



Silver Nitrate-containing biocides – is your infection control system legal?

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Silver Nitrate (CAS 7761-88-8) is considered to be a new active substance for many uses or Product Types (PTs) under the European Biocidal Products Regulation (BPR). It is **illegal** to market or use products containing Silver Nitrate as an active substance in a wide range of biocidal uses, including for hospital decontamination (PT2) using an automated airborne disinfection system.

UK Health and Safety Executive (HSE) statement:

“It would currently be illegal to make available and use a PT2 biocidal product, containing silver nitrate as the active substance, as silver nitrate has not yet been approved as a PT2 active substance and is being assessed as a new active substance.”

The Biocidal Products Regulation (BPR) came into force in September 2013. It has been adopted into national legislation of the European Union member states and, as such, forms the legal basis for the authorisation of biocidal products in member states such as the UK, Ireland, France, etc. Even in the event of a future repeal of EU legislation within the UK, all industry sources indicate that the BPR will remain in force in the UK as UK legislation.

Biocidal products contain active substances. These are the chemicals that the manufacturers of the product intend to have a biocidal action or effect. Under the BPR, active substances must be reviewed and authorised. Once they have been reviewed and approved, biocidal products that contain those actives must also go through an approval process so that they can be placed or sold on the market.

The process of authorising the large number of potential chemical active substances on the market is a lengthy one and so as to ensure chemistries could be available for use in biocidal products during the period of authorisation, the European Commission conducted a review of the biocidal substances that were being used on the European market. Any substance that was on the market on 14th May 2000 as an active substance of a biocidal product was included in a list of substances that were termed "existing active substances". Any active substance that was placed onto the market in a biocidal product after the 14th May 2000 is known as a "new active substance".

Silver Nitrate was on the market on the 14th May 2000, but only in a biocidal product that was used for human hygiene (i.e. applied to human beings) or in a group that is formally called Product Type 1 (PT1). It is presented in the list of existing active substances in European regulation 1062/2014 related to the systematic examination of all existing active substances. The key point is that Silver Nitrate is only an existing active substance in PT1. Hospital decontamination comes under Product type 2 (PT2) or public area disinfection and Silver Nitrate is not an existing active substance in this PT, it is a new active substance.

The BPR states that only existing active substances may be permitted to be made available on the market or used before the active substance has been approved.

"BPs that contain only existing active substances that are included in the Review Programme may be permitted to be made available on the market or used before the approval date of the active substance, subject to national laws of the relevant Member State (MS)."

As Silver Nitrate is a new active substance under PT2 (hospital decontamination) it cannot be marketed or used until it has been approved by the European Commission. No approval decision has been made by the European Commission on the use of Silver Nitrate as an active substance at this time.

Biocidal products containing new active substances may be made available in individual EU member states, if that state conducts a review of the biocidal product and decides to provide it with a provisional authorisation under Article 55(2) of the BPR. The UK, Belgium and Spain have confirmed that no provisional authorisation has been granted for the use of Silver Nitrate in PT2 (public area disinfection) applications and as such, any biocidal product containing Silver Nitrate as an active substance marketed or used for a PT2 use is **illegal**.

UK Health and Safety Executive (HSE) statement:

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Other European member states are currently in the process of confirming whether or not provisional authorisations for PT2 biocidal products containing Silver Nitrate are in existence for their territories.

Hospital infection control teams, facility managers and purchasing teams are urged to review the biocidal products they use, particularly those associated with automated airborne disinfection or HPV systems and confirm that they do not contain Silver Nitrate. To reiterate, as per the UK HSE statement, it is **illegal** to market or use a biocidal product containing Silver Nitrate as an active substance for a PT2 use.

Based on their available Safety Data Sheets and sales information, the following systems should be reviewed:

Hygiene Solutions Deprox / Deproxin solution

Oxypharm Nocolyse

Oxypharm Nocolyse One Shot

Sanosil Halomist

Sentinel hydrogen peroxide systems using Sanosil SO10

Any hydrogen peroxide-based decontamination system that claims to use "silver", "colloidal silver", "silver ions", "Ag", "ionic silver" or "silver salts".

1. Extracted from the European Chemical Agencies Practical Guide on Biocidal Products Regulation Approval of Active Substance.

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