



SAFETY DATA SHEET

SECTION 1: IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

1.1 Product identifiers

Product name : **vW Normal Control Plasma**

Product Number : REF **106426**

Brand : Bio/Data Corporation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses:

IVD

For in vitro diagnostic use; professional laboratory use by qualified personnel only

1.3 Details of the supplier of the safety data sheet:

Company: Bio/Data Corporation
155 Gibraltar Road
Horsham, PA 19044
UNITED STATES

Telephone: +1 215 441-4000
Fax: +1 215 443-8820
Email: customer.service@biodatacorp.com
Web Site: www.biodatacorp.com

1.4 Emergency telephone

Emergency Phone #: Follow laboratory blood / infectious hazard protocol
+1 215 441-4000 (0830 – 1630)

An ISO 13485 Registered Company

155 Gibraltar Road, Horsham, PA 19044 U.S.A.
Worldwide: (215) 441-4000 U.S.A.: (800) 257-3282 Fax Worldwide: (215) 443-8820
www.biodatacorp.com e-mail: customer.service@biodatacorp.com

SECTION 2: HAZARDS IDENTIFICATION2.1 Classification of the substance or mixture:

Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008

Product definition: Mixture

Classification of mixture: Not Classified

2.2 Label Elements: Not Applicable2.3 Other Hazards:

These products contain human plasma or platelets, and residual red blood cells. Source material used for these products was found to be negative when tested in accordance with current FDA required tests for communicable diseases. However, no known test methods can offer complete assurance that products derived from human blood will not transmit infectious agents. Accordingly, any human blood-based component should be handled and discarded as recommended for any potentially infectious human specimen.

Restricted to professional laboratory users.

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS3.1 Substances

Not applicable - the product is not a substance.

3.2 Mixture

Not Classified

Hazardous ingredients

This product does not contain substances required to be mentioned according to EU Regulation No 1907/2006 (REACH), Annex II

There are no ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment, are PBTs, vPvBs or Substances of equivalent concern, or have been assigned a workplace exposure limit and hence require reporting in this section.

3.3 Other information

Do not inject or ingest.

The preparation contains material of human origin which has been tested and found negative for HBSAg, anti-HIV and HCV. As with all materials of human origin, this product should be regarded as potentially hazardous to health. Therefore, it should be handled in compliance with appropriate laboratory safety procedures to minimize the risk of transmitting infectious pathogens.

Occupational exposure limits, if available, are listed in Section 8.

SECTION 4: FIRST AID MEASURES

4.1 Description of first-aid measures



General information

If symptoms develop or when in doubt, seek medical attention. Never give anything by mouth to an unconscious person. Do not leave a person unattended. Seek medical attention if any symptoms occur.

If inhaled

Move victim to fresh air. Seek medical attention if adverse symptoms appear.

In case of skin contact

Remove contaminated clothes and shoes. Wash affected area immediately with soap or mild detergent and plenty of water. Seek medical attention if symptoms occur.

In case of eye contact

Rinse immediately with plenty of water for at least 15 minutes holding the eyelids open. If possible, remove contact lenses. Continue to rinse. Seek medical attention if symptoms occur.

If swallowed

Rinse mouth with plenty of water provided the person is conscious. Do not induce vomiting. Seek medical attention if symptoms occur.

4.2 Most important symptoms and effects, both acute and delayed:

No known significant effects or critical hazards.

4.3 Indication of any immediate medical attention and special treatment needed:

Note to physician: In case of exposure, the onset of symptoms may be delayed.

The exposed person may need to be kept under medical supervision for 48 hours.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media:

Products are non-flammable, low risk of fire by the inflammability of the products in normal conditions of storage, manipulation, and use. In the case of the existence of sustained combustion as a result of improper manipulation, storage and use, any type of extinguishing agent can be used.

Unsuitable Extinguishing Media: Not Applicable

5.2 Special hazards arising from the substance or mixture:

Due to its non-flammable nature, these products do not present a fire risk under normal conditions of storage, manipulation or use.

Hazardous thermal decomposition products may generate toxic and hazardous fumes of carbon dioxide, carbon monoxide and other organic compounds.

5.3 Advice for firefighters:

In the event of a fire: Isolate the scene, removing all persons from the vicinity. Wear protective equipment. Self-contained breathing apparatus. Do not allow extinguishing water to enter sewerage or any water course. Do not breathe fire/explosion fumes.

5.4 Further information:

No further information available

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:

Refer to protective measures listed in section 7 and 8.

6.2 Environmental precautions:

These products are not classified as hazardous to the environment. Prevent further spillage if safe. Do not allow product to enter drains or any water course.

