# Biocidal products regulation

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Figure 1. Mould growing on an agar plate.

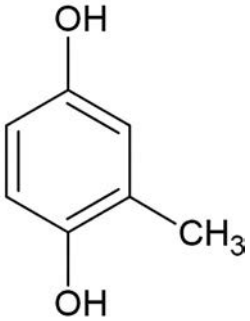


Figure 2. The chemical structure of p-chloro-m-cresol (PCMC also known as CMK).

## What is the BPR?

While REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) is a regulation of the European Union that applies to all chemical substances, there is an additional regulation focusing on biocides only: the BPR. The Biocidal Products Regulation (EU) No 528/2012 (BPR) is a successor of the Biocidal Products Directive (BPD) and came into force in 2012. It is a legally binding regulation to all Member States of the European Union and cannot be interpreted or changed for national legislation.

Both regulations – REACH and BPR – aim to improve the protection of human health and the environment from the risks that can be posed by chemicals, with the same mantra: when using a substance, the safety to human and the environment must be ensured. If the risk of a substance cannot be managed, authorities will restrict or even ban the use of it. The reason for having a standalone regulation for biocides is that biocides are known to be chemicals that need tighter control and more detailed guidance and permissions for their use, which is understandable when looking at what a biocide is.

Biocides are divided into four main groups: disinfectants, preservatives (leather biocides are found here), pest control and other products (including embalming and anti-fouling products).

Within the four groups, the BPR covers different types of products that are largely defined by the applications of the products and the industries that they are found. For the leather industry, the product type 9 (PT 9) covers the biocides used in preservation of leather intermediates. PT9 covers all biocides used in fibre, rubber, leather and polymers and any biocide intended for use in these applications must be evaluated and approved under the BPR.

A biocide is a substance (or mixture) which has an active ingredient that can prevent the action from a harmful organism or can harm that organism.

## Which products are fully approved?

Under the BPR, first the active substances are assessed to ensure that they, in general, are effective and can be safely used. Once an active substance has been approved under the BPR, the specific biocidal products must be assessed for their efficacy and to ensure that neither the active substance(s) or any of the co-formulants in them pose any unacceptable risk to operators or to downstream users processing, wearing or using the treated leather or articles made thereof.

The aim of biocidal regulations is to maximise the safety that leather manufacturers and leather retailers can have and to ensure that consumers of the leather goods are protected from harmful chemicals. The leather industry has a long history of rooting out problem chemicals and replacing them with safer chemicals.

For leather, there are the five main active substances listed in Table 1. The table shows that the only active ingredient that has already been approved for PT9 under BPR is PCMC (p-chloro-m-cresol). The other four listed have been registered with BPR and are permitted for use in the EU because of that ongoing registration. The registration of an active ingredient is a long-lasting process – the dossiers for all actives have been submitted in 2008 whereas only PCMC has been completely assessed. Prioritisation depends on Member States and cannot be influenced by the applicants. Actives not registered are not permitted for use under BPR rules.

**Table 1. The five main substances registered in Product Type 9 showing the approval status as an active and the status of any product formulation they are included in**

| Substance | CAS Number | Active approval | Products already BPR authorised |
|---|---|---|---|
| p-chloro-m-cresol (PCMC) | 59-50-7 | Yes | No |
| Thiocyano-methylthiobenzothiazole (TCMTB) | 21564-17-0 | No | No |
| N-octyl-isothiazolinone (OIT) | 26530-20-1 | No | No |
| Biphenyl-2-ol (o-phenyl- phenol, OPP) | 90-43-7 | No | No |
| Iodo-propynyl-butyl-carbamate (IPBC) | 55406-53-6 | No | No |

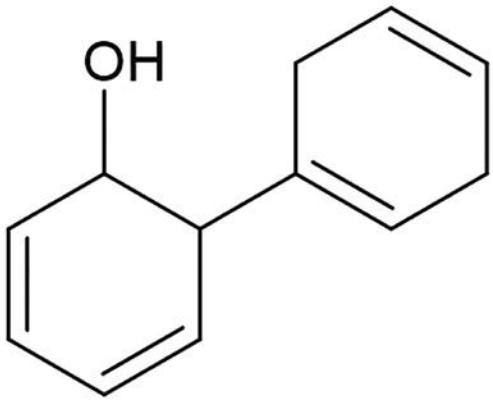


Figure 3. The chemical structure of biphenyl-2-ol (o-phenyl- phenol also known as OPP).

