

GryphusDiagnostics
Material Safety Data Sheet
Diagnōsit® BVBLUE® Control Kit

1. Product and Company Identification

Product Name: BVBLUE® Control Kit
Synonym(s): Positive Control
Negative Control
Product Use: For external quality control testing. For in vitro diagnostic use only.
Description: Aqueous solution containing sialidase enzyme (neuraminidase).

Gryphus Diagnostics, LLC
2280 Sutherland Avenue
Knoxville, TN 37919
Phone: 865-251-0101
Fax: 865-251-0108

Emergency Telephone Numbers
Gryphus Diagnostics: 1-800-924-4195
Poison Control: 1-800-876-4766

2. Composition/Information on Ingredients

Ingredient Name	CAS #	EC #	% (w/w)
Water	7732-18-5	231-791-2	90
EC R-Phrases: NONE	EC Hazard Class: NONE		
Neuraminidase	9001-67-6	232-624-6	10
EC R-Phrases: R42	EC Hazard Class: Xn		

This preparation is not classified as hazardous under U.S. OSHA 29 CFR 1910.1200; E.C. Directive 1999/45/EC; Canadian R.S. 1985, c. H-3; U.K. CHIPS 2002 No. 1689; or U.N. GHS ST/SG/AC 10/30.

NOTE - Neuraminidase (sialidase) - Enzyme source: Salmonella typhimurium, recombinant form expressed in Escherichia coli, Enzyme Commission number: 3.2.1.18

3. Hazards Identification

Emergency Overview: The chemical, physical and toxicological properties of this preparation, pertaining directly to occupational exposures, have not been thoroughly characterized.

Precautionary Statements: May be irritating to eyes and skin. Avoid contact with eyes and skin. Do not ingest or inhale. Preparation appearance: clear, colorless liquid.

Potential Health Effects:

Inhalation: Aerosol inhalation may cause sneezing, coughing or irritation of the nasal passages and throat.

Eye: Eye exposure may cause irritation, redness and tearing.

Skin: Skin contact may cause irritation, redness, dryness and itching.

Ingestion: If large amounts are ingested, symptoms could include gastric irritation, nausea and diarrhea.

Chronic Effects: Chronic effects from repeated or long-term occupational exposure to this preparation are unknown. Prolonged or repeated skin contact may cause dermatitis.

Target Organs: Possible: skin.

4. First Aid Measures

GryphusDiagnostics
Material Safety Data Sheet
Diagnōsit® BVBLUE® Control Kit

Inhalation:	If inhaled, move from exposure area to fresh air. Seek medical attention if breathing becomes difficult or if cough or other symptoms develop.
Eye Contact:	Immediately flush eyes with plenty of tepid water while separating eyelids with fingers, removing contact lenses if worn. Continue to flush for at least 15 minutes. Obtain medical attention if needed or if symptoms, such as redness or irritation persist.
Skin Contact:	In case of contact, flush skin with copious amounts of cool water and remove contaminated clothing. Wash material from skin with soap and water and rinse thoroughly with clean water. Obtain medical attention if needed or if symptoms, such as redness or irritation, persist.
Ingestion:	In case of ingestion, drink 4 to 8 ounces (120 to 240 mL) of water - to dilute. Seek medical attention if symptoms of digestive irritation or discomfort occur.

5. Fire Fighting Measures

Flammable Properties:	Aqueous solutions are typically non-flammable.
Suitable Extinguishing Media:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Specific Hazards Arising from the Chemical:	Non-combustible, substance itself does not burn.
Standard Protective Equipment and Precautions for Firefighters:	As in any fire, firefighters should wear NIOSH-approved or equivalent Self-Contained Breathing Apparatus and full protective gear.

6. Accidental Release Measures

Personal Precautions:	Wear Personal Protective Equipment (PPE) as indicated in Section 8. Avoid physical contact with material. Wash hands thoroughly after handling.
Methods and Materials for Containment and Clean-Up:	Carefully soak up spilled liquid with a non-combustible sorbent. Scoop up spilled material and transfer to an appropriate container for disposal. After material pickup is complete, wash spill site to remove any residual material and dry completely. Dispose of spilled material and contaminated waste in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.

