



EMULSIGEN[®]-D

(Emulsified Oil-in-Water Adjuvant + Immunostimulant)

Technical Bulletin

Summary of Key Points:

- EMULSIGEN[®] based
- Formulated with DDA
- Free of animal origin ingredients
- Sterile
- Ready to add to antigen -- no further processing required
- Neutral in pH
- Manufactured using components on Annex II and/or various GRAS lists
- Known to stimulate humoral and T-cell response

EMULSIGEN[®]-D is a unique, sterile, oil-in-water emulsion, free of animal origin ingredients. It's milky-white appearance creates a smooth, uniform mixture when added to your veterinary antigens. EMULSIGEN[®]-D is designed to be mixed directly with vaccine antigens, without any further processing, to enhance the immunogenicity of the finished product. Additionally, it can be combined with aluminum hydroxide and other MVP adjuvants. Contact MVP for procedures.

EMULSIGEN[®]-D 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[®]-D reduces the undesirable side effects associated with other oil-in-water adjuvants, while eliciting the rapid and strong immune response.

EMULSIGEN[®]-D incorporates dimethyldioctadecylammonium bromide (DDA) as an additional immunostimulant for weak antigens.

Oil-in-water emulsified adjuvants act by forming a mobile depot of antigen which can target immune effector cells. The depot effect with slow release improves the presentation of antigen thus providing a significant enhancement of the immune response and vaccine efficacy. The added DDA is a known T-cell immune stimulator.

EMULSIGEN[®]-D may be combined with aluminum hydroxide or other MVP adjuvants. Contact MVP Laboratories for procedures.

INFORMATION ABOUT EMULSIGEN[®]-D

Immune Response: EMULSIGEN[®]-D 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. EMULSIGEN[®]-D is an excellent adjuvant for bacterial, mycoplasma, viral, subunit or parasite antigens.

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

Stability: EMULSIGEN[®]-D 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[®]-D easily pass through a 25 gauge needle at 10°C (50°F).

Uniformity: The use of highly-skilled operators, state-of-the-art equipment and standardized manufacturing procedures ensures that each batch of EMULSIGEN[®]-D will be consistent, uniform, and in compliance with specifications.

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

Ingredients: Each lot of EMULSIGEN[®]-D is manufactured to the highest standards using the finest components available. All ingredients meet USP, NF or equivalent specifications and/or have been approved for vaccine use by USDA. **EMULSIGEN[®]-D is free of animal origin ingredients.** All components, including the containers, are sterilized prior to use to ensure sterility of the final product.

In Vitro Testing: Each ingredient contained in EMULSIGEN[®]-D must meet stringent in-house parameters for purity and consistency. Each lot is thoroughly tested to ensure that it is free of viable bacteria and fungi. Viscosity, pH, formaldehyde concentration (if applicable), macroscopic and microscopic appearance and particle size analysis, are carefully monitored to maintain batch-to-batch uniformity and stability.

Storage: EMULSIGEN[®]-D may be stored at 4°C-25°C (39°F-77°F). Temperature extremes should be avoided.

Packaging: EMULSIGEN[®]-D is available in 10 and 20 liter containers. Other sizes can be supplied to meet each customer's needs. EMULSIGEN[®]-D can also be provided in sterile bags.

INSTRUCTIONS FOR USE

- 1) For most bacterial and viral antigens, we recommend that EMULSIGEN[®]-D be used at 15% to 20% (v/v).
- 2) EMULSIGEN[®]-D should be thoroughly mixed prior to use. The adjuvant can be added to inactivated or modified live antigen and mixed using standard equipment.
- 3) After thorough mixing, the product is ready to fill. Mixing should continue throughout the filling process.
- 4) Products containing EMULSIGEN[®]-D may be administered intramuscularly or subcutaneously in a wide variety of animals.

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