SAFETY DATA SHEET

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

1.1 Product Identifiers:

Product Name: **vW SELECT™**
Ristocetin CoFactor Activity Assay System

Product Number: REF **106730**

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**
FOR PROFESSIONAL LABORATORY USE BY QUALIFIED PERSONNEL ONLY

Laboratory chemicals. Reagents used for platelet aggregation testing.

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
Website: www.biodatacorp.com

1.4 Emergency Telephone:

Follow Good Laboratory Practices Safety Protocol
Emergency Telephone #: +1 215 441-4000 (Monday – Friday 8:30 AM to 5:00 PM EST)
During Non-Business Hours, Call Local Authorities

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture:

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

2.2 Label Elements: Not Applicable

2.3 Other Hazards Restricted to professional laboratory users.

Lyophilized Platelets, vW Abnormal Control Plasma, vW Normal Control Plasma, and vW Normal Reference Plasma: These products contain human-origin components, including plasma or platelets, along with residual red blood cells. Source materials used for these products have tested negative for HBSAg, anti-HIV, and HCV, following current FDA-required tests for communicable diseases. Nevertheless, it's important to note that no test method can offer absolute assurance that products derived from human blood will not transmit infectious agents. As with all materials of human origin, these products should be considered potentially hazardous to health. Therefore, they should be handled and disposed of following appropriate laboratory safety procedures to minimize the risk of transmitting infectious pathogens.

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substances:

Synonyms:

AggRecetin
Ristocetin, Ristocetin A Sulfate, Ristomycin, Ristomycin III, Ristomycin Monosulfate, AggRecetin

AggRecetin Diluent
Reagent Diluent

Lyophilized Platelets
Formalin Fixed Platelets

TRIS Buffered Saline
TBS, 0.06M, pH 7.5

vW Abnormal Control Plasma
von Willebrand Factor Deficient Control Plasma, von Willebrand Disease Control Plasma

vW Normal Control Plasma
von Willebrand Factor Normal Control Plasma, Normal von Willebrand Factor Control Plasma, Normal vWF Control Plasma

vW Normal Reference Plasma
von Willebrand Factor Normal Reference Plasma, Normal von Willebrand Factor Reference Plasma

Molecular Weight: Refer to Chart Below

CAS-No.: Refer to Chart Below

EC-No.: Refer to Chart Below

3.2 Mixtures:

Component	Identifier	Molecular Weight	Concentration	Classification
AggRecetin	Cas No.: 11140-99-1 EC No.: N/A Formula: $C95H110N8O44\text{-}H_2SO_4$	2,116.00 g / mol	90%	Not Hazardous
AggRecetin Diluent	Cas No.: 6850-28-8 EC No.: 232-697-4	18.02 g /mol	N / A	Not Hazardous
Lyophilized Platelets	Cas No.: 20398-34-9 EC No.: N/A	N / A	N / A	Not Hazardous
Sodium Chloride	Cas No.: 7647-14-5 EC No.: N/A	N / A	N / A	Not Hazardous
TRIS Buffered Saline	Cas No.: 6850-28-8 EC No.: 232-697-4	18.02 g /mol	N / A	Not Hazardous
vW Abnormal Control Plasma	Cas No.: N/A EC No.: N/A	N / A	N / A	Not Hazardous
vW Normal Control Plasma	Cas No.: N/A EC No.: N/A	N / A	N / A	Not Hazardous
vW Normal Reference Plasma	Cas No.: N/A EC No.: N/A	N / A	N / A	Not Hazardous

No components need to be disclosed according to the applicable regulations. Please reference AggRecetin (Ristocetin), AggRecetin Diluent, Lyophilized Platelets, TRIS Buffered Saline, vW Abnormal Control Plasma, vW Normal Control Plasma, and vW Normal Reference Plasma's individual Safety Data Sheets for specific product related details.

