

The Swedish Chemicals Agency is supervisory authority under the Government. We work in Sweden, the EU and internationally to develop legislation and other incentives to promote good health and improved environment. We monitor compliance of applicable rules on chemical products, pesticides and substances in articles and carry out inspections. We review and authorise pesticides before they can be used. Our environmental quality objective is A Non-toxic Environment.

June 2016

Articles treated with biocides

Does your company sell goods under the claim that they have a special function, such as sports jumpers marketed as being anti-odour, or chopping boards alleged to be antibacterial? Here you will find information on EU Regulations governing articles treated with biocides which you then need to know in order to make demands of your supplier or manufacturer.

An increasing number of articles are being treated with chemical substances and sold under the claim that they have special properties. Certain articles may have been treated with a special type of pesticide - a so-called biocidal product - at the time of manufacture or at a later stage.



Sports shoes can be treated with a biocidal product.

Examples of articles that may have been treated with biocides

- shoes
- refrigerators and freezers
- cushions
- kitchen utensils
- different types of handles
- shower hoses
- cleaning materials
- sportswear
- drinking water filters
- cleaning cloth-changing
- tables for babies
- construction materials
- vacuum clean bags
- baths
- exterior paints
- knives
- toothbrushes
- coolants
- food containers
- mattresses
- cutting fluids
- etc

What is an article treated with biocides?

A biocidal product may be a substance or a mixture intended to kill, or render harmless, harmful and irritating organisms such as bacteria, mould and insects. An antibacterial product, for example, renders bacteria harmless. An article treated with biocides may be intentionally treated with or contain one or more biocidal products to protect against the infestation of microorganisms or insects.

EU Regulations - why you need to know about these

The *EU Biocidal Products Regulation* which came into force in 2013 contains rules governing both biocidal products and articles treated with biocides.

Anyone importing articles treated with biocides into the EU or manufacturing the article within the EU is responsible for ensuring that the article is not harmful to human health or the environment, and is responsible for ensuring that the labelling is correct in accordance with the EU Biocidal Products Regulation.

Anyone selling the article must check that the requirements regarding labelling have been met. Do not sell a treated article that is either unlabelled or incorrect labelled. Be observant if you see claims such as "anti-bacterial" or "anti-odour"; these may mean that the product requires labelling.

The purpose of labelling is to inform the consumer that the article contains biologically active substances and to explain to the consumer how to use the article without damage to his or her health or the environment.

The label information also means that the consumer can make a more conscious choice. It is therefore also important that the label is visible at the time of purchase. It is also very important that you contact your supplier or manufacturer and receive assurance that they are aware of the rules which apply and that they have checked whether or not the active substances in the article are permitted within the EU.

Contact your supplier before you start selling articles treated with biocides

If you have not already received information about the content of the articles, contact your supplier or manufacturer and ask the following questions:

- Are the active substances which the article is treated with permitted in the EU? The substances must be approved for the use intended for your article. The list of approved substances is available from the European Chemicals Agency (ECHA). *Go to the list of biocidal active substances on the ECHA website.*

- Is the substance included in the EU Review Programme for the evaluation of active substances? The substance must be evaluated for the use intended for your article. *See Annex II to Regulation (EU) No 1062/2014.*
- If the substances are permitted, check that the requirements regarding labelling have been met. The labelling regulations are provided in Article 58 of the *EU Biocidal Products Regulation*.
- If the substance is not permitted, the supplier or manufacturer of your article must apply for approval of the active substance and submit the documentation to ECHA.

Requirements regarding the labelling of articles treated with biocides

The manufacturer, importer or person releasing the article on the EU's internal market is responsible for ensuring that the article has the correct labelling in accordance with the requirements in the EU Biocidal Products Regulation when:

- the article contains a biocidal product and the manufacturer claims that the article has a biocidal effect, such as removing bad odour, or
- the conditions that apply for approval of the substance or substances require this, especially with regard to the fact that the substance or substances may come into contact with humabeings or be released into the environment.

A summary of the regulations on the labelling of articles treated with biocides

The regulations on the proper labelling of an article claimed to have biocidal properties is included in the Biocidal Products Regulation. Below is a summary of the regulations, but note that it is only the wording in the Regulation that is legally binding. Always check the legal wording itself in the Biocidal Products Regulation (Article 58).

