

Note: This product is distributed in the U.S. by Organon USA Inc. For information on BCG, call Organon USA Inc. 1-800-842-3220.

1. PRODUCT IDENTIFICATION

Product:	BCG LIVE, TICE® BCG	NDC # 0052-0602-02
	BCG Vaccine, strain TICE®	NDC # 0052-0603-02
	Onco TICE® BCG	DIN # 02153513 (Organon Canada- Distributed By Mayne Pharma)
	OncoTICE® BCG	Article Number 45010001 (N.V. Organon)
Synonyms: Bacillus Calmette-Guerin Vaccine, TICE® BCG		

2. HAZARDOUS INGREDIENTS

Hazardous ingredients :

This product is a live attenuated culture preparation of the BCG (Bacillus, Calmette-Guerin) strain of *Mycobacterium bovis*.

Contains 1 to 8 x 10⁸ colony forming units of *Mycobacterium bovis* BCG.

3. HEALTH HAZARD INFORMATION

As with all biological products, avoid unnecessary exposure to BCG.

Accidental exposure to BCG could occur through self-inoculation, by dermal exposure through an open wound, or by inhalation or ingestion.

Based on clinical experience, BCG exposure should not produce significant adverse health outcomes in healthy individuals. A symptomatic positive skin test conversion equivalent to BCG vaccination could result, however. All exposure events should be reported to a physician as PPD skin testing is advised at the time of the accident and six weeks later to detect skin test conversion. A positive skin test conversion following exposure to BCG should be evaluated by a physician. Infection and sepsis could result if exposed. Following an exposure event, a fever of unknown origin or other unexplained symptoms persisting for more than two days should be evaluated by a physician. Individuals with impaired immune response, whether congenital, drug or disease induced, are at risk of systemic infection, and should be promptly evaluated by a physician when exposure to BCG is suspected. Refer to package insert.

4. FIRST AID

Eye Contact: Flush with copious amounts of water for at least fifteen minutes while holding the eye open. Seek evaluation by a physician.

Skin Contact: In the event of skin contact, exposure of open sores, or finger lacerations, thoroughly wash the affected area with soap and water and clean the wound with alcohol. Seek evaluation by a physician.

Inhalation: Remove to fresh air. Seek evaluation by a physician.

5. FIRE FIGHTING

Fire Extinguishing Materials: This product is not flammable. Use whatever extinguishing materials are appropriate for surrounding fire.

6. SPILL AND LEAK INFORMATION

Spill Response: Cover with paper towels. Soak the towel with a tuberculocidal disinfectant. Allow soaked towel to sit for a least 10 minutes. Carefully gather all waste materials into a biohazard bag, autoclave, and dispose of properly or alternately dispose of as medical waste via a medical waste contract provider.

7. HANDLING AND STORAGE

TICE® BCG is an active biological and aseptic technique should be used while handling and reconstituting. TICE® BCG should be stored at 2° C to 8° C and protected from the light.

8. EXPOSURE CONTROL/PERSONAL PROTECTION

Good hygiene practices should be followed while handling and reconstituting this product. Disposable gloves and a laboratory coat and mask should be worn when handling TICE® BCG. If splash is possible, eye protection is recommended.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Light tan to cream colored lyophilized cake.

Soluble in Water: N/A (Product forms a suspension in water).

Boiling Point: Not Applicable

10. STABILITY AND REACTIVITY

Stability: Stable

Hazardous Polymerization: Not Applicable

11. TOXICOLOGICAL INFORMATION

BCG LIVE/BCG Vaccine is a FDA approved parenteral biological drug product. Refer to package insert for product safety information.

12. ECOLOGICAL INFORMATION

The ecological effects of this product have not been evaluated, however, due to the small quantities involved, Organon Teknika Corporation, LLC would not anticipate any adverse effects.

13. DISPOSAL CONSIDERATIONS

Handle waste as biohazardous material.

14. SHIPPING INFORMATION

DOT Hazard Class: Not Regulated

15. REGULATORY INFORMATION
This product is not subject to SARA Title III reporting requirements.

16. OTHER INFORMATION
Organon Teknika Corporation, LLC believes that the information contained above, is to the best of our knowledge, accurate as of the date of this document. Organon Teknika Corporation, LLC provides this information in good faith as a guide to safe handling, and shall not be held liable for damages resulting from the use of this information or the product to which it applies.