



KEY POINTS

- Emulsigen® based dual adjuvant
- Formulated with a block copolymer immunostimulant
- 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®-BCL is an oil-in-water dual adjuvant emulsion, containing a polymer immunostimulant. It is free of animal origin components and its milky-white appearance creates a smooth, uniform mixture when added to your veterinary antigens.

This antigen-friendly adjuvant can be mixed with your antigen at any temperature 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-BCL contains uniformly dispersed, micron- sized oil droplets which ensure maximum emulsion stability and decreased viscosity. These micron- sized 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-BCL reduces the undesirable side effects associated with other oil-in-water adjuvants while still eliciting the rapid and strong immune response.

Emulsigen-BCL contains a block copolymer immunostimulant known to induce high titers and long-lasting antibody responses, cell mediated immunity, cytotoxic T-lymphocytes (CTLs) and modulate the isotype and specificity of antibodies.

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 and provides a significant antigen enhancement of the immune response and vaccine efficacy.

INFORMATION ABOUT EMULSIGEN®-BCL

Ingredients: Each lot of Emulsigen-BCL 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-BCL 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.

Manufacturing and Testing: Each ingredient contained in Emulsigen-BCL 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 specific gravity, viscosity, pH, and formaldehyde concentration (where applicable). Macroscopic and microscopic appearance are also carefully monitored during the manufacturing process. Other testing, including mouse safety, may be conducted at the customer's request.

Immune Response: Emulsigen-BCL has the potential to elicit higher levels of humoral antibody and cell-mediated immune responses, more rapid onset of immunity, and enhanced protection with a single vaccine dose as compared with conventional aluminum-based adjuvants. Emulsigen-BCL has been demonstrated to be an excellent adjuvant for virus vaccines and is expected to provide significant immune stimulation for bacterial, subunit and parasite vaccines.

Safety: Emulsigen-BCL is less likely to result in adverse injection site reactions occasionally seen with products containing conventional oil adjuvants.

Stability: Emulsigen-BCL has a precise Hydrophilic-Lipophilic balance (HLB) to maximize stability of the oil-in-water emulsion, and oil droplets of uniform micron size, thereby eliminating problems related to undesirable product separation and poor syringeability.

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

Preservatives: Emulsigen-BCL 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-BCL may be stored at 4°C - 30°C (39°F - 86°F). Temperature extremes should be avoided.

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

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

EMULSIGEN[®]-BCL INSTRUCTIONS FOR USE

1. For most antigens, we recommend that Emulsigen-BCL be used at a concentration up to 20% (v/v).
2. Pre-mix the adjuvant prior to using by gentle agitation, e.g., with a magnetic stirrer, overhead stirrer or agitating by hand.
3. Transfer the antigen into a mixing vessel or designated container and start mixing at a moderate speed (magnetic stir bar, over-head mixer or built-in agitator for large volume).
4. While the antigen is mixing, start adding required amount of adjuvant. Adjuvant may be pumped, pipetted, or poured slowly. The procedure can be done at a temperature range between 4°C to 30°C .
5. Continue mixing at least for four hours. For smaller volumes, two hours may suffice. Mixing speed will depend on the container size, mixer type, volume, and nature of the antigen.
6. Check pH and adjust if necessary (5N to 10N NaOH and HCl). Recommended pH is 6.8 - 7.2.
7. While continuously mixing, fill into final vaccine containers. Vaccine should be stored and maintained at about 4°C . Vaccine must not be frozen.
8. It is normal for final vaccines to develop a creaming layer on top during storage. This does not adversely affect 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