



Product Specification Sheet

Alhydrogel® Vaccine Adjuvant (FDA-Approved)

<input type="checkbox"/> Cat. # AV-1010-50	Alhydrogel® 2%, Vaccine adjuvant, FDA Approved	SIZE: 50 ml
<input type="checkbox"/> Cat. # AV-1010-100	Alhydrogel® 2%, Vaccine adjuvant, FDA Approved	SIZE: 100 ml

General Information: The word '**adjuvant**' is derived from the Latin word '*adjuvare*' which means '**to help**'. Therefore, Immunologic Adjuvants are added to vaccines to stimulate the immune system's response to the target antigen, but do not in themselves confer immunity. Adjuvants act in various ways in presenting an antigen to the immune system. Adjuvants can act as a depot for the antigen, presenting the antigen over a long period of time, thus maximizing the immune response before the body clears the antigen. Examples of depot type adjuvants are oil emulsions. Adjuvants can also act as an irritant which causes the body to recruit and amplify its immune response. A tetanus, diphtheria, and pertussis vaccine, for example, contains minute quantities of toxins/toxoids produced by each of the target bacteria. The body's immune system develops an antitoxin to the bacteria's toxins, not to the aluminum, but would not respond enough without the help of the aluminum adjuvant. Adjuvants have also evolved as substances that can aid in stabilizing formulations of antigens, especially for vaccines administered for animal health.

Adjuvants augment the effects of a vaccine by stimulating the immune system to respond to the vaccine more vigorously, and thus providing increased immunity to a particular disease. Adjuvants accomplish this task by mimicking specific sets of evolutionarily conserved molecules, so called PAMPs, which include liposomes, lipopolysaccharide (**LPS**), molecular cages for antigen, components of bacterial cell walls (e.g., **flagellins**), and endocytosed nucleic acids such as double-stranded RNA (**dsRNA**), single-stranded DNA (**ssDNA**), and unmethylated CpG dinucleotide-containing DNA (**ODNs**). Natural proteins such as **ovalbumin** or OVA-peptides and key hole limpet hemocyanins (**KLH**) are also being explored not only serve as carrier protein but also as adjuvants. Because immune systems have evolved to recognize these specific antigenic moieties, the presence of an adjuvant in conjunction with the vaccine can greatly increase the innate immune response to the antigen by augmenting the activities of dendritic cells (DCs), lymphocytes, and macrophages by mimicking a natural infection. Furthermore, because adjuvants are attenuated beyond any function of virulence, they pose little or no independent threat to a host organism.

For human vaccines, aluminum hydroxide (Alum) based adjuvants (Aluminum hydroxide or Alhydrogel; Aluminium phosphate or Adjuphos) are the only **FDA-approved adjuvants**. Vaccine components that are formulated in Alum are called "Adsorbed Vaccines". The effectiveness of each salt as an adjuvant depends on the characteristics of the specific vaccine and how the manufacturer prepares the vaccine

Not all vaccines contain Alum because an adjuvant may not have been needed, was not expected to increase the desired immune response, or was going to cause an imbalance in the immune response. For example, **inactivated Polio Virus (IPV/IPOL)** vaccine, measles, mumps and rubella vaccine (**MMR/MMRII/MMRV**), **Varicella or chickenpox vaccine (Varivax/Proquad/MMRV)**, **Meningococcal conjugate (MCV4/Menomune/Menactra)** vaccine, and **influenza vaccines (Fluzone/Flulaval/Flumist/Fluvirin etc)** do not contain aluminum salts.

Product Information

Alhydrogel®, FDA approved is manufactured by Brenntag Biosector, Germany. Alhydrogel 2% has worldwide acceptance and it is used in many vaccines (see General Information). Alhydrogel is the standard preparations for immunological research on aluminum hydroxide gels. The use of aluminum adjuvants is accompanied by stimulation of IL-4 and stimulation of the T-helper-2 subsets in mice, with enhanced IgG1 and IgE production. Aluminum hydroxide gel (Alhydrogel®) is obtained by precipitation of aluminum hydroxide Al(OH)₃ under alkaline conditions. It is currently used as an adjuvant in subunit, DNA and conjugate vaccines.

CAS Number.: 21645-51-2

Formulation: Al(OH)₃, Aluminium hydroxide gel

Appearance: White gelatinous precipitate

Aluminium content: 9.0 – 11.0 mg/ml

pH: ~6-7

Binding capacity: 10-20 mg human serum albumin per ml gel at pH 7.0. Note: Protein binding will vary with protein concentration, buffer and incubation conditions.

Form: Alhydrogel ® 2% is supplied as ready to use, gel suspension, sterile solution.

Storage and Stability: Shipped at room temperature and it should be stored at room temp. DO NOT FREEZE. Stable for 6 months.

Suggested Usage: Adsorption of most proteins can be achieved by mixing protein solution with Alhydrogel (1:1 or 1:10 v/v ratio of gel:protein can be tested) with gentle mixing at room temperature for 2-24 hrs. Protein left in the supernatant can be measured by protein assay or specific ELISA.

Alhydrogel adsorbed proteins can be injected into animals at a desired dose. If diluting the stock adsorbed-protein gel, volume can be adjusted with non-adsorbed gel to keep the same amount of gel. In veterinary vaccines there is no defined maximum limit for the allowed content of aluminium adjuvants.

References: Lindblad EB (2010) in Vaccine Adjuvants, Hem SL (2007) J. Parent. Sci. Tech. 38, 2-11; Lindblad EB (2004) Vaccine 22, 3658-3668;

Related items:

Catalog# ProdDescription

AV-1000-PK-1	Alum Gel Combo, Trial Pak-1 (Contains 10 ml each of Alhydrogel, Adjuphos, and Calcium Phosphate gels)
AV-1015-100	Adjuphos® aluminum phosphate (Th2) Vaccine adjuvant, FDA Approved
AV-1015-250	Adjuphos® aluminum phosphate (Th2) Vaccine adjuvant, FDA Approved
AV-1020-100	Calcium phosphate vaccine adjuvant
AV-1020-250	Calcium phosphate vaccine adjuvant

Complete list is available at:

http://www.4adi.com/objects/catalog/product/extras/ODN_Vaccine_Flr.pdf

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