finished table. On the other hand, in the second example it appears that the protection against fungi is intended to be effective in the finished television set, which then would have to be considered a treated article.

Here are some further examples of responsible entities:

Company	Responsibilities
Company 'A' in the EU makes and sells a preservative mixture for use in plastics manufacturing in the EU.	Must be BPR compliant. Company and product should be approved, product must also be approved for intended usage, ie: correct PT. They must also have available further information for any manufacturers readily available to assist them with compliance.
Company 'B' in the EU makes a polymer-based fabric and uses Company 'A's preservative to prevent mould and bacterial growth on the fabric to sell to product manufacturers in the EU.	Must be BPR compliant. The company must ensure they are sourcing the biocide from an approved company, that the biocide is also approved and that it's approved for the specific usage (PT) that they intend to use it for. They must also correctly label their fabric product according to article 58.
Company 'C' manufactures tents in the EU and uses Company 'B's fabric for the outer material. They sell their anti mould and antibacterial tents wholesale to B2C businesses.	Must be BPR compliant. The company must ensure they source their fabric from a manufacturer who is using compliant biocides. Company 'B' should provide this information. They must also correctly label their tent product according to article 58 and have further information available on request.
Company 'D' sells tent products in the EU, and Company 'C' is their main supplier. They market the product as anti mould and antibacterial. They sell to consumers and occasionally to businesses.	Must be BPR compliant. The company must ensure they source their tents from a manufacturer who is using BPR compliant materials and biocide suppliers. Company 'C' should provide this information. They must also correctly label their tent product if they re-brand the finished treated article according to article 58 and have further information available on request.
Company 'E' is a tent rental business in the EU, they buy tents from Company 'D' and rent them to holiday-makers on-site.	Must be BPR compliant, Company 'E' is still selling a treated article by renting the tents. They are responsible for ensuring their product is BPR compliant, they should receive all the necessary information from Company 'D' and will need to make special provisions to communicate the biocidal properties of their product as labelling may be discrete on such a product. They should also keep further details about the biocides used and BPR available for their customers on request.
Consumer 'F'	Not responsible for BPR compliance, though should be aware of BPR in order to buy a compliant product.

Working With Addi-Tec

Addi-Tec are a leading chemical distributor, focussing on the additive chemical market, based in Manchester, UK.

Addi-Tec presents a sophisticated range of performance chemicals to the Plastics, PVC, Paints, Coatings, Geo Textiles and Formulator Industries.

In addition to utilising the expertise of leading producers of performance chemicals, Addi-Tec does access the group technical/laboratory facilities, now located in Urmston, Manchester. The company approach is to work closely with processors to ensure we meet ever more stringent technical and regulatory demands at reasonable cost.

Applications:

- Paints and Coatings
- PVC Film and Sheet
- Moulded Articles
- Footwear
- Apparel
- Coated Fabrics
- PVC Profiles
- Automotive
- Wall Coverings

Services:

Formulation Development

Sourcing & Sample Provision

Micro Testing

Performance Testing

Regulatory Advice

The Addi-Tec Group:

Addi-Tec HARKE GROUP

CORE ADDITIVE TECHNOLOGIES

Chemlink Specialities HARKE GROUP

Solupak

J1 TECHNOLOGIES

Case Study

Earlier this year, Addi-Tec teamed up with a few like minded businesses to help bed and mattress manufacturers in the UK tackle the BPR.

In the UK we're lucky to have some brilliant bed manufacturers and designers. However when Addi-Tec approached these leading manufacturers, very few manufacturers were even aware of BPR.

Most bed and mattress manufacturers, along with many other sectors of the furnishing industry, are not BPR compliant. There are no labels and some of the chemicals being used as biocides to generate the products' USPs are not BPR-approved, yet the marketing claims are clear and present. And while marketing the mattresses as 'mould resistant', 'antibacterial' and 'anti dustmite' (to name only a few), the products are not-compliant and will require some redevelopment and remarketing to become compliant.

That's why the Addi-Tec team joined forces with:

- D&A Bed Consultants LTD, a bed and mattress design company who provide mattress ticking and fabrics to the industry
- SANITIZED AG, the leading supplier of BPR PT9 compliant antimicrobials - Sanitized® worldwide registered trademark to label the hygiene function and material protection on the article
- Staingard, who supply a product to prevent fabric staining

This team is now able to offer treated fabrics and finished mattresses to the bed industry which are BPR compliant, stain-resistant and antimicrobial, and of top of that they can offer the required labelling and marketing advice to stay BPR compliant.

The resulting treated fabrics that the team have developed have produced brilliant test results, provided by independent laboratories. They are now able to prove that the product is effective against e-coli, MRSA, and aspergillia niger (black mould).

In addition, Allergy UK have approved the Sanitized® treated fabric, thanks to an independent test study on the reduction of dust mites to levels that are insignificant in terms of allergies. So any brands looking to promote their beds and mattresses as hypoallergenic can claim hypoallergenic under BPR and also apply for the Allergy UK seal of approval to back it up using this fabric.

Dust Mite Study Results

Sample	Replicate	Mites Alive	% Reduction
Untreated Control - 100% Cotton	1	853	
	2	837	
	3	889	
	4	815	
	mean	848.5	n/a
Sample 1 - 100% Cotton, 0.5% Sanitized®	1	0	
	2	0	
	3	0	
	4	0	
	mean	0	100%
Sample 2 - 100% Stretch Cotton, 0.5% Sanitized®	1	0	
	2	19	
	3	37	
	4	5	
	mean	15.25	98.2%

Sample	Test Point	Activity	% Reduction	Evaluation
Egyptian Cotton Mattress Ticking - 100% Cotton, 0.5% Sanitized®	Staphylococcus aureus (MRSA) ATCC 33592	>5.30	>99.99	Good Effect
	Staphylococcus aureus ATCC 6538	>5.40	>99.99	Good Effect
Stretch Cotton Mattress Ticking - 100% Cotton, 0.5% Sanitized®	Staphylococcus aureus (MRSA) ATCC 33592	>5.20	>99.99	Good Effect
	Staphylococcus aureus ATCC 6538	>5.40	>99.99	Good Effect

The team are now in discussions with several major bed manufacturers across the UK helping them to achieve compliance.

Contact Our Team

If you'd like to ensure your treated product is BPR complaint, we'd be happy to speak to you. Or if your looking to source a biocidal product for inclusion into your treated produce we're ready to assist you.

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26-30 Station Road
Urmston, Manchester M41 9JQ

Tel: 0161 629 2125
Fax: 0161 629 2128

Web: www.addi-tec.co.uk
Email: info@addi-tec.co.uk

Get directions

Helpful Resources

Consolidated BPR Document

ECHA Biocidal Active Substance List

List Of Active Substances & Suppliers (Article 95)

ERM - leading global provider of environmental, health, safety, risk, and social consulting services

Treated Articles Q&A Document

Other Useful Contacts

ERM
A leading global provider of environmental, health, safety, risk, and social consulting services.

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Notes

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