

BIOLOGICAL PRODUCT SUMMARY SHEET

Version: 1.0

Date of First Issue: 9 June 2022
Revision Date: 8-Nov-2022

Toxovax®

IDENTIFICATION

Organism: Attenuated *Toxoplasma gondii* (Strain 48)
Human or Veterinary Use: Veterinary
Biological Product Type: Attenuated Live 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 2

Special circumstances for veterinarians handling product (2):

Immune Status: Caution for compromised immune systems - consult physician.

Pregnancy (2): Consult physician for pregnancy precautions. Toxovax should not be handled by pregnant women, or women of child bearing age as the vaccine may interfere with normal fetal development.

Special circumstances for workers handling packaged product (2):

Immune Status: Caution for compromised immune systems - consult physician.

Pregnancy (2): Consult physician for pregnancy precautions. Toxovax should not be handled by pregnant women, or women of child bearing age as the vaccine may interfere with normal fetal development.

First Aid (2): Living tachyzoites can cause human disease. Care should be taken to avoid self-injection and to avoid vaccine getting into the mouth or the eyes. In case of accidental self-injection, immediate medical advice should be sought and the doctor should be informed that self-injection with a living tachyzoite toxoplasma vaccine has occurred. Pyrimethamine therapy is the current recognized treatment for toxoplasmosis in humans. Show this document to the consulting physician.

Decontamination: Skin contact-use soap and water. Eye Contact-Immediate irrigation of eyes with large amounts of tap water is beneficial. Oral Ingestion-Do not administer anything by mouth for any poison ingestion unless advised to do so by a poison control center or emergency medical personnel because it may be harmful. Possible adverse effects of water or milk administration include emesis and aspiration.

BIOLOGICAL PRODUCT SUMMARY SHEET

Version: 1.0

Date of First Issue: 9 June 2022
Revision Date: 8-Nov-2022

BIOLOGICAL SAFETY HANDLING INFORMATION

Spills of product: The standard procedure for a spill in an open area is to leave the area for 30 min prior to returning to disinfect the area. Wear gloves, safety glasses, surgical mask or respirator (as allowed by national regulation), "bunny" suit, and shoe covers. In the absence of a suitable disinfectant, a 5% ammonium hydroxide solution (NH₄OH, CAS No 1336-21-6) is applied for 30 minutes to all exposed surfaces (3). Ventilate the area well and select appropriate PPE to avoid inhalation and skin/eye exposure.

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

Comments: US CDC Import Permit is required to return overseas study samples to the US.

Final packaged products manufactured and packaged in accordance with the requirements of appropriate national authorities that being distributed for use are not subject to regulation as a Dangerous Good.

OTHER INFORMATION

References:

1. <https://www.msd-animal-health.co.nz/products/yersiniavax/>, accessed 9/Jun/2022.
2. https://www.hpra.ie/img/uploaded/swedocuments/Licence_VPA10996-080-001_15122021170355.pdf, accessed 9/Jun/2022.
3. Dubey J, Miller NL, Frenkel J. Characterization of the new fecal form of *Toxoplasma gondii*. J Parasitol. 1970;56(3):447–56.

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.