SECTION 4: FIRST-AID MEASURES

4.1 Description of First-Aid Measures:

General information	If symptoms develop or when in doubt, seek medical attention. Do not leave an exposed person unattended.
If Inhaled	Move exposed person to fresh air. Seek medical attention if adverse symptoms appear. Give artificial respiration if not breathing. If symptoms persist, consult a physician.
In Case of Skin Contact	Wash skin off with soap and plenty of water. Remove all contaminated clothing and shoes. Wash contaminated clothing before reuse. If symptoms persist, consult a physician.
In Case of Eye Contact	Wash eyes thoroughly with plenty of water for at least 15 minutes. Remove contact lenses. If symptoms persist, consult a physician.
If Swallowed	Rinse mouth with plenty of water. Never give anything by mouth to an unconscious person. Do not induce vomiting. If symptoms persist, consult a physician.

4.2 Most Important Symptoms and Effects, both Acute and Delayed:

The most important known symptoms and effects are described in the labelling.
Refer to Section 2 and in Section 11.

4.3 Indication of any Immediate Medical Attention and Special Treatment Needed:

No further information available.

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:

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

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:

Carbon oxides, Nitrogen oxides (NOx), Sulfur oxides.
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 and self-contained breathing apparatus for firefighting if necessary.
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:

Avoid dust formation. Do not breathe in vapors, mist, or gas. Avoid contact with skin, eyes and clothing. Use personal protective equipment, including lab coat and gloves. Refer to Section7 and 8.

6.2 Environmental Precautions:

If safe, prevent further spillage. Do not allow products to enter drains or sewage systems. Avoid release to the environment.

6.3 Methods and Materials for Containment and Cleaning Up:

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

6.4 Reference to Other Sections:

Refer to Section 1 for emergency contact.
Refer to Section 7 for information on safe handling.
Refer to Section 8 for information on personal protection equipment.
Refer to Section 13 for information on disposal.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for Safe Handling:

Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire protection. For precautions, refer to Section 2.

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 handing:
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. Containers which are opened must be carefully closed and kept upright to prevent leakage. Recommended storage temperature 2-8 ° C. Storage class (TRGS 510): 12: Non-Combustible Liquids.

7.3 Specific End Use(s):

Apart from the uses mentioned in Section 1.2, no other specific uses are stipulated.
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:

Does not contain substances with occupational exposure limit value.

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:

Restricted to professional laboratory use by qualified personnel. Technical measures and appropriate working operations should be given priority over the use of personal protective equipment. General industrial hygiene and good laboratory practices should be followed.

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. Prior to use, check in any case suitability of protective glove for the specific workplace conditions. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Replace protective gloves immediately when they become worn and damaged. Wash and dry hands. The selected protective gloves must satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it. Dispose of contaminated gloves after use in accordance with applicable laws

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

Body Protection:

Lab coat is required. When more protection is desired, 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.
When 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:

Do not let product enter drains.
Prevent further spillage/release of material if safe. Do not allow the product to enter drains or sewer systems. Avoid release into the environment.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

a) Appearance Form:

AggRecetin:	Crystalline	Color: Light Yellow
AggRecetin Diluent:	Liquid	Color: Colorless
Lyophilized Platelets:	Lyophilized Powder	Color: White / Yellow
TRIS Buffered Saline:	Liquid	Color: Colorless
vW Abnormal Control Plasma:	Liquid	Color: Colorless
vW Normal Control Plasma:	Liquid	Color: Clear to Yellowish
vW Normal Reference Plasma:	Liquid	Color: Colorless

b) Odor:

AggRecetin:	No Data Available
AggRecetin Diluent:	No Data Available
Lyophilized Platelets:	No Data Available
TRIS Buffered Saline:	No Data Available
vW Abnormal Control Plasma:	Odorless
vW Normal Control Plasma:	Odorless
vW Normal Reference Plasma:	Odorless

c) Odor Threshold: No Data Available

d) pH:

AggRecetin:	No Data Available
AggRecetin Diluent:	7.5
Lyophilized Platelets:	No Data Available
TRIS Buffered Saline:	7.5
vW Abnormal Control Plasma:	Neutral pH
vW Normal Control Plasma:	Neutral pH
vW Normal Reference Plasma:	Neutral pH

e) Melting Point / Freezing Point:

AggRecetin:	No Data Available
AggRecetin Diluent:	0.0 °C (32.0 °F)
Lyophilized Platelets:	No Data Available
TRIS Buffered Saline:	0.0 °C (32.0 °F)
vW Abnormal Control Plasma:	No Data Available
vW Normal Control Plasma:	No Data Available
vW Normal Reference Plasma:	No Data Available

f) Initial Boiling Point and Boiling Range:

