SAFETY DATA SHEETS

This SDS packet was issued with item:

078934937

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078934935

1031 Mendota Heights Road Saint Paul, MN 55120 800.328.5536

To Whom It May Concern:

In response to your request for a Safety Data Sheet [SDS] for the Patterson product in question, please be advised that this product is not subject to SDS requirements outlined in 29 CFR 1910.1200 because it meets one or more criteria below:

Article is designed as a manufactured item other than a fluid or particle which is formed to a specific shape or design during manufacture; which has end use function(s) dependent in whole or in part upon it shape or design during end use; and which under normal conditions of use does not release more than very small quantities, e.g., minute or trace amounts of a hazardous chemical that does not pose a physical hazard or health risk to employees.

<u>Drug</u>, as defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), when it is in solid, final form for direct administration to the patient (e.g., tablets or pills); drugs which are packaged by the chemical manufacturer for sale to consumers in a retail establishment (e.g., over-the-counter drugs); and drugs intended for personal consumption by employees while in the workplace (e.g., first aid supplies);

<u>Cosmetic</u> which are packaged for sale to consumers in a retail establishment, and cosmetics intended for personal consumption by employees while in the workplace.

<u>Consumer product</u> or hazardous substance, as those terms are defined in the Consumer Product Safety Act (15 U.S.C. 2051 et seq.) and Federal Hazardous Substances Act (15 U.S.C. 1261 et seq.) respectively, where the employer can show that it is used in the workplace for the purpose intended by the chemical manufacturer or importer of the product, and the use results in a duration and frequency of exposure which is not greater than the range of exposures that could reasonably be experienced by consumers when used for the purpose intended;

Non-Hazardous Products

Paragraph 29 CFR 1910.1200(g)(8) states that the "employer shall maintain in the workplace copies of the required SDSs for each hazardous chemical". OSHA does not require nor encourage employers to maintain SDSs for non-hazardous chemicals.

Pesticides

Pesticides as defined in the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 126 et seq.), when subject to the labeling requirements of that Act and labeling regulations issues under that Act by the Environmental Protection Agency.

Food, Additive, Medical or Veterinary Device

Any food, food additive, color additive, drug, cosmetic, or medical or veterinary device or product, including materials intended for use as ingredients in such products (e.g. flavors and fragrances), as such terms are defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or the Virus-Serum-Toxin Act of 1913 (21 U.S.C. 151 et seq.), and regulations issued under those Acts, when they are subject to the labeling requirements under those Acts by either the Food and Drug Administration or the Department of Agriculture.

Hazardous Waste

Any hazardous waste as such term is defined by the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C. 6901 et seq.), when subject to regulations issued under that Act by the Environmental Protection Agency

Hazardous Substances for Remediation

Any hazardous substance as such term is defined by the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) (42 U.S.C. 9601 et seq.) when the hazardous substance is the focus of remedial or removal action being conducted under CERCLA in accordance with Environmental Protection Agency regulations.

Tim Blodgett, MS, CIH, CSP Director, Environmental Health and Safety Patterson Companies

BIOLOGICAL PRODUCT SUMMARY SHEET

Version: 1.0 Date of First Issue: 9-Aug-20 Revision Date: 9-Aug-20

Prestige 3+WNV®

IDENTIFICATION

Organism: Inactivated Clostridium tetani toxin, inactivated equine

encephalomyelitis viruses (Eastern and Western) and inactivated West

Nile virus-flavirus chimera

Human or Veterinary Use: Prestige 3+WNV ®

Biological Product Type: A combination of inactivated, concentrated, adjuvanted viral vaccine

COMPANY INFORMATION

Company Address: Merck & Co., Inc.

