



## KEY POINTS

- Emulsigen® based dual adjuvant
- Free of animal origin ingredients
- Ready to add to antigen - no temperature control or homogenization is required
- Manufactured using components on Annex II, EC Regulations No. 470/2009 and/or various GRAS lists
- Known to stimulate humoral and T-cell responses

Emulsigen®-D is a unique oil-in-water emulsion containing dimethyl dioctadecyl ammonium bromide (DDA), a potent immunostimulant, which is incorporated into a stable emulsion. It is free of animal origin ingredients. Its milky-white appearance creates a smooth, homogenous mixture when added to vaccine antigens.

This adjuvant can be mixed with your antigen at any temperature using only standard mixing (no homogenization). Such a process can serve to enhance immunogenicity of the finished product and improve the vaccine's safety profile.

Emulsigen-D contains uniformly dispersed, oil droplets which helps ensure maximum emulsion stability and decreased viscosity. The micron-sized oil droplets also increase the surface area available to antigen-adjuvant interactions. The technology used in the manufacturing reduces the undesirable side effects associated with water-in-oil or water-in-oil-in-water adjuvants, while eliciting a rapid and strong immune response.

Dimethyl dioctadecyl ammonium bromide is a potent T-cell stimulator and promotes strong antibody and cell-mediated responses. Oil-in-water emulsion adjuvants form a mobile depot of antigen, activate recruitment of immune effector cells and improve overall antigen presentation. The combination of DDA and oil-in-water emulsion makes an effective adjuvant for strong protective immune response.

Emulsigen-D may be used in combination with aluminum hydroxide or other MVP adjuvants.

## INFORMATION ABOUT EMULSIGEN®-D

**Ingredients:** All ingredients are non-animal origin and 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. 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.

**Manufacturing and Testing:** Each ingredient contained 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 batch to batch consistency each lot is tested for viscosity, pH, specific gravity, and formaldehyde concentration (where applicable). Macroscopic and microscopic appearance is also carefully monitored during the manufacturing process. Other testing, including mouse safety, may be conducted at the customer's request.

**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. This is an excellent adjuvant for bacterial, mycoplasma, viral, subunit or recombinant antigens.

**Safety:** Emulsigen-D is less likely to cause adverse injection site reactions than conventional oil adjuvants.

**Stability:** Emulsigen-D has a precise HLB (hydrophilic-lipophilic balance) to create a stable emulsion. The use of precise HLB, particular emulsification process, and added emulsion-stabilizer resulted in uniform oil droplets and maximize stability thereby eliminating problems related to product separation and poor safety.

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

**Preservatives:** Emulsigen-D 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.

**Storage:** Emulsigen-D may be stored at  $4^{\circ}\text{C} - 30^{\circ}\text{C}$  ( $39^{\circ}\text{F} - 86^{\circ}\text{F}$ ). Temperature extremes should be avoided.

**Packaging:** Emulsigen-D is available in 10-, 20- and 50-liter containers. Other sizes can be supplied to meet each customer's needs and can also be provided in sterile bags.

**Uniformity:** The use of highly skilled operators and standardized manufacturing procedures helps ensure that each batch of Emulsigen-D will be consistent, uniform, and in compliance with established specifications.

## INSTRUCTIONS FOR USE

1. For most antigens, we recommend that Emulsigen-D be used at a concentration up to 20% (v/v).
2. Pre-mix the adjuvant prior to using. This may be done by agitating the container mechanically, or using magnetic stirrer or overhead stirrer. During storage, there could be a visible layering, which is normal for Emulsigen-D (it is not separation of the emulsion).
3. Start mixing the antigen at a moderate speed that may be done with a magnetic stir bar or a Lightning Mixer or other built-in mixer.
4. While the antigen is mixing, start adding required amount of adjuvant into the antigen containing vessel. Adjuvant may be pumped, pipetted, or poured slowly. The procedure can be done at a temperature range between  $4^{\circ}\text{C}$  to  $30^{\circ}\text{C}$ .
6. Continue mixing at least for 4 hours. For smaller volumes, 2 hours may suffice. Mixing speed will depend on the container size, mixer type, volume, and nature of the antigen. Generally, a moderate speed is recommended.
7. While continuously mixing, fill into final vaccine containers.
8. Vaccine should be stored and maintained at about  $4^{\circ}\text{C}$  or temperature range specified in your vaccine manufacturing guideline. Vaccine must not be frozen.
9. It is normal for final vaccines to develop a thin creamy layer on top during storage. This does not adversely affect the antigenicity or immunogenicity. Simple inversion of the vaccine bottle is adequate to obtain smooth homogeneous content.

## The Adjuvant Company That Understands Vaccines

To speak with an adjuvant expert: 402.331.5106 or 800.856.4648

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