

Product Information Sheet for NR-10476

Fluzone[®] Influenza Virus Vaccine, 2004-2005 Formula

Catalog No. NR-10476

This reagent is the property of the U.S. Government.

For research use only. Not for human use.

Contributor:

National Institutes of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH)

Manufacturer:

Aventis Pasteur, Inc.

Product Description:

NR-10476 is a split-virus vaccine prepared from influenza viruses A/New Caledonia/20/99 (H1N1), A/Wyoming/3/03 (H3N2) [an A/Fujian/411/02 (H3N2)-like strain] and B/Jiangsu/10/03 (a B/Shanghai/361/02-like strain) that were predicted to circulate in the United States during the 2004 to 2005 influenza season. 1.2

NR-10476 was prepared from the extra-embryonic fluid of embryonated chicken eggs. The fluid containing the virus was harvested and inactivated with formaldehyde. The inactivated virus was concentrated and purified in a linear sucrose density gradient solution using a continuous flow centrifuge. The virus was then chemically disrupted using a nonionic surfactant (Triton® X-100) producing a split-virus. The split-virus was further purified by chemical means and suspended in sodium phosphate-buffered isotonic sodium chloride solution. Gelatin 0.05% was added as a stabilizer. NR-10476 was formulated without preservatives but contains a trace amount of thimerosal (mercury derivative) from the manufacturing process.²

The hemagglutinin content was standardized according to U.S. Public Health Service requirements. Each 0.25 mL syringe contains the recommended ratio of 7.5 µg each of the hemagglutinin antigens from influenza viruses A/New Caledonia/20/99 (H1N1), A/Wyoming/3/03 (H3N2) and B/Jiangsu/10/03.

Please note that this vaccine preparation is being released <u>for research use only</u> and not for human use. Vaccines produced for the 2004-2005 season are now past their expiration dates.

Material Provided:

Each syringe contains 0.25 mL of split-virus vaccine in phosphate-buffered saline containing 0.05% gelatin and a trace amount of thimerosal (≤ 0.5 µg mercury).

Packaging/Storage:

NR-10476 contains a pre-filled 0.25 mL syringe. The product is provided on refrigerated bricks and should be stored at 2°C to 8°C immediately upon arrival. Do not freeze.

Citation:

Acknowledgment for publications should read "The following reagent was obtained through the NIH Biodefense and

Emerging Infections Research Resources Repository, NIAID, NIH: Fluzone® Influenza Virus Vaccine, 2004-2005 Formula, NR-10476."

Biosafety Level: 1

Appropriate safety procedures should always be used with this material. Laboratory safety is discussed in the following publication: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, and National Institutes of Health. Biosafety in Microbiological and Biomedical Laboratories. 5th ed. Washington, DC: U.S. Government Printing Office, 2007; see www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm.

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References:

- Harper, S. A., et al. "Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP)." <u>MMWR</u> <u>Recomm. Rep.</u> 53 (2004): 1-40. PubMed: 15163927.
- http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm127192.htm

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