The labelling shall be clear, in official national language, easy to read and still be legible during the entire period of use of the article, and shall contain the following information:

- the fact that the article contains a biocidal product
- the name of the active substance that is included
- the purpose of the treatment, and how the active substance aids the function of the article, such as the adding of a substance to remove bad odour
- relevant instructions for use and any essential precautionary measures, such as the user of the article having to take certain action to protect people or the environment
- if nanomaterial is included in the biocidal product, state its name. Nano is a designation for extremely small particles.



Examples of labelling on a shirt treated with a silver salt in order to avoid bad smell.

The marking regulations are provided in Article 58 of the *EU Biocidal Products Regulation*.

Note that there may be further labelling regulations for certain treated articles which will apply, regardless of whether or not the conditions regarding labelling as given above have been fulfilled. An article treated with biocides shall be labelled with all the relevant instructions for use, including any precautionary measures which must be taken, if this is necessary for

protecting human beings, animals and the environment. Special rules may also be included in the decision for approving the biocidal product with which the article has been treated. One example is articles treated with permethrin against insects.

If the treated article is in itself a substance or a mixture, the labelling regulations for chemical products will also apply.

Distinguish between a biocidal product and an article treated with biocides

There are different rules in the EU Biocidal Products Regulation for a biocidal product and for an article treated with biocides

In order to determine whether something is a biocidal product or article treated with biocides, you must be clear about whether the article has primarily a biocidal function or whether the biocidal function is one of several functions.

- If the primary purpose of your article is to protect against, render harmless or deter harmful or irritating organisms (such as insects or bacteria),

your article is then a biocidal product. A biocidal product must be authorised before it may be sold or used.

- A T-shirt which is treated with a biocidal product but whose main purpose is to keep the wearer warm is, in contrast, an article treated with biocides. It need not be authorised before being sold, but the person selling an article treated with biocides must provide information about which biocidal product it contains and must make sure that the article has the correct labelling.

The risks associated with articles treated with biocides

Biocidal products usually act as a poison to one or more target organisms. An article treated with biocides is meant to be protected against infestation or it helps protect the user from infestation. However, several of these biocides also act as a poison to other organisms, including human beings. It is therefore important that articles treated with biocides are not used unnecessarily or in an incorrect way.

If biocides are used more and more often and end up in increasing quantities in waste or water, this could create problems for the environment and, indirectly so, for human beings.

The overuse of treated articles may encourage bacteria to become resistant to products that are essential to hygiene and health in other contexts. For example, there are suspicions that certain biocides may render antibiotics inactive, which would make it harder to cure infectious illnesses.

Informing consumers

Even if an article treated with biocides does not always require labelling, the person selling the article still has an obligation to inform the consumer about which biocidal treatment the article has undergone should the consumer request this. This information should be supplied within 45 days.

Prove the benefit of the biocidal treatment

According to the EU Biocidal Products Regulation and marketing legislation, any claims relating to biocidal properties may not be stated unless the efficacy of the product has been proven and demonstrated. A manufacturer who releases a treated article on the market and claims that it has certain biocidal properties must be able to prove such claims. Unless the product is of benefit and effective, it is unnecessary to take the risks to health and the environment which are often associated with biocides.

The Nordic countries have developed the guidance document "Efficacy Assessment of Treated Articles", which shows how business owners can test and demonstrate the efficacy of their treated articles.

The guidance document is available on the Council of Nordic Ministers' website

Examples of active substances which can be found in articles treated with biocides

Substance	Properties
Boric acid	This has been shown in animal experiments to damage the testicles, reduce fertility and damage the foetus in the case of several animal species.
Iodopropynyl butylcarbamate (IPBC)	Toxic to marine plants and animals.
Copper	Very toxic to marine plants and animals. Copper pollutants are bioaccumulative; that is to say, the substances are stored in tissue.
Permethrin	Very toxic to marine plants and animals. For treatment against insects.
Propiconazole	Toxic to marine plants and animals.
Silver	Very toxic to marine plants and animals. Suspected of giving rise to antibiotic resistance; that is to say, the risk of infections and illnesses no longer being successfully treated with antibiotics.
Tebuconazole	Toxic to marine plants and animals; has damaged the foetus in animal experiments.
Zinc	Very toxic to marine plants and animals. Can accumulate in marine plants and animals. Often appears in the form of zinc pyrithione, which is a strong eye irritant.