
# BactiBlock® EHS Questions

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# BactiBlock® EHS Questions

This document contains discussion points regarding BactiBlock and the use of silver, silver nanoparticles and bacterial resistance in general to assist general EHS due diligence process. In terms of potential risks, the only element in the BactiBlock formulations is silver, so the EHS discussion would be about silver in general.

## Bacterial Resistance and Silver

One of the first things to discuss when considering an antimicrobial surface solution is to determine which type of solution to use to avoid bacterial resistance.

With increasing drug-resistance and growing concern regarding the over-prescribing of antibiotics, there has been a resurgent interest in the use of antimicrobial silver. Unlike antibiotics, silver appears to be immune to resistance (Chopra I et al., 2007). The reason is due in large part to silver's multi-pronged approach to killing infection-causing bacteria.

Antibiotics are typically microorganism and site specific—each one effective against a particular type of bacteria and single-minded in its method of attack. Penicillin for instance, kills bacteria by interfering with cell wall synthesis; sulfonamides act by disrupting folic acid synthesis. As the bacterium multiplies, mutations naturally occur. Eventually a cell may be produced that is not affected by the antibiotic's single form of attack. These mutated cells then multiply until a completely new resistant strain begins to spread. The more antibiotics are used, the greater the chance that resistant strains develop and proliferate.

Silver, on the other hand, is a broad-spectrum, multi-site antimicrobial. Ionic Silver not only disrupts folic acid synthesis, but it also disrupts protein synthesis, inhibits DNA synthesis, disrupts electron transport and interferes with cell wall synthesis. This multi-pronged attack makes almost impossible for the bacteria to mutate in a way that would lead to resistance.

*(Percival S.L., 2005).*

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Figure I. Single-target mode of action of antibiotics

