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Clean Touch Medical Oy

Valuraudantie 5

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BPR Article 95(2) compliance for Clean Touch Medical Oy ViralSafe -product

Sweco Industry is assisting Clean Touch Medical Oy (CTM) in fulfilling the legal compliance under Biocidal Products Regulation (BPR, (EU) 528/2012) for ViralSafe -product marketed in the EU.

CTM Oy placing on the market the biocidal products for use in product-type 2, which contains the active substances [*Copper, EC 231-159-6 and Silver EC 231-131-3*[1]], declares that for the above named biocidal product a company listed as substance supplier pursuant to Article 95(1) of Regulation (EU) No 528/2012, is the substance supplier.

Based on the documentary review, CTM is part of the supply chain with the Article 95 listed substance supplier and therefore fulfills[2] the requirement of BPR Article 95(2) of market access.

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[1] As available from ECHA's list of active substances and suppliers available from https://echa.europa.eu/information-on-chemicals/active-substance-suppliers

[2] The product supplier remains in full responsibility on the legal requirements.

Frequently Asked Questions on Biocidal Products

The following paragraphs are presented to provide you with a brief but non-legal and non-technical overview of the regulatory environment of Biocidal Products, especially on the view of Active Substances Silver and Copper.

Which Regulation covers the Biocidal Products?

The Biocidal Products Regulation (BPR, Regulation (EU) 528/2012) concerns the placing on the market and use of biocidal products, which are used to protect humans, animals, materials or articles against harmful organisms like pests or bacteria, by the action of the active substances contained in the biocidal product.

What are Product Types?

In Annex V to the BPR the biocidal products are classified into 22 biocidal product-types (PTs).

Each product type describes the use conditions where it can be used.

PT2 products are disinfectants and algaecides not intended for direct application to humans or animals.

Where can I use Product Type 2 products?

Any of these uses:

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.

What is Article 95 list?

Article 95 creates an obligation on persons making available BPs on the market to make sure that either the “substance supplier” or “product supplier” is included in the list published by ECHA under Article 95 (for the PT to which the product belongs).

These existing active substances can be placed on the market when substance is directly or indirectly coming from an Article 95 list approved supplier.

Not all companies are required being included on the Article 95 list. It is sufficient that one company in the supply chain is listed.

This Article 95 procedure is therefore a transitional measure to allow market access for these biocidal products and it applies until the approval decision on the substance. After that, a Product Approval stage begins. This transitional period may take years.

Can you provide the Active Substance Application number?

Product supplier does not hold nor is required to hold the reference number for the Active Substance Application, as the applicant is the substance supplier, who is part of the Biocidal Copper Task Force and listed in Article 95 list.

Is it enough if either the manufacturer of the active substance or the manufacturer of the biocidal product is on the Article 95 list?

Either one is enough within a given supply chain, that is to say there must be a clear connection to the product made available on the market.

What is Active Substance and Biocidal Product and how are they regulated?

‘Active substance’ means a substance or a micro-organism that has an action on or against harmful organisms, for example Silver.

‘Biocidal Product’ is the final form of the product which contains the active substance.

Biocidal approvals are divided in two parts: Active Substance Approvals and Biocidal Product Approvals.

Biocidal Product approvals are requested only after the Active Substance has been evaluated and approved.

For Silver and Copper, the evaluation of Active Substance approval is ongoing, and during this evaluation period products can be placed on the market under Article 95 transitional measures.

Can we place a biocidal product on the market if it contains Copper and/or Silver as Active Substance?

Yes, as long as the Article 95 requirement of the supply chain is fulfilled.