



SAFETY DATA SHEET

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

1.1 Product Identifiers:

Product Name: **AGG/PAK™ 5 Combo Kit
Platelet Aggregation Reagent Test Kit**

Product Number: REF **107650**

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:

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

An ISO 13485:2003 Registered Company

155 Gibraltar Road, Horsham, PA 19044 USA

Worldwide: +1 215-441-4000 USA: 1-800-257-3282 Fax Worldwide: +1 215-443-8820

Website: www.biodatacorp.com Email: 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

2.2 Label Elements: Not Applicable2.3 Other Hazards None
Restricted to Professional Laboratory User by Qualified Personnel**SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS**3.1 Substances:

<i>Synonyms:</i>	ADP:	Adenosine-5'-Diphosphate
	ARACHIDONIC ACID:	Arachidonic Acid, Arachidonate 5-8-11-14 Eicosatetraenoic Acid
	COLLAGEN:	Soluble Calf Skin, Type 1
	EPINEPHRINE:	Adrenaline, (-) Adrenaline, L-Epinephrine, L-Adrenalin, (R)-(-)-3,4-Dihydroxy-a-(methyl amino methyl) benzyl alcohol
	RISTOCETIN:	Ristocetin, Ristocetin A Sulfate, Ristomycin, Ristomycin III, Ristomycin Monosulfate

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
ADP	Cas No.: 20398-34-9 EC No.: N / A	N / A	N / A	Not Hazardous
Arachidonic Acid	Cas No.: 506-32-1 EC No.: 208-033-4	304.50	~ 90%	Not Hazardous
Collagen	Cas No.: 9007-34-5 EC No.: 232-697-4	N / A	N / A	Not Hazardous
Epinephrine	Cas No.: 51-43-4 EC No.: 200-098-7	333.29	0.02%	H-302, H318 H301, +H331
Physiologic Saline (0.85%)	CAS No.: 7647-14-5 EC No.: 231-598-3 Formula: NaCl	58.44 g / mol	0.85%	Not Hazardous
Ristocetin A Sulfate	Cas No.: 11140-99-1 EC No.: N / A Formula: C ₉₅ H ₁₁₀ N ₈ O ₄₄ -H ₂ SO ₄	2,116.00 g / mol	90%	Not Hazardous

No components need to be disclosed according to the applicable regulations. Please reference ADP, Arachidonic Acid, Collagen, Epinephrine, and Ristocetin (AggRecetin) Individual Safety Data Sheets for specific product related details.

SECTION 4: FIRST-AID MEASURES

4.1 Description of First-Aid Measures:



General

Do not leave unattended. Consult a physician. Show this Safety Data Sheet to the physician.

If Inhaled

Move person into fresh air. If not breathing, give artificial respiration. If symptoms persist, consult a physician.

In Case of Skin Contact

Wash skin off with soap and plenty of water. If symptoms persist, consult a physician or take the person to hospital.

In Case of Eye Contact

Wash eyes thoroughly with plenty of water for at least 15 minutes. If symptoms persist, consult a physician.

If Swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water. 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 Section 11).

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

ADP, Arachidonic Acid, Collagen, and Ristocetin:

No further information available.

Epinephrine:

Increased platelet aggregation may occur after contact with wounds or intrusion into the blood system.

SECTION 5: FIREFIGHTING MEASURES**5.1 Extinguishing Media:**

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

5.2 Special Hazards Arising from the Substance or Mixture:

Carbon oxides, Nitrogen oxides (NO_x), Sulfur oxides, Sodium oxides.

Vapors are heavier than air and may spread along floors.

5.3 Advice for Firefighters:

Wear self-contained breathing apparatus for firefighting if necessary.

5.4 Further Information:

Arachidonic Acid:

Forms explosive mixtures with air on intense heating. It emits toxic fumes when burned. It emits irritating fumes if the bottles are kept open too long. Prevent fire extinguishing water from contaminating surface water or the ground water system.

ADP, Collagen, Epinephrine, Ristocetin:

No further information available.

SECTION 6: ACCIDENTAL RELEASE MEASURES**6.1 Personal Precautions, Protective Equipment and Emergency Procedures:**

Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Use personal protective equipment. For personal protection, refer to Section 8.

6.2 Environmental Precautions:

Do not let products enter drains or sewers.

6.3 Methods and Materials for Containment and Cleaning Up:

Sweep up and shovel without creating dust. Store in suitable, closed containers in a dry, well-ventilated area for disposal in accordance with national and local regulations. Follow laboratory policies for containing and cleaning up chemical spills.

6.4 Reference to Other Sections:

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.

Protective Action Criteria for Chemicals

PAC-1: Substances are not listed.

PAC-2: Substances are not listed.

PAC-3: Substances are not listed.

SECTION 7: HANDLING AND STORAGE**7.1 Precautions for Safe Handling:**

Use disposable gloves, eye protection, and wear a lab coat or apron.

Avoid inhalation or contact with skin or eyes.
Provide appropriate ventilation at places where dust is formed.
Normal measures for preventive fire protection.
For precautions refer to Section 2.

