



Material Safety Data Sheet

BCG VACCINE, FREEZE-DRIED

1. PRODUCT AND COMPANY IDENTIFICATION

Manufacturer: Bul Bio – NCIPD Ltd.
Sofia, Yanko Sakazov blvd. 26,
1504 Bulgaria

Emergency Phone: +359 2 944 61 91
+359 894 44 91 53

E-mail: bulbio@bulbio.com

Product Name: BCG Vaccine, Freeze-dried
0.05mg/dose powder and solvent for suspension for injection

Synonym(s): *Mycobacterium bovis* BCG Vaccine

2. PHYSICAL DATA

Physical State and color: Dry whitish powder.
After reconstitution – homogenous, slightly opalescent suspension.

Boiling point: N/A

Melting point: N/A

Vapor pressure: N/A

Specific gravity: N/A

Evaporate rate: N/A

Solubility in water: Yes

Vapor density: N/A

Odor: N/A

3. COMPOSITION/INFORMATION ON INGREDIENTS			
<i>COMPONENTS</i>	<i>CONCENTRATION</i>	<i>CAS No</i>	<i>NOTES</i>
BCG LIVE	0.5 mg/ampoule	-	-
MONOSODIUM GLUTAMATE	3 mg/ampoule	6106-04-3	-
WATER	N/A	7732-18-5	-
Exposure limits: N/A			
Contains no hazardous components ($\leq 1\%$) and no carcinogens ($\leq 0.1\%$).			
4. FIRST AID MEASURES			
<p><i>Skin contact:</i> Remove contaminated clothing and shoes and clean before reuse. Wash thoroughly exposed area with soap and water.</p> <p><i>Ingestion:</i> If swallowed, immediately give large amounts of water.</p> <p><i>Eye contact:</i> Immediately flush with water for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers.</p> <p><i>Inhalation:</i> If the person breathes in large amounts, move to fresh air. Treat symptomatically. Get medical attention if symptoms persist.</p>			
5. FIRE-FIGHTING MEASURES			
<p><i>Fire and explosion hazard:</i> Slight fire hazard when exposed to heat or flame.</p> <p><i>Flash point:</i> N/A</p> <p><i>Upper exposure limit:</i> N/A</p> <p><i>Lower exposure limit:</i> N/A</p> <p><i>Firefighting media:</i> Dry chemical, carbon dioxide, water spray or standard foam.</p> <p><i>Firefighting:</i> Move container from firefighting area if possible. Do not scatter spilled material with high pressure water streams. Use agents suitable for type of surrounding fire. Avoid breathing hazardous vapors, keep upwind.</p>			
6. REACTIVITY			
<p><i>Reactivity:</i> see section 2.</p> <p><i>Hazardous decomposition:</i> N/A</p> <p><i>Hazardous polymerization:</i> N/A</p>			

7. TOXICITY

Toxicity data: 17 000 mg/kg oral-rat LD50; 12900 mg/kg oral-mouse LD50; 3300 mg/kg IV-rat LD50; (data refers to Monosodium Glutamate component only.)

Carcinogen status: None

Acute toxicity level: Relative non-toxic by ingestion

Target effects: Nuisance dust

8. STORAGE AND DISPOSAL

Storage: Keep only in original container at a temperature between 2-8°C, protected from light. Do not freeze.

Disposal: Dispose of reconstituted product by autoclaving to a 121°C for 20 minutes or place in boiling water for 2 hours or immerse the product in bleach that has been diluted 1:5 and then dispose with other medical waste.

Observe all Federal, State and Local regulations when storing or disposing of this substance. For assistance, contact the District Director of the Environmental Protection Agency.

9. SPILL AND LEAK PROCEDURE

Occupational spill: Contain spill quickly. Dilute with 1:5 bleach solution and wipe up with disposable clean rags. Place in a suitable container for disposal with other medical waste.

10. PROTECTIVE EQUIPMENT

Ventilation: Provide general dilution ventilation.

Gloves: Not required but recommended.

Respirator: Not required.

Eye Protection: Not required, but advisable.

Clothing: *Not required.* Avoid repeated or prolonged contact.

BB-NCIPD Ltd. provides the information contained herein in good faith. Individuals receiving this information must exercise their independent judgment in determining its appropriateness for a particular purpose. BB-NCIPD Ltd. makes no representations, or warranties, either express or implied, of merchantability, fitness for a particular purpose with respect to the information set forth herein or to the product to which the information refers. Accordingly, BB-NCIPD Ltd. will not be responsible for damages from use of or reliance upon this information.

31.08.2016

Evelina Vetskova
Evelina Vetskova, MSc
Quality Assurance Specialist



Withdrawn October 2018