6.3 Methods and materials for containment and cleaning up:

Pre-treat the spillage with disinfectant with full biocidal activity. Do not place spilled material back in the original container. Collect spilled material with absorbent material. Clean contaminated surfaces and devices in compliance with all applicable legal requirements and regulations. Transfer to suitable, closed, and labelled containers for storage/disposal.

6.4 Reference to other sections:

For emergency contact, see section 1.

For appropriate personal protective equipment, see section 8.

For disposal see section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling:

All blood products should be treated as potentially infectious. Human blood-based products should be handled and discarded as recommended for any potentially infectious human specimen.

Advice on safe handling

Put on appropriate personal protective equipment prior to working with the mixture. For safe product handling, select and apply appropriate prevention and control measures that will reduce to a minimum the intrinsic risk hazard. Design and operate processes, insofar as the state of technology permits, in such a way that dangerous substances may not be released / contact with the skin can be ruled out.

General protective and hygiene measures

Do not eat, drink, or smoke in areas where these mixtures are handled, stored, or processed. Wash hands with soap and water after handling the mixture and before eating, drinking, or smoking. Removed contaminated clothing and protective equipment before entering eating areas. See Section 8 for additional information.

Advice on protection against fire and explosion

No special measures necessary.

7.2 Conditions for safe storage, including any incompatibilities:

Keep container tightly closed in a dry and well-ventilated place.

Store in cool place. Air, light, and moisture sensitive.

Recommended storage temperature 2-8 ° C.

7.3 Specific end use(s):

These products are medical devices/diagnostic products or components of medical devices/diagnostic products intended for in-vitro diagnostic use. Use the product in accordance with Good Laboratory Practice.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Ingredients with workplace control parameters:

Occupational exposure limit values

No parameters available for monitoring.

Biological limit values

No data available

8.2 Exposure controls:

Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

Appropriate engineering controls:

Technical measures and appropriate working operations should be given priority over the use of personal protective equipment. Any measure taken shall comply with good hygiene practice.

Personal protective equipment:

During product handling, wear appropriate protective clothing in compliance with the applicable rules.

Eye/Face protection:

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection:

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface). Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Appropriate footwear and any additional skin protection measures should be selected based on the task at hand and the risks involved.

Body protection:

The type of protective equipment must be selected according to the concentration and amount of dangerous substances at the specific workplace.

Respiratory protection:

Respiratory protection is not required.

Where protection from nuisance levels of dust is desired, use type N95 (US) or type P1 (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Control of environmental exposure:

Prevent further spillage/release of material if safe. Do not allow the product to enter drains or any water course. Avoid release into the environment.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**9.1 Information on basic physical and chemical properties:**

a)	Appearance Form	:	Liquid Color: Clear to Yellowish
b)	Odor	:	Odorless
c)	Odor Threshold	:	No Data Available
d)	pH	:	Neutral pH
e)	Melting point / freezing point	:	No Data Available
f)	Initial boiling point and boiling range	:	No Data Available No Data Available
g)	Flash point	:	Product does not sustain combustion
h)	Evaporation rate	:	No Data Available
i)	Flammability (solid, gas)	:	No Data Available
j)	Upper/Lower flammability or explosive limits	:	No Data Available
k)	Vapor pressure	:	No Data Available

l)	Vapor density	:	No Data Available
m)	Relative density	:	No Data Available
n)	Water solubility	:	No Data Available
o)	Partition coefficient - n-octanol/water	:	No Data Available
p)	Autoignition temperature	:	No Data Available
q)	Decomposition temperature	:	No Data Available
r)	Viscosity	:	No Data Available
s)	Explosive properties	:	No Data Available
t)	Oxidizing properties	:	No Data Available

9.2 Other safety information:

No Other Data Available

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity:

No dangerous reactions known, if handled in compliance with applicable provisions/under normal conditions of use.

10.2 Chemical stability:

The mixture is stable if handled and stored as recommended under Section 7.

10.3 Possibility of hazardous reactions:

Under the normal conditions of storage and use, hazardous reactions will not occur.

10.4 Conditions to avoid:

Not Applicable.

10.5 Incompatible materials:

Avoid strong acids, alkalis, or strong bases.

10.6 Hazardous decomposition products:

Under the normal conditions of storage and use, hazardous decomposition should not occur.