7. Handling and Storage

Handling:	Follow good laboratory hygiene practices. Wear proper Personal Protective Equipment (PPE) and employ exposure controls as indicated in Section 8. Avoid physical contact. Wash hands thoroughly after handling.
Storage:	Refer to product label and/or literature for specific storage conditions.

8. Exposure Controls/Personal Protection

Exposure Guidelines:	Not established
Engineering Controls:	This preparation is aqueous and non-volatile and is not expected to necessitate special ventilation measures. A dilution ventilation system is a suitable health

GryphusDiagnostics
Material Safety Data Sheet
Diagnōsit® BVBLUE® Control Kit

hazard control for this preparation. Facilities storing or utilizing this preparation should be equipped with an eyewash fountain and a safety shower.

Personal Protective Equipment (PPE):

Respiratory A respiratory protection program that meets U.S. Federal OSHA 29 CFR 1910.134 and ANSI Z99.2, Canadian CSA Standard Z94.4-93, European Standard CR 529, or other applicable regulatory standards must be followed whenever exposure limits are exceeded and engineering controls are not feasible, or if insufficient ventilation or workplace conditions warrant a respirator's use. In such cases an air purifying respirator equipped with appropriate vapor cartridges, selected to provide a filtration efficiency appropriate to your workplace, is recommended.

Eye/Face Wear appropriate protective safety eye wear as described in the ANSI standard 787.1-2003.

Skin Wear appropriate protective clothing, such as a lab coat or other long-sleeved garment over your clothes, to minimize contact and contamination of clothing. Change into clean clothes promptly if clothing becomes contaminated. Remove and wash contaminated clothing before re-use.

Gloves Prevent skin exposure by wearing protective gloves impermeable to this material/preparation. Change gloves regularly or immediately if they are contaminated, torn or punctured.

General Consult your company's safety manager/industrial hygienist or your safety equipment manufacturer/supplier for assistance with your selection of appropriate PPE.

9. Physical and Chemical Properties

Appearance:	Clear, colorless liquid	pH:	6.5 – 7.5
Odor:	Not Available	Solubility:	Water-soluble
Specific Gravity	1 (approx)	Vapor Pressure:	Not available
Boiling Point:	Not available	Partition Coefficient	Not available
Melting Point:	Not applicable	(n-octanol/water):	
Freezing Point:	Not available	Vapor Density:	Not available

10. Stability and Reactivity

Chemical Stability: Stable under ordinary conditions of use and storage; (see handling and storage information in Section 7).

Conditions to Avoid: Excessive heat may damage the product.

Incompatible Materials: Unknown

Hazardous Decomposition Products: None expected under normal conditions of use.

Possibility of Hazardous Reactions: Hazardous polymerization will not occur.

11. Toxicological Information

Routes Of Typical occupational exposure routes are inhalation, eye and skin contact.

GryphusDiagnostics
Material Safety Data Sheet
Diagnōsit® BVBLUE® Control Kit

Exposure: Effects of Exposure:	The chemical, physical and toxicological properties of this preparation, pertaining directly to occupational exposures, have not been thoroughly characterized.
Acute Effects:	May be irritating to the eyes and skin.
Chronic Effects:	Data indicating the presence or absence of chronic effects from repeated or long-term occupational exposure to this preparation is not yet available. Prolonged or repeated skin contact may cause dermatitis.
Target Organs:	Preparations expected target organ(s): skin.
Carcinogenicity:	None of the components present in this preparation at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA or ACGIH as a carcinogen.
Reproductive Effects:	Neuraminidase has been investigated as a reproductive effector in mice by intravenous injection; tests cited in Registry of Toxic Effects of Chemical Substances (RTECS). TDL ₀ 4000 IU/kg, Female Mouse, Intravenous, Day 4-6 of pregnancy - Post-implantation mortality, reduction in litter size TDL ₀ 2000 IU/kg, Female Mouse, Intravenous, Day 4 of pregnancy - Pre-implantation mortality

12. Ecological Information

Ecotoxicity: No information available for product. Not expected to exhibit ecotoxic characteristics at any stage of use.

13. Disposal Considerations

**Methods of
Disposal:** Dispose of unused product, spilled material and waste in accordance with all applicable federal, state, local and provincial environmental and hazardous waste regulations. This product, in its present state, when discarded or disposed of, is not a hazardous waste according to Federal regulations (40 CFR 261.4 (b)(4)). Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.

