AddaS03™

Oil-in-water nano-emulsion adjuvant

Catalog Code: vac-as03-10

https://www.invivogen.com/addas03-adjuvant

For research use only. Not for use in humans.

Version 24C20-NJ

PRODUCT INFORMATION

Contents

• 10 ml AddaS03™ provided as a ready-to-use sterile emulsion

Storage and stability

- AddaS03™ is shipped at room temperature. Upon receipt, store product at $4^{\circ}\text{C}.$
- AddaSO3™ is stable for at least 1 year when properly stored.
- DO NOT FREEZE

Formulation

AddaS03™ is a nano-emulsion of:

- DL- α -tocopherol (5% v/v) in squalene oil 5% (v/v)
- Tween80® (1.8% v/v) in phosphate-buffered saline (pH 6.8)

The nano-emulsion is produced using a microfluidizer and filtered through a 0.22-µm filter to remove large droplets and sterilize the final product.

Quality control

- AddaSO3™ is VacciGrade™ (preclinical grade). It is prepared under strict aseptic conditions and is tested for the presence of endotoxins.
- AddaSO3[™] is guaranteed sterile and its endotoxin level is <10 EU/ml (determined using the HEK-Blue[™] LPS Detection Kit 2).
- Physio-chemical characteristics of AddaS03™ have been confirmed by sizing and HPLC.

PRODUCT DESCRIPTION

Adda $S03^{TM}$ is an oil-in-water emulsion adjuvant, with a formulation similar to that of the adjuvant system ASO3®, a fundamental component of pandemic influenza and protein-based covid vaccines [approved by relevant regulatory authorities]¹. It is composed of the same percentage of two biodegradable oils, squalene and DL- α -tocopherol, and for stability, the surfactant polysorbate 80 (Tween 80®).

<u>Please note:</u> ASO3® is a registered trademark of GSK, and is used for comparative purposes only. AddaSO3 $^{\text{m}}$ is not made by, affiliated with, sponsored by or endorsed by GSK. GSK has not evaluated or approved the representations contained herein.

Squalene oil-in-water emulsions, such as MF59® or ASO3®, allow for antigen dose sparing and result in mixed cell-mediated and humoral immune responses (Th1/Th2) $^{2-5}$. A consistent signature pattern of early post-vaccine activation of myeloid and lymphoid cells following the administration of these adjuvants has emerged across multiple studies in humans 1 .

1. O'Hagan, DT. et al., 2021. "World in motion" - emulsion adjuvants rising to meet the pandemic challenges. npj vaccines 6(1):158. 2. Morel, S. et al., 2011. Adjuvant System AS03 containing alpha-tocopherol modulates innate immune response and leads to improved adaptive immunity. Vaccine 29:2461. 3. Calabro, S. et al. 2013. The adjuvant effect of MF59 is due to the oil-in-water emulsion formulation, none of the individual components induce a comparable adjuvant effect. Vaccine 31:3363. 4. Wilkins, AL et al., 2017. AS03- and MF59-Adjuvanted Influenza Vaccines in Children. Front Immunol 8:1760. 5. Shi, S. et al., 2019. Vaccine adjuvants: Understanding the structure and mechanism of adjuvanticity. Vaccine 37:3167.

METHODS

Preparation of antigen-AddaS03™ mixture

Antigens should be preferentially diluted in a saline or phosphate buffer. The amount of antigen (e.g. protein or conjugated peptide) used for the primary immunization should be adjusted (e.g. 1 - 15 μ g) depending upon availability and immunogenicity of the antigen.

- 1. Bring AddaS03™ to room temperature.
- 2. Shake the capped bottle of AddaSO3™ before opening.
- 3. Mix equal volumes of the prepared antigen and AddaS03 $^{\!\scriptscriptstyle\mathsf{TM}}\!.$ Notes:
- The volume of injection depends on the site of administration.
- To avoid anaphylaxis, do not use adjuvants for intravenous injection.

RFI ATED PRODUCTS

Product	Cat. Code
Vaccine Adjuvants	
AddaVax™	vac-adx-10
Adju-Phos® adjuvant	vac-phos-250
Alhydrogel® adjuvant 2%	vac-alu-250
CFA	vac-cfa-10
IFA	vac-ifa-10
ODN 1826 VacciGrade™	vac-1826-1
ODN 2006 VacciGrade™	vac-2006-1
OVA Antigens	
EndoFit™ OVA (endotoxin-free)	vac-pova
OVA protein	vac-stova