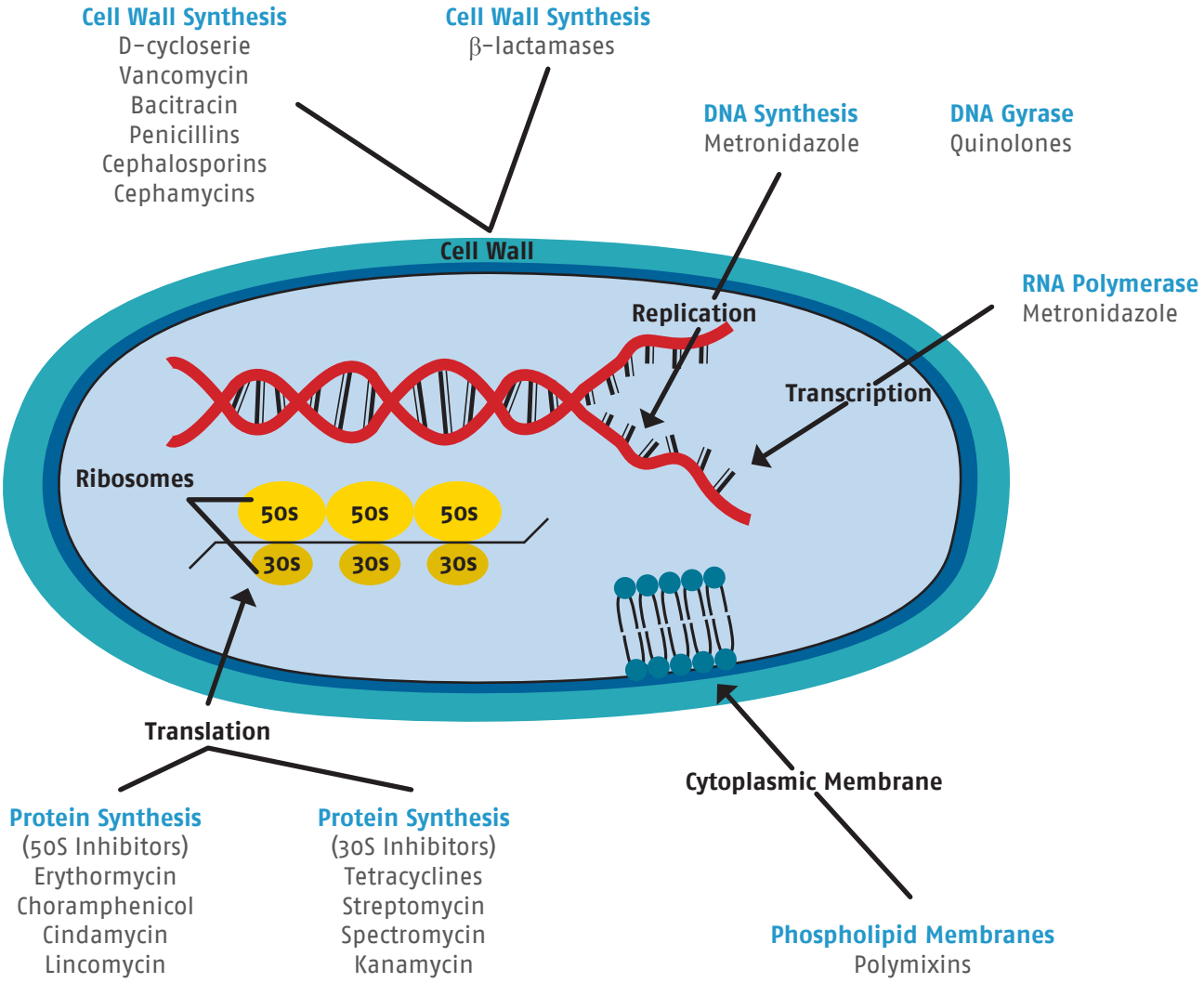

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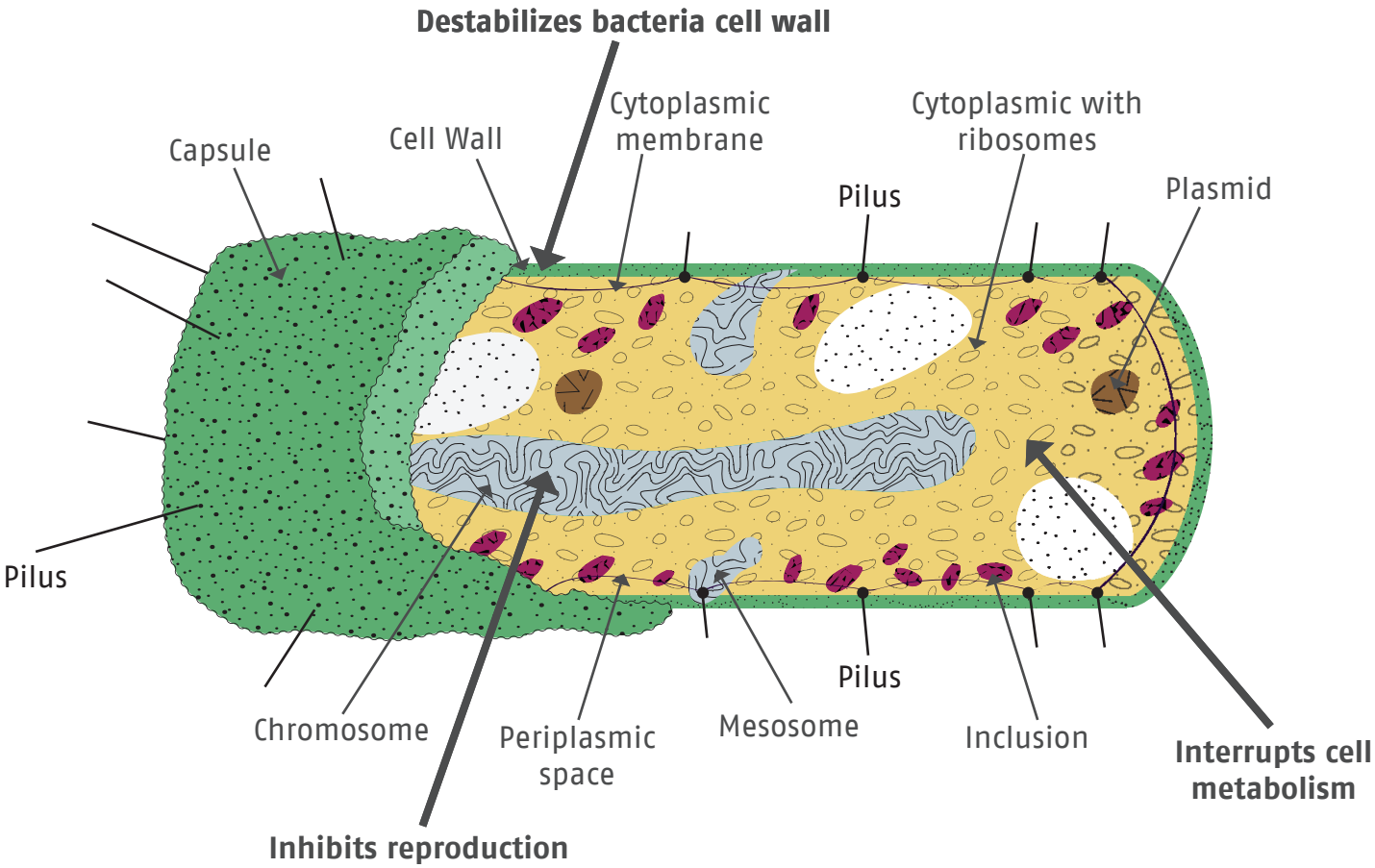
Figure II. Multi-target mode of action of silver



