SAFETY DATA SHEETS

This SDS packet was issued with item: 078935389

N/A

BIOLOGICAL PRODUCT SUMMARY SHEET

Version: 1.0

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

Prestige 3

IDENTIFICATION					
Organism:	Inactivated <i>Clostridium tetani</i> toxin; inactivated equine encephalomyelitis viruses (Eastern and Western)				
Human or Veterinary Use:	Prestige 3				
Biological Product Type:	Formaldehyde inactivated, 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):

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.

Immune Status: No immune status issues.

Pregnancy: No issues with pregnancy.

Medical risk for medical professionals or veterinarians handling live agent (if needed): None

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.

Decontamination:

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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.

Shipping Classification Keywords:	Infectious Human	Infectious Animal	🗆 CAT A	
CAT B GMO				

Comments: None

OTHER INFORMATION

References:

1. ENCEVAC[®] T WITH HAVLOGEN[®] product information sheet, http://www.merck-animal-healthusa.com/products/130_120669/productdetails_130_121127.aspx, accessed 10/29/2020.

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