

ALUM-CONTAINING COATING FORMULATIONS FOR MICRONEEDLE VACCINE PATCHES

Background

5 Devices including arrays of relatively small structures, sometimes referred to as microneedles or micro-pins, have been disclosed for use in connection with the delivery of therapeutic agents such as vaccines through the skin and other surfaces. The devices are typically pressed against the skin in an effort to pierce the stratum corneum such that the
10 therapeutic agents and other substances can pass through that layer and into the tissues below.

Microneedle devices having a fluid reservoir and conduits through which a therapeutic substance may be delivered to the skin have been proposed, but microneedle devices having a dried coating on the surface of a microneedle array have desirable features compared to fluid
15 reservoir devices, as they are generally simpler and can directly inject a therapeutic substance into the skin without the need for providing reliable control of fluid flow through very fine channels in the microneedle device.

In the field of immunology it has been well known for many years that immune response to certain antigens which are otherwise weakly immunogenic can be enhanced through the use of vaccine adjuvants. Such adjuvants potentiate the immune response to specific antigens and are
20 therefore the subject of considerable interest and study within the medical community. Alum, or aluminum compounds, are the only adjuvants widely used in vaccines, and in some cases are the only approved vaccine adjuvants.

Therefore, there is a need for compositions and methods for coating microneedles with aluminum adjuvant-containing coating formulations.

Summary

25 The present disclosure provides compositions and methods for coating microneedles and microneedle arrays with aluminum-adjuvanted vaccines.

In one aspect, the present disclosure provides a composition comprising: an aluminum-containing wet gel suspension selected from aluminum hydroxide wet gel suspension and aluminum phosphate wet gel suspension; a vaccine in an amount effective to stimulate an
30 immune response in a mammal; a sugar, sugar alcohol, or combinations thereof; and a thickener; wherein the composition has a viscosity of 500 to 30,000 cps when measured at 100s⁻¹ and temperature of 25 °C.