



EMULSIGEN®

(Oil-in-Water Emulsified Adjuvant)

Technical Bulletin

Summary of Key Points:

- ❑ Stable mineral oil-in-water emulsion
- ❑ Free of animal origin ingredients
- ❑ Consistent in particle size (1 – 2 microns)
- ❑ Ready to add to antigen -- no further processing required
- ❑ Demonstrated safety since 1983
- ❑ Manufactured using components on Annex II, EC Regulation No. 470/2009 and/or various GRAS lists

EMULSIGEN® is a unique, oil-in-water emulsion that is free of animal origin ingredients. Its milky-white appearance creates a smooth, uniform mixture when added to your veterinary antigens. EMULSIGEN® is designed to be mixed directly with vaccine antigens, without any further processing, to enhance the immunogenicity of the finished product.

EMULSIGEN® contains uniformly dispersed, micron size oil droplets which ensure maximum emulsion stability and decreased viscosity. Micron size 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 which can target immune effector cells. The depot effect with slow antigen release improves the presentation of antigen thus providing a significant 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®

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 based adjuvants. It may be used with bacterial, mycoplasma, viral or subunit vaccines.

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

Stability: MVP utilizes HLB (Hydrophile-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 at 10°C (50°F).

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.

Preservatives: EMULSIGEN[®] is normally manufactured with formaldehyde (< 740 ppm) and/or gentamicin (30 mcg/ml) as preservatives. Other preservative combinations are available upon request. It can also be formulated without preservatives, if desired.

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 numerous other countries. **EMULSIGEN[®] is free of animal origin ingredients.** All components, including the containers, are sterilized prior to use to ensure purity of the final product.

Testing: Each ingredient contained in EMULSIGEN[®] must meet stringent in-house parameters for identity and consistency. Key ingredients are tested for purity prior to use. Each lot of final product is thoroughly tested to ensure that it is free of viable bacteria and fungi. To assure batch-to-batch quality and consistency each lot is tested for viscosity, stability, 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.

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 and 20 liter containers. Other sizes can be supplied to meet each customer's needs. EMULSIGEN[®] can also be provided in sterile bags.

INSTRUCTIONS FOR USE

- 1) For bacterial and viral antigens, we recommend that EMULSIGEN[®] be added to antigen at a concentration up to 20% v/v.
- 2) EMULSIGEN[®] should be thoroughly mixed prior to use. The adjuvant can be added to inactivated or modified live antigens and mixed using standard equipment.
- 3) For soluble antigens such as Gram positive toxoids and Gram negative endotoxins, we recommend the use of EMULSIGEN[®] in combination with an aluminum hydroxide adjuvant such as Rehydrigel[®]-LV. In this case, the aluminum hydroxide adjuvant should be added to the antigen first, at 5% (v/v), mixed at least one hour, then EMULSIGEN[®] should be added at 15% (v/v).
- 4) After thorough mixing, the product is ready to fill. Mixing should continue throughout the filling process.
- 5) Products containing EMULSIGEN[®] may be administered intramuscularly or subcutaneously in a wide variety of large and small animals.

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