



EMULSIGEN[®]-BCL

(Emulsified Oil-in-Water Adjuvant + Immunostimulant)

Technical Bulletin

Summary of Key Points:

- EMULSIGEN[®] based
- Formulated with a block copolymer immunostimulant
- Free of animal origin ingredients
- Sterile
- Ready to add to antigen -- no further processing required
- Neutral in pH
- Manufactured using components on Annex II and/or various GRAS lists
- Known to stimulate humoral and T-cell response

EMULSIGEN[®]-BCL is a sterile, oil-in-water emulsion that is free of animal origin components. It's milky-white appearance creates a smooth, uniform mixture when added to your veterinary antigens. EMULSIGEN[®]-BCL is designed to be mixed directly with vaccine antigens, without any further processing, to enhance immunogenicity of the finished product.

EMULSIGEN[®]-BCL 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[®]-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 enhancement of the immune response and vaccine efficacy.

EMULSIGEN[®]-BCL may be combined with aluminum hydroxide. Contact MVP Laboratories for procedures.

INFORMATION ABOUT EMULSIGEN[®]-BCL

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.

Animal Safety: EMULSIGEN[®]-BCL is less likely to result in adverse injection site reactions occasionally seen with products containing conventional oil adjuvants. Each batch is safety tested in mice prior to release.

Stability: EMULSIGEN[®]-BCL 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[®]-BCL easily pass through a 25 gauge needle at 10°C (50°F).

Uniformity: The use of highly-skilled operators, state-of-the-art equipment and standardized manufacturing procedures ensures that each batch of EMULSIGEN[®]-BCL will be consistent, uniform, and comply with specifications.

Preservatives: EMULSIGEN[®]-BCL 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[®]-BCL is manufactured to the highest standards using the finest components available. All ingredients meet USP, NF or equivalent specifications. **EMULSIGEN[®]-BCL is free of animal origin ingredients.** All components, including the containers, are sterilized prior to use to ensure sterility of the final product.

In Vitro Testing: Each ingredient contained in EMULSIGEN[®]-BCL must meet stringent in-house parameters for purity and consistency. Each lot is thoroughly tested to ensure that it is free of viable bacteria and fungi. Viscosity, pH, formaldehyde concentration (if applicable), macroscopic and microscopic appearance and particle size analysis, are carefully monitored to maintain batch-to-batch uniformity and stability.

Storage: EMULSIGEN[®]-BCL may be stored at 4°C-25°C (39°F-77°F). Temperature extremes should be avoided.

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

INSTRUCTIONS FOR USE

- 1) For most antigens, we recommend that EMULSIGEN[®]-BCL be used at 15% to 20% (v/v).
- 2) EMULSIGEN[®]-BCL should be thoroughly mixed before adding to the antigen. It can be added to inactivated or modified live antigen 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[®]-BCL have been administered intramuscularly to young pigs with no adverse reactions being noted. Further animal testing is underway.

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