SECTION 11: TOXICOLOGICAL INFORMATION**11.1 Information on toxicological effects:**

<i>Acute toxicity</i>	:	No Data Available
<i>Skin corrosion/irritation</i>	:	No Data Available
<i>Serious eye damage/eye irritation:</i>		No Data Available
<i>Respiratory or skin sensitization :</i>		No Data Available
<i>Germ cell mutagenicity</i>	:	No Data Available
<i>Carcinogenicity</i>	:	IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
Reproductive toxicity	:	No Data Available
Specific target organ toxicity	:	single exposure - No Data Available
Specific target organ toxicity	:	repeated exposure - No Data Available
Aspiration hazard	:	No Data Available

11.2 Additional Information : No Data Available

SECTION 12: ECOLOGICAL INFORMATION

12.1 <u>Toxicity</u>	:	No Data Available
12.2 <u>Persistence and degradability</u>	:	No Data Available
12.3 <u>Bio accumulative potential</u>	:	No Data Available
12.4 <u>Mobility in soil</u>	:	No Data Available
12.5 <u>Results of PBT and vPvB assessment:</u>		PBT/vPvB assessment not available as chemical safety assessment not required/not conducted.
12.6 <u>Other adverse effects</u>	:	No known significant effects or critical hazards

SECTION 13: DISPOSAL CONSIDERATIONS**13.1 Waste treatment methods**

<i>Product:</i>	Dispose of bio-hazardous waste in accordance with applicable policies and regulations.
Contaminated Packaging:	Dispose of bio-hazardous waste in accordance with applicable policies and regulations.
Special Precautions:	The material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residue. Avoid dispersal of spilled material.

SECTION 14: TRANSPORT INFORMATION

The product is not covered by international regulations on the transport of dangerous goods (IMDG, IATA, ADR/RID).

14.1	<u>UN number:</u>	3373, category B
14.2	<u>UN proper shipping name:</u>	Biological
14.3	<u>Transport hazard class(es):</u>	ADR/RID: Not dangerous goods IMDG: Not dangerous goods US DOT: Not dangerous goods IATA: Not dangerous goods
14.4	<u>Packaging group:</u>	Not Applicable
14.5	<u>Environmental hazards:</u>	ADR/RID: N IMDG Marine pollutant
14.6	<u>Special precautions for user:</u>	

Transport within user premises: Always transport in closed containers that are upright and secure. Ensure the person transporting the product knows what to do in the event of an accident or spillage,

SECTION 15: REGULATORY INFORMATION

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2008.

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:

CEPA Toxic Substances:	No Components Listed
TSCA:	All Components Listed or Exempt
SARA 302/304 and 311/312,	
EPA list of lists:	Not Applicable
	No Products were Found
Massachusetts:	No Components Listed
New Jersey:	No Components Listed
Pennsylvania:	No Components Listed
California Prop 65:	No Components Listed
EU Regulations and Lists	
EC No. 1907/2006 (REACH)	
Annex XIV List of substances Subject to authorization:	No Components Listed
Annex XVII Restrictions on the manufacture, placing on the market and use of certain Dangerous substances, mixtures and articles:	Not applicable
C & L Inventory:	All Components Listed

15.2 Chemical Safety Assessment:

No chemical safety assessment has been carried out by the supplier.

SECTION 16: OTHER INFORMATION

Restrictions on use: For professional laboratory use by qualified personnel only.

Further information:

Preparation Date: April 1, 2023

Revision Level and Date: Revision A, February 1, 2024

Key literature references and sources of data:

This SDS was prepared on the basis of sheets of individual components and online databases (e.g., ECHA, RTECS) as well as our knowledge and experience, taking into account current legislation and Regulations

Abbreviations and Acronyms:

SDS:	Safety Data Sheet
PBT:	Persistence, Bioaccumulation, Toxicity
vPvB:	Very persistent and very bio accumulative
STOT	specific target organ toxicity
SCBA:	Self-contained breathing apparatus
ADR:	Agreement concerning the carriage of dangerous goods by road
RID	Regulation concerning the international carriage of dangerous goods by rail
IMDG	International Maritime Dangerous Goods code
IATA	International air transport organization
DOT	US Department of Transportation
ANSI	American National Standards Institute
OSHA	Occupational Safety & Health Administration (US)

Information related to the Regulation EC/1272/2008

This product is intended for **IN VITRO diagnostic use only**. NOT FOR INJECTION OR INGESTION. The information herein is believed to be correct as of the date hereof and excludes any guarantee related with the final use given to the product, being the recipient the last responsible for observing the local laws applicable in each case.

Notice to reader:

To the best of our knowledge, the information contained herein is accurate. Neither the above-named supplier nor any of its subsidiaries or distributors assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of the suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and must be used with caution. Although certain hazards are described herein, we cannot guarantee these are the only hazards that exist.