CARBIGEN® -VP

(Polymer Adjuvant)

KEY POINTS

- Carbomer based
- Free of animal origin ingredients
- EC Regulation No. 470/2009, and USP-NF compendia compliant
- Ready to use
- Best with pH stable antigens
- Stimulates humoral and cellular responses
- Suitable and effective for mucosal application

Carbigen®-VP polymer adjuvant is a ready-to-use, carbomer-based adjuvant containing a proprietary emulsified component. It contains a cross-linking polymer that encapsulates the antigen, which improves antigen stability, processing, and presentation to effector cells; thus, significantly enhancing the immune response and vaccine efficacy. It has a milky-white appearance and creates a smooth, homogenous mixture when added to your veterinary vaccine.

It is prepared in a non-buffered base and has a low pH. ***Antigen-adjuvant binding is more efficient when the adjuvant is used directly without preadjusting the pH.*** The adjuvant works best with pH stable antigens. For antigens that are sensitive to low pH, the adjuvant may be diluted with a buffer such as PBS, and its pH raised to about 6.0 by slowly adding NaOH solution, which then can be added to the antigen. ***Carbigen-VP is suitable for antigen delivery by mucosal routes such as intranasal, intraocular, and oral, as well as by immersion for fish vaccine.***

INFORMATION ABOUT CARBIGEN-VP

Ingredients: Free of animal origin, this product contains carbomer and various lipids. All ingredients meet USP-NF and EP monographs.

Manufacturing and Testing: Each ingredient is tested to meet stringent in-house parameters for identity and consistency. The adjuvant is manufactured under aseptic conditions following standardized manufacturing procedures. Consistency of manufacturing is monitored by specific gravity, pH and appearance. Purity (freedom from viable bacteria and fungi) is tested according to USDA guidelines for veterinary biologicals.

Immune Response: Carbigen-VP has the potential to elicit higher levels of humoral antibody and cellular immunity, with a rapid onset and longer protection in a single vaccine dose, as compared with conventional aluminum-based adjuvants. It may be used with any type of antigen such as whole organisms, proteins, polysaccharides, DNA, RNA, VLP and others. It can also be used with certain live and vectored antigens. Vaccines containing Carbigen-VP can be administered parenterally or by mucosal routes as well as by immersion for fish.

Safety: Carbigen-VP is safe in all animal species. All ingredients are safe for use in food producing animals being recognized as either food additives that require no MRL, are on EC 37/2010 or EC 470/2009 as requiring no MRL or substances considered as not falling within the scope of Regulation (EC) No. 470/2009, with regard to residues of veterinary medicinal products in foodstuffs of animal origin ('out of scope list').

Stability: Carbigen-VP is a stable polymer-emulsion suspension.

Syringeability: Vaccines containing up to 20% Carbigen-VP can easily pass through a 25-gauge needle.

Preservatives: Carbigen-VP is supplied without a preservative; however, it is compatible with most preservatives. No re-sterilization is required.

Storage: This product is shipped at ambient temperature and should be stored at 4°C - 30°C (39°F - 86°F).

Packaging: Available in 10-, 20- and 45- liter containers, Carbigen-VP can also be supplied in custom bags.

CARBIGEN®-VP INSTRUCTIONS FOR USE

Depending on the type of antigen you are working with, these are the basic steps to follow:

1. Determine the amount of adjuvant required based on targeted inclusion rate; the standard inclusion rate for injectables can be up to 15% v/v, and for mucosal and immersion applications 20% - 40% v/v.
2. Mix the adjuvant by gentle agitation or with a stir bar prior to addition to the antigen.

   * *If the antigen is SENSITIVE to low pH, the pH of Carbigen-VP may be raised before adding it to the antigen. Increase the pH with NaOH solution to the lowest pH that the antigen can tolerate, approximately a pH of 6.0. The viscosity will increase as the pH increases. Addition of a small amount of NaCl or PBS can reduce the viscosity and aid in mixing.*
3. Mix the antigen at moderate speed - mixing speed will depend on the volume, mixing vessel size and mixer type. For large scale mixing tanks use median speed. For small scale, magnetic stir bars or an overhead mixer will work.
4. While the antigen is mixing, start adding required volume of Carbigen-VP slowly. This may be accomplished by pouring, pipetting, or pumping into the mixing vessel.
5. After all required volume of adjuvant has been added, continue mixing for at least two hours while slowly raising the pH to between 6.8 and 7.2 using either 5N or 10N NaOH solution. The viscosity of the antigen-adjuvant mixture will increase with the pH change. It is best to make a small mock batch to gauge approximately how much volume of NaOH will be required. Raising the pH swiftly can damage the antigen. Addition of acids to bring pH down, such as hydrochloric and citric acid, may decrease the effectiveness of the adjuvant.
6. Continue mixing until pH is stabilized, at least four hours for small volumes and six hours or longer for large volumes.
7. When different fractions or types of antigens are present, it is advisable to adjuvant each fraction separately for optimal adjuvant-antigen interaction. After individual fractions are adjuvanted, pool all together and mix for two to six hours to obtain consistency.

The Adjuvant Company That Understands Vaccines

MVP adjuvants®

To speak with an adjuvant expert: 402.331.5106 or 800.856.4648

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