AggRecetin:	No Data Available
AggRecetin Diluent:	100.0 °C (212.0 °F)
Lyophilized Platelets:	No Data Available
TRIS Buffered Saline:	100.0 °C (212.0 °F)
vW Abnormal Control Plasma:	No Data Available
vW Normal Control Plasma:	No Data Available
vW Normal Reference Plasma:	No Data Available

g) Flash Point:

AggRecetin:	No Data Available
AggRecetin Diluent:	Not Applicable
Lyophilized Platelets:	No Data Available
TRIS Buffered Saline:	Not Applicable
vW Abnormal Control Plasma:	Product does not sustain combustion
vW Normal Control Plasma:	Product does not sustain combustion
vW Normal Reference Plasma:	No Data Available

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:

AggRecetin:	Soluble
AggRecetin Diluent:	Completely Miscible
Lyophilized Platelets:	No Data Available
TRIS Buffered Saline:	Completely Miscible
vW Abnormal Control Plasma:	No Data Available
vW Normal Control Plasma:	No Data Available
vW Normal Reference Plasma:	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:

AggRecetin:	No Data Available
AggRecetin Diluent:	Not classified as explosive
Lyophilized Platelets:	No Data Available
TRIS Buffered Saline:	Not classified as explosive
vW Abnormal Control Plasma:	No Data Available
vW Normal Control Plasma:	No Data Available
vW Normal Reference Plasma:	No Data Available

t) Oxidizing Properties:

AggRecetin:	No Data Available
AggRecetin Diluent:	None
Lyophilized Platelets:	No Data Available
TRIS Buffered Saline:	None
vW Abnormal Control Plasma:	No Data Available
vW Normal Control Plasma:	No Data Available
vW Normal Reference Plasma:	No Data Available

9.2 Other Safety Information:

No Further Information 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 preparation and mixtures are stable if handled and stored as recommended under section 7.

10.3 Possibility of Hazardous Reactions:

When Instructions for Use (IFU) are followed, no hazardous reactions will occur.

10.4 Conditions to Avoid:

When Instructions for Use (IFU) are followed, there are no conditions to avoid.

10.5 Incompatible Materials:

AggRecetin, vW Abnormal Control Plasma, vW Normal Control Plasma, and vW Normal Reference Plasma:

Avoid strong acids, alkalis, or strong bases.

AggRecetin Diluent, Lyophilized Platelets and TRIS Buffered Saline:

Not Applicable.

10.6 Hazardous Decomposition Products:

When Instructions for Use (IFU) are followed, hazardous decomposition should not occur.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Acute Toxicity:

AggRecetin:	DL50 intravenous - mouse - 1000 mg/kg Intraperitoneal – rat – 1500 mg/kg
AggRecetin Diluent:	No Data Available
Lyophilized Platelets:	No Data Available
TRIS Buffered Saline:	No Data Available
vW Abnormal Control Plasma:	No Data Available
vW Normal Control Plasma:	No Data Available
vW Normal Reference Plasma:	No Data Available

Skin Corrosion/Irritation:

AggRecetin:	Non-irritant
AggRecetin Diluent:	No Data Available
Lyophilized Platelets:	No Data Available
TRIS Buffered Saline:	No Data Available
vW Abnormal Control Plasma:	No Data Available
vW Normal Control Plasma:	No Data Available
vW Normal Reference Plasma:	No Data Available

Serious Eye Damage/Eye Irritation: No Data Available

Respiratory or Skin Sensitization: No Data Available

Germ Cell Mutagenicity: No Data Available

Carcinogenicity:

IARC: No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

ACGIH: No ingredient of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

NTP: No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

OSHA: No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

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:	RTECS - No Data Available

11.2 Additional Information:

AggRecetin:	RTECS: VJ8650000 Promotes agglutination of normal platelets in plasma.
AggRecetin Diluent:	No Data Available
Lyophilized Platelets:	No Data Available
TRIS Buffered Saline:	No Data Available
vW Abnormal Control Plasma:	No Data Available
vW Normal Control Plasma:	No Data Available
vW Normal Reference Plasma:	No Data Available

