EMULSIGEN®

(Oil-in-Water Emulsified Adjuvant)

KEY POINTS

- Stable oil-in-water emulsion
- Free of animal origin ingredients
- Consistent emulsion particle size
- Ready to add to antigen – no temperature control or homogenization is required
- SAFE
- Manufactured using components on Annex II, EC Regulations No. 470/2009 and/or GRAS lists

Emulsigen® was the first commercial oil-in-water adjuvant approved by USDA for use in pigs when injected intramuscularly or subcutaneously.

This antigen-friendly adjuvant can be mixed with your antigen at any temperature using only mild mixing (no homogenization). Such a process can serve to enhance immunogenicity of the finished product and improve the vaccine's safety profile.

Emulsigen contains uniformly dispersed, micron- sized oil droplets which ensure maximum emulsion stability and lower viscosity. These micron- sized oil droplets also increase the surface area available to antigens, reducing the quantity of oil required in the final vaccine. The technology used in manufacturing Emulsigen reduces the undesirable side effects associated with other oil-in-water adjuvants, while still eliciting the rapid and strong immune response.

Oil-in-water emulsified adjuvants act by forming a mobile depot of antigen and increase recruitment of macrophages. The depot effect with slow antigen release improves the presentation of antigens to immune-effector cells thus providing a significant antigen enhancement of the immune response and vaccine efficacy.

Emulsigen can be used alone or in combination with aluminum hydroxide, Carbigen®, and other adjuvants or immune stimulators, depending on your needs and applications. It may be administered parenterally in a wide variety of species of large and small animals

INFORMATION ABOUT EMULSIGEN®

Ingredients: Each lot of Emulsigen is manufactured to the highest standards using the finest components available. All ingredients meet USP, NF, EC Regulation No. 470/2009 or equivalent specifications and/or have been approved for vaccine use by USDA and regulatory agencies in other countries. Emulsigen is free of animal origin ingredients. All components are sterilized prior to use to ensure the purity of the final product. Containers, depending on size, are terminally sterilized or are irradiated.

Manufacturing and Testing: Each ingredient contained in Emulsigen must meet stringent in-house parameters for identity and consistency. Each lot of final product is thoroughly tested to ensure that it is free of viable bacteria and fungi as provided in 9 CFR 113.26. To assure batch-to-batch quality and consistency each lot is tested for viscosity, specific gravity, pH, and formaldehyde concentration (where applicable). Macroscopic and microscopic appearance are also carefully monitored during the manufacturing process. Other tests, including mouse safety, may be conducted at the customer's request.

Immune Response: Emulsigen has the potential to elicit higher levels of humoral antibody, more rapid onset of immunity, and enhanced protection with a single vaccine dose as compared with conventional aluminum-salt adjuvants. It may be used with bacterial, mycoplasma, viral, subunit or DNA vaccines.

Safety: Emulsigen is less likely to cause adverse injection site reactions than conventional oil adjuvants.

Stability: MVP utilizes HLB (Hydrophilic-Lipophile Balance) technology to maximize stability of the oil-in-water emulsion. Use of HLB technology results in oil droplets of uniform micron size, thereby eliminating problems related to undesirable product separation and poor syringeability.

Syringeability: Vaccines containing up to 50% Emulsigen easily pass through a 25-gauge needle.

Preservatives: Emulsigen is normally manufactured without preservatives. Preservatives such as formaldehyde (≤ 0.74g/L) and/or gentamicin (≤ 30 mcg/ml) may be added. Other preservative combinations are available.

Storage: Emulsigen may be stored at 4˚C - 30˚C (39˚F - 86˚F). Temperature extremes should be avoided.

Packaging: Emulsigen is available in 10-, 20- and 50-liter containers. Other sizes can be supplied to meet each customer's needs and can also be provided in sterile bags.

Uniformity: The use of highly skilled operators and standardized manufacturing procedures ensures that each batch of Emulsigen will be consistent, uniform, and in compliance with established specifications.

EMULSIGEN® INSTRUCTIONS FOR USE

1. For most antigens, we recommend that Emulsigen be added to antigen at a concentration up to 20% (v/v).
2. Agitate or pre-mix the adjuvant prior to using. This may be done by shaking the container, with a magnetic stirrer or using an over-head mixer.
3. Transfer the antigen(s) into a mixing vessel or designated container and start mixing at a moderate speed (magnetic stir bar, over-head mixer or built-in agitator for large volume).
4. While the antigen is mixing, start adding required amount of Emulsigen. It may be pumped, pipetted, or poured slowly.
5. Continue mixing at least for four hours. For smaller volumes, two hours may suffice. Mixing speed will depend on the container size, mixer type, volume, and nature of the antigen(s).
6. Check pH and adjust, if necessary. The recommended range is 6.8 - 7.2.
7. While continuously mixing, fill into final vaccine containers.
8. It is normal for final vaccines to develop a creaming layer on top during storage. This does not adversely affect the antigenicity or immunogenicity. Simple inversion of the vials prior to injection is adequate to remix all components.

The Adjuvant Company That Understands Vaccines

MVP adjuvants®

To speak with an adjuvant expert: 402.331.5106 or 800.856.4648