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## Why use biocides (considering the above problem with resistance)?

Hospital acquired infections (HAI's) are becoming increasingly common worldwide and occur in more than 2 million hospitalizations in the United States each year. Due to an increase in invasive procedures and a growing resistance to antibiotics, HAI's have increased by 36% in the last 20 years and are consuming more health care dollars each year. The burdens these infections place on our health care system can be divided into the cost of human lives, quality cost, and financial cost. The human cost is over 99,000 deaths per year in the United States which represents a 5% death rate for HAI's.

Quality costs include increased ICU stays by 8 days, and increased average hospital stay between 7.4 and 9.4 days. Total dollar costs added to the health care system are between $4.5 and $5.7 billion annually with the average mean cost per infection of $13,973 and an increased cost to patients (who survived) approximately $40,000.6 Specifically, *methicillin-resistant Staphylococcus aureus* (MRSA) has become endemic, even epidemic in many US hospitals and added 2.7 million extra days in the hospital with an average cost of $35,367 (Schwegman D).

Many strategies to control antibiotic resistance have been proposed. Thus, for the case of MRSA and considering current therapeutic regimens, vancomycin usage has proven to be the most reliable to treat resistant staphylococcal infections. However, some staphylococcal strains have become resistant, at least to some extent, even to vancomycin -- indicating a need for new alternative therapeutic approaches (Sieradki, K.).

A specific strategy has been the use of natural products with low potential for the development of resistance. Among natural antimicrobials, silver presents a wide range of action, thermal stability for an appropriate manufacture process and, as mentioned in a previous section, low evidence exists regarding to its induced resistance.

## BactiBlock® silver based products – Nanoparticles?

The BactiBlock product range consists in simple terms of silver ions that are deposited on the surface of an organo-clay platelet, which ensures that BactiBlock® is highly cost competitive, combined with long term durability and exceptional polymer compatibility. In other words, this technology is not based on producing silver nano particles (AgNP) or the use of metallic silver.

According to reports issued by Nanobiomatters during the EPA evaluation for approval of BactiBlock® products, it has been shown through morphological studies of the Bactiblock commercial samples that they did not contain elemental silver, since the silver cation is ionically exchanged within the clay and is further stabilized in its ionic form through a specific proprietary technology, which mean that no AgNP's are produced.

Extensive toxicological tests were performed as a requirement for EPA registration of the BactiBlock® product range and all fell within the required limits. Nanobiomatters is currently carrying out approval procedures for FDA to complement the EPA registration and extend the application space to food contact applications. Currently one approval has been obtained for a specific application.