

Non Animal Origin Squalene Emprove® Expert

A high-purity excipient suitable for high-risk vaccine applications

Product Description

Non Animal Origin (NAO) Squalene is an Emprove® Expert high-purity, fermentation-derived alternative to shark squalene that is suitable for high-risk pharmaceutical applications. With ≥99% purity, low endotoxins (≤2.25 EU/mL), and low bioburden, it meets the highest quality standards. Its scalable manufacturing process ensures batch-to-batch consistency and supply security.

Application

Squalene-based nanoemulsions are composed of squalene and surfactants, which stabilize the emulsion and act as an adjuvant, enhancing efficacy of vaccines in eliciting an immune response. Squalene is currently used in commercially available adjuvants in vaccines against seasonal influenza, pandemic influenza, and Corona SARS-CoV-2 viruses.

Non Animal Origin (NAO) Squalene Emprove® Expert demonstrates high purity, stability, and the ability to form stable nanoemulsions that effectively activate cytokine stimulation, supporting its use in vaccine adjuvants. Additionally, NAO Squalene Emprove® Expert complies with analytical specifications outlined in the Ph. Eur. monograph 2805. Due to its high purity and low microbial and endotoxin limits as reported on the Certificate of Analysis (CoA), NAO Squalene Emprove® Expert is suitable for high-risk applications. It is manufactured under strict quality control procedures, meeting excipient GMP standards according to IPEC-PQG Pharmaceutical Excipients GMP/EXCiPACT guidelines.

Product Data

	Testing	Specification
NAO Squalene Emprove® Expert	Appearance	Clear, colorless or light yellow, oily liquid
	Purity	≥99.0%
	Peroxide Value	≤5.0
	Endotoxins	≤2.25 EU/mL
	Aerobic Bacteria (TAMC)	≤50 CFU/g
	Yeast & Mold (TYMC)	≤50 CFU/g

Shelf Life

24 months. Do not use after expiration date.

Quality Segment

MQ500

Storage

2 to 8 °C

Chemical Information

Molecular Formula

C₃₀H₅₀

Ordering Information

The product will be packaged in a nitrogen blanket to protect against oxidation and in amber glass bottles to protect against light. Two standard pack sizes are available:

Product Description	Material Number	Pack Size
NAO Squalene Emprove® Expert	1.37166.0100	100 mL
	1.37166.1000	1 L

The Emprove® Program

The Smart Way to Master Compliance and Control

Ensuring the compliance of your pharma and biopharma products involves the compilation of a vast amount of data, which can be time- and resource-intensive. In order to facilitate and accelerate this process, we developed our Emprove® Program. Beside a selection of filtration and single-use components, it contains more than 500 pharma raw and starting materials addressing different levels of risk. Each product in the portfolio is complemented with different types of dossiers supporting you with reliable technical, regulatory, and supply information: API Information Package, Elemental Impurities Information, Material Qualification Dossier, Quality Management Dossier, and Operational Excellence Dossier.

For more information, please visit:
SigmaAldrich.com/emprove

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