SECTION 12: ECOLOGICAL INFORMATION

12.1	Toxicity:	No Data Available
12.2	Persistence and Degradability:	No Data Available
12.3	Bio Accumulative Potential:	No Data Available
12.4	Mobility in Soil:	No Data Available

12.5 Results of PBT and vPvB Assessment:

AggRecetin:	This substance / mixture does not contain components considered persistent, bio accumulative or toxic (PBT) or very persistent and very bio accumulative (vPvB) at concentrations of 0.1% or higher.
AggRecetin Diluent:	PBT and vPvB assessment not available as chemical safety assessment not required or not conducted.
Lyophilized Platelets:	PBT and vPvB assessment not available as chemical safety assessment not required or not conducted.
TRIS Buffered Saline:	PBT and vPvB assessment not available as chemical safety assessment not required or not conducted.
vW Abnormal Control Plasma:	PBT and vPvB assessment not available as chemical safety assessment not required or not conducted.

vW Normal Control Plasma:	PBT and vPvB assessment not available as chemical safety assessment not required or not conducted.
vW Normal Reference Plasma:	PBT and vPvB assessment not available as chemical safety assessment not required or not conducted.

12.6 Other Adverse Effects:

AggRecetin:	No Data Available
AggRecetin Diluent:	No Data Available
Lyophilized Platelets:	Do not discharge product unmonitored into the environment
TRIS Buffered Saline:	No Data Available
vW Abnormal Control Plasma:	No known significant effects or critical hazards
vW Normal Control Plasma:	No known significant effects or critical hazards
vW Normal Reference Plasma:	No known significant effects or critical hazards

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SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods

Product:	Dispose of as a biohazardous material in accordance with applicable regulations and laboratory policies. Do not allow the product to enter drains or sewage systems. Offer surplus to a licensed disposal company.
Contaminated Packaging:	Dispose of as an unused product.

SECTION 14: TRANSPORT INFORMATION

14.1 UN Number:

AggRecetin, AggRecetin Diluent, Lyophilized Platelets, and TRIS Buffered Saline:

ADR/RID: - IMDG: - IATA: -

vW Abnormal Control Plasma, vW Normal Control Plasma, and vW Normal Reference Plasma:

3373, category B

14.2 UN Proper Shipping Name: Biological

ADR/RID: Not dangerous good

IMDG: Not dangerous good

US DOT: Not dangerous good

IATA: Not dangerous good

14.3	Transport Hazard Class(es):	ADR/RID: -	IMDG: -	IATA: -
14.4	Packaging Group:	ADR/RID: -	IMDG: -	IATA: -
14.5	Environmental Hazards:	ADR/RID: No	IMDG Marine Pollutant: No	IATA: No

14.6 Special Precautions for User:

AggRecetin and Lyophilized Platelets:
No Data Available

AggRecetin Diluent and TRIS Buffered Saline:
Not classified as dangerous in the meaning of transport regulations.

vW Abnormal Control Plasma, vW Normal Control Plasma, and vW Normal Reference Plasma:
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 Data Sheet complies with the requirements of Regulation No EC 1272/2008 and EU 2020/878

15.1 Safety, Health and Environmental Regulations / Legislation Specific for the Substance or Mixture:

AggRecetin:	No Data Available
Lyophilized Platelets:	No Data Available
AggRecetin Diluent and TRIS Buffered Saline:	
SARA 302 Components	No Components Listed
SARA 313 Components	No Components Listed
SARA 311/312 Hazards	No Components Listed
Massachusetts Right To Know Components	No Components Listed
Pennsylvania Right To Know Components	water; CAS-No. 7732-18-5
New Jersey Right To Know Components	water; CAS-No. 7732-18-5
California Prop. 65 Components	No Components Listed

vW Abnormal Control Plasma, vW Normal Control Plasma, and vW Normal Reference Plasma:

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:

Chemical safety assessments have not been carried out for these products.

SECTION 16: OTHER INFORMATION

Preparation Date: May 6, 2024

Revision Level and Date: Revision -, May 6, 2024

Further information:

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 No EC 1272/2008 and EU 2020/878

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.