HeiQ Viroblock and HeiQ Pure
Labelling Requirements and Permitted Claims on Treated Articles

Background

HeiQ manufactures and markets three key antimicrobial (antibacterial and/or antiviral) and odor control textile finishing globally: HeiQ Pure TAG, HeiQ Pure SPQR and HeiQ Viroblock NPJ03. These technologies are based on the same active substance, namely, reaction mass of titanium dioxide and silver chloride[1]. Articles treated with this active substance are fully compliant to be marketed into countries as indicated in the table below:

Treated Articles with:	US FIFRA / EPA	EU BPR	JP MITI	KR K-BPR
HeiQ Viroblock NPJ03	compliant	compliant	compliant	compliant
HeiQ Pure TAG	compliant	compliant	compliant	compliant
HeiQ Pure SPQR	compliant	compliant	compliant	compliant

The requirements for labelling of articles treated with an antimicrobial, biocidal, viricidal product can vary from country to country. For brands adopting the aforementioned HeiQ textile technologies, this document intends to convey our understanding of the relevant regulations and give an overview of the labelling requirements in countries where the marketing of such treated articles is regulated. Countries not mentioned below are known to HeiQ as not having specific requirements. It is the brand's responsibility to ensure labels and claims of their products are fully compliant with local laws of markets where the products are sold into. Please check your claims ahead of going to market with HeiQ and do not hesitate to contact us in case of doubt.

Labelling requirements of different countries

European Union and countries in Europe that adopt the EU BPR

Definition of biocidal products: Any treated article that has a primary biocidal function shall be considered a biocidal product and will therefore fall under the obligations to register as a biocidal product in accordance with the Regulation. Textiles and apparel that have been treated with an antimicrobial product to preserve freshness or to prevent spoilage or contamination by Germs and Microbes are not considered biocidal products.

In the European Union treated articles are regulated under the biocidal products regulation (BPR). For articles manufactured in or imported into the EU, the active substance(s) must have been approved or be currently in the ongoing review process under the BPR. In order to comply with BPR Art. 58.3 (a), (b), (c), (d), (e) such treated articles must bear a label with the following information:

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

- "This Product is treated with biocidal silver to prevent contamination by Germs and Microbes"

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

- "Germ and Microbe resistant Product" (No primary biocidal function and therefore a 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;

- (e.g. "contains reaction mass of titanium dioxide and silver chloride")

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

- (irrelevant)

(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.

- e.g. "Wash after use at 40°C"

Label Recommendation

HeiQ supports the following, fully BPR compliant labelling claims for articles treated with HeiQ Pure TAG, HeiQ Pure SPQR or HeiQ Viroblock NPJ03

[a]Contains a biocide [b]to protect the textile from microbes and germs. [c]Active ingredient: Reaction mass of titanium dioxide and silver chloride. [e]May be disposed of in household waste.

[a]Contains a biocidal product [b]to preserve freshness. [c]Active ingredient: Reaction mass of titanium dioxide and silver chloride. [e]May be disposed of in household waste.

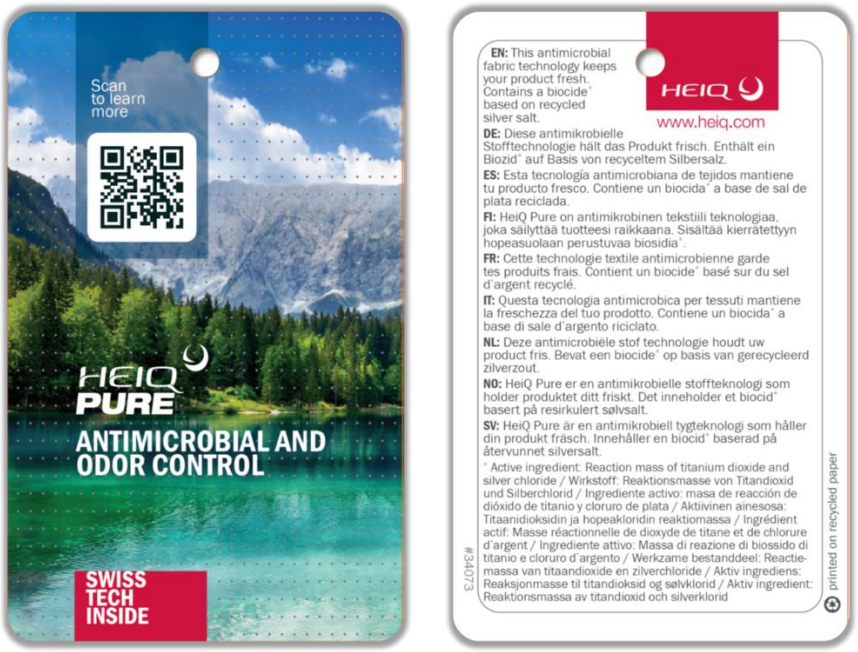
Label Positioning

The labelling text should be positioned on the article or packaging. 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.

Please refer to the regulation online for more details: https://echa.europa.eu/regulations/biocidal-products-regulation/understanding-bpr

Strictly speaking, any claims stating the textiles' antimicrobial function outside of its intended purpose of protecting the textile from microbes and germs or odor control is not advised.