126 East Lincoln Ave. P.O. Box 2000,

Rahway, NJ 07065

Emergency Telephone Number: 1-908-423-6000 (24/7/365)

BIOLOGICAL SAFETY HAZARD IDENTIFICATION

Biosafety Risk Group Classification: Risk Group 1

Special circumstances for medical professionals or veterinarians handling live agent (if needed):

Live cultures: Workers handling live cultures shall utilize BSL-2 and BSL-2 Large Scale precautions.

Inactivated cultures: Once the whole fermentation broth is formalin treated, there is no infectious or toxin risk. The inactivated toxins (toxoid) function as an antigen. Appropriate chemical safety precautions shall be taken while handling concentrated formalin and thimerosal.

Active toxin (any concentration): Exposure to crude toxin is expected to cause local tissue damage; however, the exposure site is not infectious as clostridial spores/vegetative cells are absent.

Inactive toxin (any concentration): Exposure to inactive crude toxin may cause local tissue irritation or damage; however, the exposure site is not infectious as clostridial spores/vegetative cells are absent.

Immune Status: No Immune status issues.

Pregnancy: No issues with pregnancy.

Special circumstances for workers handling packaged product (if needed):

Immune Status: No immune status issues.

Pregnancy: No issues with pregnancy.

Medical risk for medical professionals or veterinarians handling live agent (if needed):

Final vaccine product: There is no active toxin or live virus present. The vaccine is not infectious to humans or animals. Accidental injection via puncture or cuts can cause serious local reactions.

Medical Surveillance for workers handling packaged product (if needed): None

First Aid: In case of accidental self-injection, seek medical advice immediately and show the package insert or label to the physician. Show this document to the consulting physician.

BIOLOGICAL PRODUCT SUMMARY SHEET

Version: 1.0 Date of First Issue: 9-Aug-20 Revision Date: 9-Aug-20

Decontamination:

BIOLOGICAL SAFETY HANDLING INFORMATION

Spills of product:

Live cultures, including concentrated active toxin: Follow instructions found in your site biosafety risk assessment.

Inactivated cultures and toxins: The final formulated vaccine does not contain live organisms; therefore special biosafety spill procedures are not required. Spill cleanup is to be handled as per departmental SOP. If no SOP available, contain material using a spill pillow or absorbent material and dispose of according to departmental procedures. Soap and water can be used to clean up the area. Minimal personal protective equipment includes safety glasses, lab coat/work uniform, gloves and slip resistant shoe covers.

OTHER INFORMATION					
	Comments: None				
• •	g Classification Keywords:	☐ Infectious Human	☐ Infectious Animal	□ CAT A	
sarety g	glasses, lab coat/work uniform,	gioves and slip resistant	snoe covers.		

References:

1. ENCEVAC® T + WNV WITH HAVLOGEN® product information sheet, http://www.merck-animal-health-usa.com/products/encevac/overview.aspx, accessed 10/29/2020.

This information in this Biological Product Summary Sheet (BPSS) is a compilation of publicly available information and is correct to the best of our knowledge and belief at the date of its publication.

This is NOT a Safety Data Sheet (SDS) nor is it intended to meet the requirements of an SDS. SDSs convey the hazards of chemicals, not biologicals. Merck is providing this BPSS WITHOUT WARRANTY OR GUARANTEE OF ANY KIND, WHETHER EXPRESSED, IMPLIED OR STATUTORY, INCLUDING WITHOUT LIMITATION ANY AND ALL WARRANTIES OF MERCHANTABILITY, FITNESS FOR PARTICULAR PURPOSE OR INTELLECTUAL PROPERTY INFRINGEMENT. The information is designed only as a guidance for safe handling, transportation, disposal and release. The information provided relates only to the specific material identified at the top of this BPSS and may not be valid when the BPSS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the BPSS material in the user's product, if applicable.

Questions may be directed to email: EHSDATASTEWARD@merck.com. Reference "Biological Product Summary Sheet Inquiry" in the subject line to ensure your request is appropriately directed. Include the Product Name, Revision Date, BAR ID Number and details of the request in the body of the email.