

## Anthrax and Squalene Q&A

### Does the anthrax vaccine contain squalene?

There is no evidence that squalene was intentionally added to the anthrax vaccine

In 1999 studies by the FDA and Stanford Research International identified trace level of squalene, between 10 and 83 parts per billion, in anthrax (as well as diphtheria and tetanus) vaccines. These trace levels were thought to be due to contamination from fingerprints on lab glassware. Research groups stated "trace amounts of squalene is unlikely to have any biological effect, given that it is already present in the body." The amounts detected were well below the concentration naturally present in human blood. In Congressional testimony in October 2000, an FDA official said the trace quantities of squalene detected were "both naturally occurring and safe." (4-6)

### What is squalene?

Squalene is a naturally occurring substance.

Squalene is found in plants, animals, and humans. It is an organic compound used for commercial purposes when derived from shark liver oil. It is found in a variety of foods, cosmetics, over-the-counter medications, and health supplements. The human body naturally contains about 250 parts per billion in the blood stream. Squalene is found on the surface of the skin (fingerprint oil), and squalene is a building block in the synthesis of cholesterol and steroid hormones. Research suggests squalene may increase oxygen transportation and boost the immune system as an antioxidant. (1)

### Is squalene in vaccines?

Squalene has been used for decades in some vaccines in many countries.

Squalene emulsions (MF59, AS03) have been used by some vaccine manufactures (Novartis, Ciba-Geigy, Chiron, Glaxo Smith Kline) as adjuvants in some influenza, tetanus, and diphtheria vaccines outside the USA to help stimulate an immune response. In 2016, the US FDA approved FLUAD (an influenza vaccine containing the MF59 adjuvant) for use in the USA. The amount of squalene found in these vaccines is a million times greater than the traces found in a few lots of anthrax vaccine in the 1990s.(2,3)

### Is squalene in vaccines harmful?

Squalene used in vaccines has not been shown to be harmful.

Although Tulane University researchers published concerns about anti-squalene antibodies found in some veterans who had received anthrax vaccine and who were suffering from “Gulf War Syndrome,”(8,9) other researchers have not been able to support these concerns, based on the information previously described.(1-7) To further address the concern that squalene in any quantity in a vaccine might be associated with long term disability, a 2009 study examined the relationship between anti-squalene antibodies and chronic symptoms reported by more than 570 Navy construction workers. The researchers found no association between squalene antibody status and chronic multi-symptom illness. They concluded that anti-squalene antibody status is unrelated to these health challenges.(10)

Multiple other research studies on squalene have failed to find any association between squalene and chronic illness. US public health authorities and the World Health Organization have concluded that squalene-adjuvanted vaccines are safe.(11)

A study in 2006 examined whether immunization with influenza vaccine containing MF59 would stimulate antibody responses against squalene. Blood samples were obtained pre-immunization and post-immunization from USA and European adults. Blood was also tested from unvaccinated adults. The researchers found anti-squalene antibodies were frequently in low titers in both healthy unvaccinated and vaccinated adults. Therefore, they concluded that MF59 emulsion adjuvant does not induce anti-squalene antibodies. (7)

The US Department of Defense appreciates that there remain many unanswered questions regarding the causes of some chronic illnesses. However, evidence does not support any association between chronic illness and intentional or unintentional addition of squalene to any vaccines.

#### Does squalene cause Gulf War Syndrome?

No, squalene does not cause Gulf War Syndrome.

There were concerns related to this after Tulane University researchers published papers on concerns about anti-squalene antibodies found in some veterans who had received anthrax vaccine and who were suffering from “Gulf War Syndrome.” These findings legitimately raised concern of a possible connection between anthrax vaccine and health problems.

However, as detailed above, intensive, high quality research by multiple distinguished groups subsequently proved that squalene was not intentionally added to the anthrax vaccine and that anti-squalene antibodies were not associated with Gulf War Syndrome or chronic multi-symptom illnesses. In 2006, the World Health Organization, among many others, “concurred that fears of squalene and vaccine-inducing pathological anti-squalene antibodies were unfounded.”

#### Will I receive 100% disability if I received certain vials of anthrax vaccine?

Unfortunately, this is a rumor that recent social media postings resurrected with the earlier concerns without acknowledging the subsequent research dispelling both the intentional use of squalene in any lots of anthrax vaccine and the connection of this adjuvant with chronic disease. The rumor circulating in social media that the VA is starting to rate "100% disability" to any Service member who received a specific lot of anthrax vaccine has been reviewed with the Veterans' Administration and was found to be completely without merit.

What do I do if I have a question about anthrax vaccine that I may have received?

If you have other vaccine-related health concerns, please contact our health care team at 1-877-438-8222 (or DSN 761-4245), press Option 1. See also: [www.health.mil/vaccines](http://www.health.mil/vaccines)

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