HeiQ provides the following hangtags containing the BPR compliant claims in the official languages covering most EU member states. Please apply for the hangtag(s) at www.heiq.com/hangtags



USA

The active substances are registered under the Federal Insect Fungicide and Rodenticide Act (FIFRA) in the US, which enables the marketing of articles treated therewith in the US.
Treated articles for sale in the US may be placed on the market without biocidal labelling requirements provided the active substance(s) has been registered and approved for that specific use, and any claims made on said articles are neither explicit or implied health claims. This condition is referred to as the Treated article exemption, under FIFRA.
https://www.epa.gov/sites/production/files/2014-04/documents/pr2000-1.pdf.
Articles with an active health care claim must themselves be registered as biocidal products and/or medical devices. HeiQ is currently pursuing authorization for antiviral claims for HeiQ Viroblock with the US EPA.

Until further update is communicated, HeiQ supports the following maximal label claim in the US for labelling on a treated article **Product**:

"Antimicrobial properties built in to protect the Product" always to be written **together** with *"Product does not protect users or others against pathogens. Always clean this product thoroughly after each use."*

Both sentences must be printed in typing of the same size, style, and colour, and should be given equal prominence. Moreover, such references should not be given any greater prominence than any other described product feature. And, importantly, the name of the product itself or any of its components must **not** imply a healthcare claim (e.g. Germkiller). Statements related to the textiles' antimicrobial function against viruses, in particular, is considered as active health care claim.

Canada

Biocidal products are regulated as pesticides by the Pest Management Regulatory Agency. The operating legislation is the Pest Control Products Act (PCPA). For treated articles to be manufactured or imported, the articles must only be treated with active substances for which there is a valid registration for such use.

HeiQ Fresh FFL (non-antimicrobial, not listed above) is the only product recommended for articles being sold into Canada to preserve the freshness of the product.

China

HeiQ Viroblock with virus resistant claims is permitted for use in China.

China Disinfection Product Regulations (also called disinfectant regulations or sterilizing product regulations, adopting parts of PT 1 and all PT 2 of EU BPR) were reformed by the end of 2014. This regulation includes two parts:

- Information on label and specification of disinfection product must be true;
- Product cannot claim or impact it can treat any diseases or exaggerate its efficacy.

New disinfection products must obtain a “hygiene license” prior to being commercialized in China. This Regulation specifies material requirement and administrative license procedure in detail.

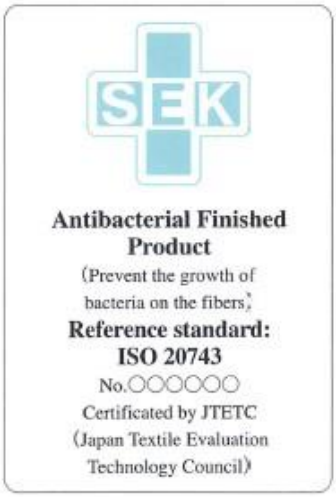
The Regulation requires that a China based entity must make the necessary submissions.

Efficacy testing is the most significant test for all disinfection products. A company can perform a simple efficacy testing before formal detection to roughly analyse if the product meets the Chinese Standard. If yes, the product can start formal testing for safety evaluation report. If no, the product cannot enter the China Market, the producer company should revise the formula or re-design the product as applicable.

Companies should be aware it is key consideration to take care with marketing and claims on their treated articles as this can make a distinction between a non-biocidal treated article and a new biocidal product.

Japan

In Japan, the biocidal product has to comply with MITI and must be approved by the Japan Textile Evaluation Technology Council (JTETC). Treated articles can then get the SEK approval and certification and apply their official label to be placed on the Japanese market.
http://www.sengikyo.or.jp/english/sek.php?eid=00003
The SEK label is applied as follows:



The antibacterial finishing appeals only for prevention of the growth of bacteria on fibres. The labelling is prohibited to represent, expressly or suggestively, “the use for the healing or prevention of human diseases as well as the effect on the construction or performance of the human body”. The labelling is also prohibited to represent, expressly or suggestively, “secondary control or sterilizing effect on bacteria”, “effect in combination with other performances” or other similar descriptions.
HeiQ supports the same claims as for the US. See US labeling.

Korea

The Consumer Chemical Products and Biocides Safety Act (K-BPR) can be broken into 2 parts: consumer chemical products and biocides. The consumer chemical product part is transferred from K-REACH while the biocide part is taken from EU biocidal products regulation (BPR). For consumer chemical products designated as products subject to safety confirmation, the Act requires that companies comply with relevant product safety and labelling standards and confirm compliance to authority by carrying out testing in designated labs (KEITI, etc.) once every 3 years. For biocidal products (both active substances and formulated products), the Act requires that companies apply for pre-market approval from the Ministry of Environment (MOE). In addition, the Act has set some rules for biocide-treated articles.

Main Requirements for Biocide-treated Articles

The Act requires that articles only be treated with biocidal products containing active substances that have been approved in Korea. Any person who purchases treated articles can be provided or ask suppliers for biocidal chemicals info. If manufacturer claims that a treated article has biocidal properties, the manufacturer must label the treated article with info on biocidal products used and potential risks.

Manufacturers and suppliers of treated articles.

- Only use approved biocidal products to treat articles
- Label treated articles with biocidal info if a biocidal claim is made.

HeiQ supports the identical language of claims as for the EU in KR. See EU labelling.

We aim to keep all of our customers updated with relevant information as the active authorisations proceed and to actively support you in compliance going forward. In the meantime, if you have further questions or concerns on labelling requirements please do not hesitate to contact us.

[1]Sourced from Article 95 listed supplier.

Director of Compliance and Quality

Mark McKay