



Squalene-based adjuvants in vaccines

What is squalene?

- Squalene is a naturally occurring substance found in plants, animals, and humans. It is manufactured in the liver of every human body and circulates in our bloodstream.
- Squalene is also found in a variety of foods, cosmetics, over-the-counter medications, and health supplements.
- Squalene is commercially extracted from fish oil, and in particular shark liver oil. Squalene used in pharmaceutical products and vaccines is purified from this source.

Is there squalene in vaccines?

- Since 1997, an influenza vaccine (FLUAD, Chiron) which contains about 10 mg of squalene per dose, has been approved in health agencies in several European countries. Squalene is present in the form of an emulsion and is added to make the vaccine more immunogenic.
- Squalene is being added to improve the efficacy of several experimental vaccines including pandemic flu and malaria vaccines which are being developed.

Why is squalene added to vaccines?

- Squalene is a component of some adjuvants that are added to vaccines to enhance the immune response.
- MF59, an adjuvant produced by Novartis and added to the FLUAD flu vaccine, is such an example.
- Squalene by itself is not an adjuvant, but emulsions of squalene with surfactants do enhance the immune response.

What is known about the safety of squalene in vaccines?

- Twenty two million doses of Chiron's influenza vaccine (FLUAD) have been administered safely since 1997. This vaccine contains about 10mg of squalene per dose. No severe adverse events have been associated with the vaccine. Some mild local reactogenicity has been observed.
- Clinical studies on squalene-containing vaccines have been done in infants and neonates without evidence of safety concerns.

Why do some people think squalene in vaccines carries a risk?

- A few people have tried to link the health problems of Gulf War veterans to the possible presence of squalene in the vaccines these soldiers received.
- One published report suggested that some veterans who received anthrax vaccines developed anti-squalene antibodies and these antibodies caused disabilities.
- It is now known that squalene was not added to the vaccines administered to these veterans, and technical deficiencies in the report suggesting an association have been published.

[More information](#)

What is the relevance of anti-squalene antibodies and are these linked to squalene in vaccines?

- Most adults, whether or not they have received vaccines containing squalene, have antibodies against squalene.
 - In one study the incidence of these antibodies appeared to increase with age.
- In one clinical trial, immunization with the licensed flu vaccine containing squalene did not affect the frequency or titer of anti-squalene antibodies. (unpublished data shared with the GACVS by Novartis).

[Reference for first bullet point above](#)

Matyas G, Rao M, Pittman P, Burge R, Robbins I, Wassef N et al. Detection of antibodies to squalene III. Naturally occurring antibodies to squalene in humans and mice. JIM 286 (2004) 47-67

Are squalene-containing vaccines safe?

- Over 22 million doses of squalene-containing flu vaccine have been administered. The absence of significant vaccine-related adverse events following this number of doses suggests that squalene in vaccines has no significant risk. This vaccine has been given primarily to older age groups.
- As this vaccine and new squalene-containing vaccines are introduced in other age groups, post-marketing follow-up to detect any vaccine-related adverse events will need to be performed.

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