specific information is identified as to what properties and/or composition a clay must have in order to exhibit antibacterial (bactericidal) properties.

[0009] Haydel et al., "Broad-spectrum in vitro antibacterial activities of clay minerals against antibiotic-susceptible and antibiotic-resistant bacterial pathogens," *J. of Antimicrobial Chemotherapy* (2008) 61, 353-361, reported that two iron-rich clay minerals, which are similar in major phases and bulk chemistry, have striking and opposite effects on bacterial populations, ranging from enhanced microbial growth to complete growth inhibition. The article states that "of the six independent clay samples collected from the French supplier and tested against various bacteria . . . only CsAg02 displayed antibacterial effects . . . there is not a single component of CsAg02 clay (e.g. transition metals) that stands out as an obvious antibacterial agent, so it may be a fortuitous combination of factors (multiple components) responsible for the inhibitory property." (at p. 359)

[0010] Applicants studied many different natural clays and clay minerals, and the present invention is a result of these studies. For example, Applicants studied the original sample of Argicur used in the Ivory Coast study, and found it to be bactericidal. They further studied subsequent samples of the Argicur green clay collected from the company mill (Argicur Inc. Le Buisson de Cadouin, France), and found that these were not bactericidal. Therefore, although teachings exist that set forth that Argicur clays have antibacterial/bactericidal properties, it is the Applicants' experience, based on their analysis, that not all Argicur clays have similar bactericidal activity; they were not alike. In addition, of note is that most clays and clay minerals that Applicants studied were found to either have minimal to no bactericidal effect or to actually promote bacterial growth.

[0011] Through their extensive research, applicants did, however, identify a property which renders the natural antibacterial clays tested (i.e., the Argicur used in the Ivory Coast and Pyroclay) antibacterial. In particular, applicants identified that the presence of particular reducing agents (pyrite in these), in particular amounts, and in fine particle form, is what renders these natural clays antibacterial. These reducing agents were found to be absent in clays found to not have bactericidal properties. It is the identification of these reducing agents that lead to the present invention. Applicants are now able to artificially produce an antibacterial (bactericidal) composition having clay-like properties—referred to herein as synthetic antibacterial composition or synthetic bactericidal composition. These compositions may have some advantages over simply using a natural antibacterial clay in that they can be customized to illicit desired properties—i.e., purity level. In particular, the present invention relates to synthesized antibacterial compositions, containing a clay or clay mineral and a bactericidal effective amount of a reducing agent, that Applicants believe may be used to topically treat most, if not all, bacterial skin infections, including those caused by antibiotic resistant bacteria. In use, the composition within the scope of the invention is hydrated to form a paste, which is applied to the affected area. Although Brunet de Courssou reported that treatment of Buruli ulcer with clay was found to be painful, it is applicants' belief that some patients may find the treatment reasonably painless; some may even find it soothing.

BRIEF SUMMARY OF THE INVENTION

[0012] The invention relates to synthetic antibacterial compositions for the topical treatment of bacterially-caused skin infections, and methods of using the same. These synthetic compositions have the properties of clay (clay-like properties), and contain therein an antibacterial effective amount of a reducing agent in a clay. These compositions may be prepared by adding an antibacterial effective amount of a reducing agent (for example, pyrite) to a clay or clay mineral, wherein said reducing agent renders the composition antibacterial.

[0013] The invention further relates to synthetic antibacterial clays or clay minerals, which may be prepared by synthesizing a clay or clay mineral, or by otherwise treating or altering the chemistry of a natural clay or clay mineral, to yield an antibacterial effective amount of a reducing agent within the clay mineral's crystal structure. In the latter preparation, for example, ferrous iron is incorporated into the octahedral sheet of a synthetic clay mineral, or is introduced by the reduction of ferric iron already present in the octahedral sheet. Ferrous iron also could be introduced into the exchange positions of clay minerals (for example, into the interlayer position of smectitic clay minerals) by cation exchange.

[0014] The reducing agents that the applicants have identified as suitable to render the compositions herein bactericidal are the polymorphs of FeS_2, which include pyrite and marcasite, but other similar agents may work as well, agents, such as manganese oxides, pyrrhotite, FeS, $FeSO_4$, and other minerals (natural or synthetic) or compounds that contain reducing transition metals with like properties, or reducing agents that are present within the structure of the clay mineral itself. Reducing agents may be employed and be present in the compositions in the form of fine (submicron) particles. Their fine particulate sizes, as well as the amounts of these reducing agents present in the composition of the invention, do not materially affect the clay-like properties of the composition.

[0015] Natural and/or synthetic clays or clay minerals are employed in the composition, and serve as a carrier for the reducing agents. They bind/sorb the reducing agent and may play a role in buffering the chemical reaction(s) produced by the reducing agent(s). They also serve as an absorbent and low permeability barrier when the composition is in use. In addition, the exchange properties of the clay mineral may enhance the solubility of sparingly soluble reducing agents, as has been found for the enhanced dissolution of other sparingly soluble compounds in the presence of montmorillonite (Eberl and Landa 1985). The reducing agent imparts antibacterial properties to the clay containing compositions herein.

[0016] Smectite-clays, illite-clays, rectorite-clays and clays having like properties, or a combination of these, may be suitably employed as the carrier for the reducing agent in the present invention. These clays may be natural or synthetic. In addition to serving as a carrier for the reducing agent, the clays serve as a low permeability barrier to keep atmospheric oxygen from reaching the skin or other surfaces being treated with the composition herein, and may serve as a scavenger for oxygen. They also must be suitable to keep the system moist. In addition to the suitability of natural and/or synthetic clays for use as the carrier herein, applicants submit that polymers, for example, and other materials having clay-like properties (for example, kaolinites, chlorites) may be employed in this role as well. One having ordinary skill in the art with knowledge of the teachings herein would be readily able to identify the types of carriers that may be suitably employed herein and