

Product Data Sheet – Native Antigen

Name of product	Diphtheria Toxoid
Order No.	BA130VS
Lot No.	Lot specific
Agent	Corynebacterium diphtheriae (tox+)
Culture system	Broth culture
Preparation	Purification of Diphtheria Toxin from culture medium filtrate by chromatography. Chemical detoxification by formalin treatment. The Toxoid is presented in glycine buffer at pH 9.5.
Pathogen inactivation	The pathogen raw material used in this product has been treated with formalin and has passed sterility testing during quality control. It has demonstrated no reversion of toxicity in the Schick test. No specific biological hazards are known to be associated with this product. It should be handled with appropriate safety precautions for biological materials.
Storage	-65 °C or below. Avoid repeated freeze-thaw cycles. Sonicate before use.
Date of manufacture	Lot specific
Expiry	10 years from date of manufacture (when stored under recommended conditions)
Manufacturer	Institut Virion\Serion GmbH, Germany

For research or manufacturing use only. Not for use in diagnostic procedures.

2020-08-03

Analysis:

Test	Method	Specification
Protein concentration	Kjeldahl	> 0.5 mg/mL
Immunoreactivity	SERION ELISA classic Diphtheria IgG (ESR130G)	QC serum panel (multiple negative, borderline and positive sera) within defined reactivity range
Bioburden	Membrane filtration test	≤ 100 cfu/mL