



MedImmune

Medical Affairs Department

Phone: 800-949-3789 Fax: 800-959-4033

One MedImmune Way, Gaithersburg, MD 20878

Website: <http://www.medimmune.com>

July 14, 2011

Anna Podlas
DLA Troop Support
700 Robbins Ave
Philadelphia, PA 19111

Dear Anna Podlas:

Thank you for your recent inquiry concerning the use of **FLUMIST**, forwarded to me for a reply by our representative.

Attached are individual answers and a bibliography for each of the questions you asked. These are itemized below:

• **FluMist® (Influenza Vaccine Live, Intranasal) and MSDS [CAIVMS503]**

Your interest in FLUMIST is appreciated. This letter and citations are not intended to offer an opinion or advice on administering our products in a manner inconsistent with product labeling. A copy of the currently approved U.S. package insert(s) is enclosed for your review. Please feel free to call us if we can be of further assistance.

Sincerely,

Eddie Carver, PharmD
Senior Information Specialist
(Phone: 800-949-3789 / e-mail: CarverE@medimmune.com)

RE: FluMist® (Influenza Vaccine Live, Intranasal) and MSDS [CAIVMS503]

In accordance with 29 CFR 1900.1200, the OSHA Hazard Communication Standard, this product is not deemed to be hazardous. **Based on a hazard determination as required by the Standard, FluMist® does not meet the definition of a hazardous chemical.** Therefore, there is no MSDS for this product.

MedImmune recognizes that you want to provide as much safety information as possible to your employees regarding the materials they handle and we are happy to assist you in your efforts.

FluMist is a live attenuated trivalent vaccine given via nasal administration. There is no toxicity or transmission of influenza expected from incidental occupational exposure to this product. Those administering FluMist should utilize universal precautions, including hand washing. Gloving may be appropriate at the health care provider's discretion. Clean up spills of the product with a disinfectant such as 0.05% sodium hypochlorite solution or 3% hydrogen peroxide. The package insert **DOSAGE AND ADMINISTRATION/Administration instructions**, Section 2.2, provides additional information regarding the product, including how to dispose this product:

“Once the vaccine has been administered, the sprayer should be disposed of according to the standard procedures for medical waste (e.g., sharps container or biohazard container).”

If you have any further questions regarding an MSDS, please call our Medical Information Department at 1-877-633-4411.

LITERATURE CITED: Cited references are listed alphabetically by lead author surname. Copies are available upon request.

*FluMist® (Influenza Vaccine Live, Intranasal). 2010-2011 Formulation. MedImmune, LLC. Product/prescribing information as of July 2010. [[MRM 48778](#)]

*AAP (American Academy of Pediatrics). Policy Statement. Prevention of influenza: Recommendations for influenza immunization in children, 2010-2011. *Pediatrics* 2010; 126:1-12 Published online Aug 30, 2010; DOI: 10.1542/peds.2010-2216 [[MRM48894](#)]

*Belshe RB, Gruber WC, Mendelman PM, et al. Correlates of immune protection induced by live, attenuated, cold-adapted intranasal influenza virus vaccine. *J Infect Dis.* 2000;181:1133-1137. [[MRM 19,176](#)]

*Boyce TG, Gruber WC, Coleman-Dockery SD, et al. Mucosal immune response to trivalent live attenuated intranasal influenza vaccine in children. *Vaccine.* 2000;18:82-88. [[MRM 19,385](#)]

*CDC-ACIP (Centers for Disease Control and Prevention/Advisory Committee on Immunization Practices). Prevention and Control of Influenza. Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 2010/July 29; 59 (Early Release):1-62 [[MRM48881](#)]

*Treanor JJ, Kotloff K, Betts RF, et al. Evaluation of trivalent, live, cold-adapted (CAIV-T) and inactivated (TIV) influenza vaccines in prevention of virus infection and illness following challenge of adults with wild-type influenza A (H1N1), A (H3N2), and B viruses. *Vaccine.* 2000;18(9-10):899-906. [[MRM 19,170](#)]

Important Safety Information for FluMist®

FluMist is a vaccine indicated for active immunization of individuals 2 - 49 years of age against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine. FluMist is contraindicated in individuals with history of hypersensitivity to eggs, egg proteins, gentamicin, gelatin or arginine or with life-threatening reactions to previous influenza vaccinations, and in children and adolescents receiving concomitant aspirin or aspirin-containing therapy.

Do not administer FluMist to children <24 months of age due to an increased risk of hospitalization and wheezing that was observed in clinical trials. FluMist should not be administered to any individual with asthma and to children <5 years of age with recurrent wheezing unless the potential benefit outweighs the potential risk. Do not administer FluMist to individuals with severe asthma or active wheezing.

If Guillain-Barré syndrome has occurred with prior influenza vaccination or if an individual is immunocompromised, the decision to give FluMist should be based on careful consideration of the potential benefits and risks. FluMist should not be administered to individuals with underlying medical conditions predisposing them to wild-type influenza infection complications unless the potential benefit outweighs the potential risk. FluMist should be given to a pregnant woman only if clearly needed.

Most common adverse reactions (occurring at $\geq 10\%$ in individuals receiving FluMist and at least 5% greater than in placebo) are runny nose or nasal congestion in recipients of all ages, fever $>100^{\circ}\text{F}$ in children 2-6 years of age, and sore throat in adults.

FluMist may not protect all individuals receiving the vaccine. FluMist is for intranasal administration only.

Please see accompanying complete Prescribing Information.