All actives listed in Table 1 except for PCMC are currently still undergoing risk assessment to understand if any exclusion criteria, as below, are met or whether there are any other considerations that could make their use under BPR difficult. The next stage, after the actives are registered and approved, is to have the product formulation (that they are used in) fully approved by BPR.

Actives (and the products they are used in) will not be approved if they meet any of the criteria listed below:

- Carcinogens, mutagens and reprotoxins (categories 1A or 1B) according to the CLP Regulation
- Endocrine disruptors
- Persistent, bioaccumulative and toxic (PBT) substances
- Very persistent and very bioaccumulative (vPvB) substances.

All active substances and the chemical companies supplying them are included in the list of active substances and suppliers, the so-called "Article 95" list, which can be found on the website of the European Chemicals Agency (ECHA). The website also has more information and guidelines for use of all active substances registered.

## Leather supply chain obligations

Tanneries and leather traders need to be aware that the sale and importation of intermediate and final materials, as well as leather articles, need to comply with BPR in terms of the use of biocides. That is, they should not be using a biocidal product that has not been appropriately registered under national requirements or, once this becomes possible, BPR authorised in the country of use.

The chemical companies supplying the active ingredients must be included in the Article 95 list (for PT9). Tanneries that are in the EU itself should be only using BPR-compliant products. Tanneries outside the EU must ensure that any used active substance is BPR-compliant if they are exporting leather into the EU.

In the United States, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) legislation is very similar to the EU BPR. Products for use and imported within leather products must comply with FIFRA. Like BPR, FIFRA requires registration and licensing of the use of biocides. Some other countries have regulations that control the use of biocides, and it is wise for tanneries and leather traders to be familiar with the legislation to use only biocides which are legally compliant.

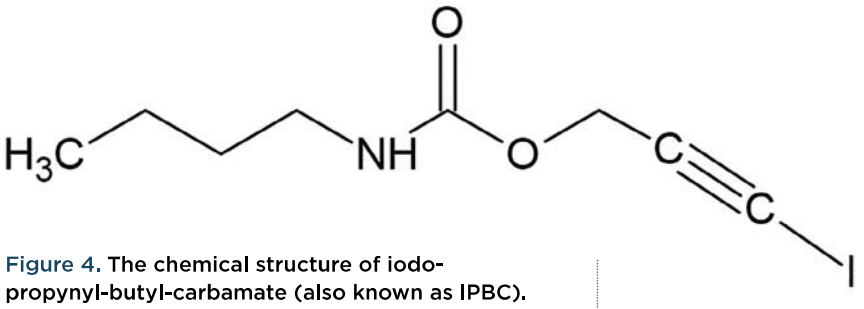


Figure 4. The chemical structure of iodo-propynyl-butyl-carbamate (also known as IPBC).

## The future work

It is important to remember why biocides, especially fungicides, are used in the production of leather. The material can be vulnerable to the growth of mould at many stages of its manufacture and use. Fungicides will be useful in leather intermediates when the water content of that leather gets to the level that fungi can begin to grow. Chromium-free and vegetable-tanned leathers often require a little more protection than wet-blue, especially when wet. Once microbial growth is visible to the naked eye, irreversible damage to the leather has already occurred and treatment at this stage can only prevent further degradation.

Eventually, only biocides which have been fully evaluated and approved will remain available. The current biocide offer is effective and will likely pass the safety requirements requested by ECHA. It's rather unlikely that new active substances may be added as the scientific data required is extensive, with high costs and a long-time frame.



## References

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.