



EMULSIGEN[®]-P

(Emulsified Oil-in-Water Adjuvant + Immunostimulant)

Technical Bulletin

Summary of Key Points:

- ❑ EMULSIGEN[®] based
- ❑ Formulated with POLYGEN[™] (copolymer immune stimulator)
- ❑ Free of animal origin ingredients
- ❑ Ready for addition to antigen - no further processing required
- ❑ Manufactured using components on Annex II, EC Regulation No. 470/2009, various GRAS lists or in registered veterinary products
- ❑ Known to stimulate humoral and T-cell responses

EMULSIGEN[®]-P 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[®]-P is designed to be mixed directly with vaccine antigens, without any further processing, to enhance immunogenicity of the finished product.

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

EMULSIGEN[®]-P's POLYGEN[™] ingredient is an immunostimulant that improves the antigenicity of virus, subunit and parasite vaccines. It has been demonstrated to stimulate T-cell responses, including interferon gamma.

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.

INFORMATION ABOUT EMULSIGEN[®]-P

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

Animal Safety: EMULSIGEN[®]-P is less likely to result in adverse injection site reactions occasionally seen with products containing conventional oil adjuvants. It is normal for EMULSIGEN[®]-P to exhibit some toxicity in laboratory mice when injected at vaccine concentrations. Each lot is titered in mice for safety prior to release.

Stability: EMULSIGEN[®]-P 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[®]-P 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[®]-P will be consistent, uniform, and in compliance with established specifications.

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

Ingredients: Each lot of EMULSIGEN[®]-P 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[®]-P is free of animal origin ingredients.** All components, including the containers, are sterilized prior to use to ensure the purity of the final product.

Testing: Each ingredient contained in EMULSIGEN[®]-P 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.

Storage: EMULSIGEN[®]-P may be stored at 4°C-30°C (39°F-86°F). Temperature extremes should be avoided.

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

INSTRUCTIONS FOR USE

- 1) For most antigens, we recommend that EMULSIGEN[®]-P be used at 10% to 20% (v/v).
- 2) EMULSIGEN[®]-P should be thoroughly mixed before adding to the antigen. The adjuvant can be combined with inactivated or modified live antigens 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[®]-P may be administered intramuscularly or subcutaneously in a wide variety of animals.

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