

## The Adjuvant Company That Understands Vaccines

## Discover the Difference

## WE DO THE HOMOGENIZATION FOR YOU SO YOU DON'T HAVE TO!

NO SPECIAL TEMPERATURE OR MIXING REQUIREMENTS WHEN ADDING MVP'S ADJUVANTS TO YOUR ANTIGENS – USER FRIENDLY – ANTIGEN FRIENDLY

MVP has been in the business of manufacturing and selling adjuvants since 1981. MVP began as a vaccine manufacturing company but, because good adjuvants are critical for the development of effective vaccines, their adjuvant formulation expertise was established first. Vaccine manufacturers throughout the world became interested in MVP adjuvants, and soon, MVP was selling its EMULSIGEN® family of adjuvants in forty-five countries and six continents. Since that time, MVP has expanded its EMULSIGEN® family by adding immunostimulants and polymers to produce new and improved adjuvants.

MVP's adjuvants are of two basic types: 1) oil-in-water; and 2) polymer, which are macromolecules, composed of many repeated subunits. All can be manufactured free of ingredients of animal origin. In addition, all ingredients meet USP, NF, EC Regulations or equivalent specifications and/or have been approved for vaccine production by USDA and/or regulatory agencies in other countries. MVP adjuvants are added to vaccine antigens at low concentrations (1-20%) and are, therefore, very cost-effective. In many cases, because of their capability to stimulate both humoral and cell mediated immune responses, reduced amounts of antigens can be used – increasing profitability of the final vaccines. Historical use and data indicate that MVP adjuvants are at least as effective as water-in-oil adjuvants or water-in-oil-in-water adjuvants with a more desirable safety profile.

One of the longstanding hallmarks of MVP adjuvants is the ease of vaccine preparation. Our adjuvants are carefully emulsified by a thorough milling process. This results in an emulsion that is extremely stable and uniform over the two-year life span of the adjuvant product. When preparing a vaccine, all that is required is a simple mixing procedure, using a Lightnin mixer or magnetic stirrers for a relatively short period of time of only 2 to 24 hours depending on volume. Temperature control and homogenization are not required. This simplicity makes the scale-up of vaccines from the R&D stage to manufacturing a straightforward process that results in batch to batch consistency and a shorter project timeline to market.

Generally, MVP adjuvants tend to be antigen-friendly as they can be mixed with your antigen over a broad range of temperatures using only mild mixing and no homogenization. Such a comparatively gentle process can serve to optimize immunogenicity of the finished product and improve the vaccine's safety profile.

EMULSIGEN®, MVP's pioneer product, was used in the first vaccine that contained an oil-in-water adjuvant that was approved by USDA for both intramuscular and subcutaneous injection of pigs. Since that approval in 1982, it has been used globally in 45 countries and has a proven track record of being consistently safe and effective in all species of animals.

As a forerunner, EMULSIGEN® now leads a family of oil-in-water adjuvants that incorporate various immunostimulants. EMULSIGEN®-D and EMULSIGEN®-DL90 are the most significant of these newer adjuvants. Both are formulated with dimethyldioctacecyl ammonium bromide (DDA) producing unique dual-adjuvant systems. These adjuvants have been demonstrated to have superior immunostimulating and safety characteristics when compared with water-in-oil and water-in-oil-in-water adjuvants. Available data and/or publications demonstrate the value of integrating these adjuvants into inactivated vaccines for swine influenza (IAV-S), Porcine Reproductive and Respiratory Syndrome (PRRSv), Porcine Epidemic Diarrhea (PEDv), Foot and Mouth Disease (FMD) and Newcastle Disease of poultry to cite a few examples. The EMULSIGEN® family of adjuvants also includes EMULSIGEN®-BCL and EMULSIGEN®-P that incorporate other types of immunostimulants.

CARBIGEN™ and POLYGEN™ are MVP's polymer-type adjuvants. Because of its muco-adhesive properties, CARBIGEN™ has been found to be particularly applicable for presenting inactivated antigens to mucosal membranes (e.g., intranasal). Intranasal vaccines incorporating inactivated antigens with CARBIGEN™ have been used successfully in horses, pigs and small animals. It has also shown exceptional performance in adjuvanting PCV2 antigens.

POLYGEN™ has an inherent ability to stimulate cell mediated immunity and is especially useful in small animal and bovine vaccines where increased T-cell responses are required. It has been shown to stimulate \( \cap \)-interferon and IL-12 when used in subunit and/or parasite vaccines.

EMULSIMUNE™ is the newest adjuvant being offered by MVP. It was initially developed for use with aquaculture antigens. Some of these microorganisms produce enzymes that break emulsions and allow the vaccines to leak out of the injection sites. EMULSIMUNE™ overcomes this problem. It has been shown to provide significant protection when evaluated in a vaccination/challenge model using *Streptococcus agalactiae* in Tilapia.

MVP adjuvants utilize HLB (Hydrophile-Lipophile Balance) technology to maximize the stability of the oil-in-water emulsion. The HLB eliminates problems related to undesirable product separation and poor syringeability. The particle size is carefully maintained so as to increase the contact surface area available to antigens, reducing the quantity of oil required in the final product. Maintaining optimum particle size assures a maximum adjuvant stability and decreased viscosity. These characteristics result in improved safety of final vaccine products by reducing injection site issues.

The low viscosity aids in the physical addition of the adjuvants to vaccine antigens during production mixing and allows for ease of administration of the final vaccine products, even in colder temperatures.

MVP adjuvants have been successfully utilized with a multitude of antigens including those associated with bacteria, viruses and parasites. These antigens have been produced from whole cultures, recombinant and subunit technology, and DNA purification or synthesis. Routes of administration include IM, SQ, IP and IN, all of which aid vaccine manufactures in producing safe and efficacious vaccines. They have been used in vaccines for numerous animal species including zoo animals such as elephants and alligators.

MVP adjuvants are known for: 1) their ease of use in vaccine formulation wherein no temperature control or homogenization is required; 2) friendliness to antigens of all types including bacterial, viral, subunit, recombinant, parasite, and DNA; 3) effectiveness when used with all types of antigens, including FMD; and 4) safety when compared with water-in-oil and water-in-oil-in-water adjuvants.