Packaging: Containers of this material may retain product residues. Handle contaminated packaging in the same way as the substance itself, by disposing in accordance with all applicable federal, state, local, and provincial environmental and hazardous waste regulations. If not officially specified differently, non-contaminated packaging may be treated like household waste or recycled.

**Waste
Classification:** Chemical waste generators must refer to the relevant hazardous waste regulations to ensure complete and accurate classification. Disposal regulations may vary according to geographic location.

14. Transport Information

**Additional
Information:** Contact Gryphus Diagnostics for specific shipping information.

15. Regulatory Information

GryphusDiagnostics
Material Safety Data Sheet
Diagnōsit® BVBLUE® Control Kit

US Federal Regulations: This preparation is a component of an FDA-regulated in vitro diagnostic device.
Inventory - United States - Section 8(b) Inventory (TSCA)
 Neuraminidase 9001-67-6 XU

International Regulations: **This product is regulated under the In Vitro Diagnostic Medical Devices Directive (98/79/EC).**
Inventory - Australia - Inventory of Chemical Substances (AICS)
 Neuraminidase 9001-67-6 Present
Inventory - Canada - Organisms on the Non-Domestic Substances List (NDSL)
 Neuraminidase 9001-67-6 IUB #3.2.1.18
Inventory - China
 Neuraminidase 9001-67-6 Present
Inventory - European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)
 Neuraminidase 9001-67-6 232-624-6

Canadian Hazardous Products: **WHMIS Status** Non-controlled
European Communities Dangerous Substances/Preparations:
Symbols
EC Classification None
Risk Phrases None
Safety Phrases
 S24/25 Avoid contact with skin and eyes.

16. Other Information

Recommended Use: For in vitro diagnostic use only. Not for human or drug use.

Further Information: BVBLUE® is a registered trademark of Gryphus Diagnostics, LLC.

This MSDS has been prepared in accordance with the ANSI Z400.1 format. Every effort has been made to adhere to the hazard criteria and content requirements of the US OSHA Hazard Communication Standard, European Communities Safety Data Sheets Directive, Canadian Controlled Products Regulations, UK Chemical Hazard Information and Packaging Regulations, and UN Globally Harmonized System of Classification and Labeling of Chemicals.

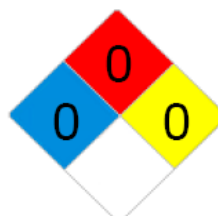
The hazard ratings on this MSDS are for appropriately trained workers using a Hazardous Materials Identification System (HMIS®) or a National Fire Protection Association (NFPA) 704 program. The ratings are estimates and should be treated as such. The hazard rating scales range from (0) minimal hazards to (4) significant hazards or risks. Chronic (long-term) health effects are indicated in the HMIS® by an asterisk (*). HMIS® is a registered trade and service mark of the NPCA. For details on HMIS® ratings visit www.paint.org/hmis. For details on NFPA 704 visit www.nfpa.org.

HMIS® RATINGS

HEALTH	*	1
FLAMMABILITY		0
PHYSICAL HAZARD		0

Target Organ(s):

NFPA RATINGS



GryphusDiagnostics
Material Safety Data Sheet
Diagnōsit® BVBLUE® Control Kit

Skin

Disclaimer:

The information above is provided in good faith. It is believed to be accurate and represents the best information currently available to us. HOWEVER, WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OF ANY OTHER TYPE, EXPRESSED OR IMPLIED, WITH RESPECT TO PRODUCTS DESCRIBED OR DATA OR INFORMATION PROVIDED, AND WE ASSUME NO LIABILITY RESULTING FROM THE USE OF SUCH PRODUCTS, DATA OR INFORMATION. Users should make their own investigations to determine the suitability of the information for their particular purposes, and the user assumes all risk arising from their use of the material. The user is required to comply with all laws and regulations relating to the purchase, use, storage and disposal of the material, and must be familiar with and follow generally accepted safe handling procedures. In no event shall Gryphus Diagnostics be liable for any claims, losses, or damages of any individual or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if Gryphus Diagnostics has been advised of the possibility of such damages.