

KEY POINTS

- EMULSIGEN® based dual adjuvant
- Formulated with a copolymer immune stimulator
- Free of animal origin ingredients
- Ready to add to antigen – no temperature control or homogenization is 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 including γ -interferon and IL-12

EMULSIGEN®-P is an oil-in-water dual adjuvant emulsion, containing a unique polymer immunostimulant, 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 antigen-friendly in that it can be mixed with your antigen at any temperature and 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-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 copolymer 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 and interleukin 12.

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 antigen 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 **POLYGEN** to exhibit some toxicity in laboratory mice when injected intraperitoneally at vaccine concentrations.

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.

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 without preservatives. Preservatives such as formaldehyde ($\leq 0.74\text{g/L}$) and/or gentamicin ($\leq 30\text{ mcg/ml}$) may be added. Other preservative combinations are available.

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 are sterilized prior to use to ensure the purity of the final product. Containers, depending on size, are terminally sterilized or are irradiated.

Testing: Each ingredient contained in **EMULSIGEN-P** 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. To assure batch-to-batch quality and consistency each lot is tested for viscosity, pH, specific gravity 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, 20 and 50 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 a concentration up to 20% (v/v).
- 2) **EMULSIGEN-P** should be gently mixed for up to 2 hours before adding to the antigen. During addition to the antigen, it is recommended that gentle mixing using standard equipment (e.g. Lightnin mixer or magnetic stirrers) be continued for from 2 to 24 hours.
- 3) It is recommended that the product continue to be gently mixed throughout filling to assure consistency.
- 4) Products containing **EMULSIGEN-P** may be administered intramuscularly or subcutaneously in a wide variety of animals.
- 5) 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

To speak with an adjuvant expert: 402.331.5106 or 800.856.4648

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