



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
- EC Regulation No. 470/2009, and USP-NF compendia compliant
- Known to stimulate humoral and T-cell responses including γ -interferon and IL-12

Emulsigen®-P is a ready to use oil-in-water emulsion dual adjuvant, containing a unique polymer immunostimulant. Its milky-white appearance creates a smooth, uniform mixture when added to your veterinary antigens.

All ingredients in Emulsigen-P are non-animal origin.

It can be mixed with your antigen at any temperature using gentle mixing without high shear (high-speed) homogenization. Such a process is essential to preserve structural integrity of the antigen and improve immunogenicity and vaccine safety.

This adjuvant contains uniformly dispersed micron-sized oil droplets with polymer, which helps ensure maximum emulsion stability and increases the surface area available for antigen-adjuvant interactions.

The technology used in manufacturing Emulsigen-P reduces the undesirable side effects associated with oil emulsion adjuvants, while eliciting rapid and strong immune response with longer duration.

The polymer ingredient is an immunostimulant that enhances T-cell responses.

Oil-in-water emulsions with polymer act by forming a depot of antigen for slow release and improve the presentation of antigen thus providing an enhancement of the immune response and vaccine efficacy.

INFORMATION ABOUT EMULSIGEN®-P

Ingredients: All ingredients meet USP, NF, EC Regulation No. 470/2009 or equivalent specifications and/or have been approved for vaccine use by USDA, EMA and regulatory agencies in other countries. Emulsigen-P is free of animal origin ingredients. All components are properly sterilized prior to use to ensure the purity of the final product.

Manufacturing and Testing: Each ingredient contained in Emulsigen-P must meet stringent in-house parameters for identity and consistency. Each lot of adjuvant is thoroughly tested to ensure purity, i.e., absence of viable bacteria and fungi. To assure quality and batch-to-batch consistency each lot is tested for viscosity, pH, specific gravity and formaldehyde concentration (where applicable). Particle size and microscopic appearance are also carefully monitored during the manufacturing process.

Immune Response: Emulsigen-P has the potential to elicit higher levels of humoral and cellular responses. As an oil-in-water based polymer-emulsion, it induces rapid onset of immunity, while providing a good duration of immunity. Emulsigen-P is an excellent adjuvant for bacterial, mycoplasma, viral, subunit or parasite antigens.

Safety: Emulsigen-P is less likely to cause adverse injection site reactions that are often seen with products containing conventional oil adjuvants. Certain polymers may exhibit toxicity in mice when injected intraperitoneally, hence, intramuscular and subcutaneous routes are advised if conducting safety testing in laboratory rodent models.

Stability: Emulsigen-P has a precise hydrophilic-lipophilic balance (HLB) that maximizes stability of the oil-in-water emulsion and is attributed to oil droplets of uniform size and distribution.

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

Preservatives: Emulsigen-P is normally manufactured without preservatives. It is compatible with commonly used preservatives such as formaldehyde ($\leq 0.74\text{g/L}$) and gentamicin ($\leq 30\text{ mcg/ml}$) that can be added during its production upon customer's request. Other preservatives are also available.

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 customer's needs and can also be provided in sterile bags.

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

EMULSIGEN[®]-P 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 before adding to the antigen to make it homogenous. This may be achieved by agitating the container or using a magnetic stirrer or overhead stirrer. During storage, layering could appear, which is normal appearance for MVP adjuvants; it is not emulsion breakage or separation of the polymer.
3. Start mixing the antigen(s) at moderate speed enough to create a vortex. Mixing may be done with built-in propellers, lightning mixer, or with magnetic stir bar for small volumes. While the antigen is mixing, start adding required amount of adjuvant into the antigen-containing vessel. The recommended concentration for most species is 10% to 20% v/v adjuvant/antigen ratio. Adjuvant may be pumped, pipetted, or poured slowly. The procedure can be done at a temperature range between 4°C to 30°C.

Continue mixing at constant speed for 2 to 12 hours. Mixing time and speed will depend on antigen volume, complexity, mixing vessel and mixer conditions.
4. Monitor and adjust pH. Emulsigen-P has a low pH. It is recommended to adjust the final product pH to between 6.8 – 7.2 with NaOH solution.
5. It is recommended to continue mixing throughout vaccine filling to assure consistency.
6. 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.
7. Products containing Emulsigen-P may be administered intramuscularly or subcutaneously in a wide variety of animals.

The Adjuvant Company That Understands Vaccines



To speak with an adjuvant expert call: 402.331.5106 or 800.856.4648
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