7.2 Conditions for Safe Storage, Including any Incompatibilities:

ADP, Arachidonic Acid, Collagen, and Ristocetin:
Store in cool place. Keep container tightly closed in a cool, dry, and well-ventilated place. Store in accordance with information listed on the Instructions For Use (IFU). Recommended Storage Temperature is 2-8 ° C. Sensitive to light, air and moisture. Hygroscopic. German storage class (TRGS 510): Solid incombustible.

Epinephrine:

Store in cool place. Keep container tightly closed in a dry and well-ventilated place. Keep away from heat, sparks and flames. Store in accordance with information listed on the Instructions For Use (IFU). Recommended Storage Temperature is 2-8 ° C. Sensitive to light, air and moisture. Never allow product to get in contact with water during storage. Do not store near acids. Keep away from food and drinks.

7.3 Specific End Use(s):

For in-vitro diagnostic use only by qualified laboratory personnel only following the instructions for use. Apart from the uses mentioned in Section 7.1 and 7.2, no other specific uses are stipulated.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION**8.1 Control Parameters**

Ingredients with workplace control parameters: It doesn't contain substances with occupational exposure limit value.

8.2 Exposure Controls**Appropriate Engineering Controls:**

Restricted to professional laboratory use by qualified personnel. General industrial hygiene and good laboratory practices should be followed. Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.

Personal Protective Equipment:***Eye/Face Protection:***

Collagen:

Not required

ADP, Arachidonic Acid, Epinephrine, and Ristocetin:

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

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.

Body Protection:

Collagen:

Not required

ADP, Arachidonic Acid, Epinephrine, and Ristocetin:

Wear Lab coat. The type of protective equipment must be selected according to the concentration and amount of dangerous substances at the specific workplace. Use body protection in accordance with applicable local workplace rules and laboratory policies.

Respiratory Protection:

Respiratory protection is not required. Where protection from nuisance levels of dust is desired or risk assessment shows air-purifying respirators are appropriate, use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. 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 products enter drains or sewer systems.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

a)	Appearance Form:		
	ADP	Lyophilized Powder	Color: White
	ARACHIDONIC ACID	Lyophilized Powder	Color: Off-White
	COLLAGEN	Lyophilized Powder	Color: White
	EPINEPHRINE	Lyophilized Powder	Color: White
	RISTOCETIN	Lyophilized Powder	Color: Light Yellow
b)	Odor:		
	ADP		No Data Available
	ARACHIDONIC ACID		No Data Available
	COLLAGEN		Indeterminate
	EPINEPHRINE		No Data Available
	RISTOCETIN		No Data Available
c)	Odor Threshold:		No Data Available
d)	pH:		
	ADP		No Data Available
	ARACHIDONIC ACID		No Data Available
	COLLAGEN		Indeterminate
	EPINEPHRINE		~ 7.4
	RISTOCETIN		No Data Available

e)	Melting Point / Freezing Point:	No Data Available
f)	Initial Boiling Point:	No Data Available
	Boiling Range:	No Data Available
g)	Flash Point:	No Data Available
h)	Evaporation Rate:	No Data Available
i)	Flammability (solid, gas):	
	ADP	No Data Available
	ARACHIDONIC ACID	No Data Available
	COLLAGEN	Not Flammable
	EPINEPHRINE	No Data Available
	RISTOCETIN	No Data Available
j)	Upper/Lower Flammability or Explosive Limits:	
	ADP	No Data Available
	ARACHIDONIC ACID	No Data Available
	COLLAGEN	No Data Available
	EPINEPHRINE	Not Explosive
	RISTOCETIN	No Data Available
k)	Vapor Pressure:	No Data Available
l)	Vapor Density:	No Data Available
m)	Relative Density:	No Data Available
n)	Water Solubility:	
	ADP	No Data Available
	ARACHIDONIC ACID	Insoluble
	COLLAGEN	Insoluble
	EPINEPHRINE	Soluble
	RISTOCETIN	Soluble
o)	Partition Coefficient - n-octanol/water:	No Data Available
p)	Autoignition Temperature:	
	ADP	No Data Available
	ARACHIDONIC ACID	No Data Available
	COLLAGEN	No Data Available
	EPINEPHRINE	Not Combustible
	RISTOCETIN	No Data Available
q)	Decomposition Temperature:	No Data Available
r)	Viscosity:	No Data Available

s)	Explosive Properties:	No Data Available
	ADP	No Data Available
	ARACHIDONIC ACID	No Data Available
	COLLAGEN	See Section 10
	EPINEPHRINE	No Data Available
	RISTOCETIN	No Data Available

t)	Oxidizing Properties:	
	ADP	No Data Available
	ARACHIDONIC ACID	No Data Available
	COLLAGEN	No Data Available
	EPINEPHRINE	No Data Available
	RISTOCETIN	None

9.2 Other Safety Information:

No Further Information Available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity:

No Data Available

10.2 Chemical Stability:

ADP, Collagen, Epinephrine, and Ristocetin:
Stable under recommended storage conditions.

Arachidonic Acid:
Stable under recommended storage conditions.
Decomposes easily. it is unstable at room temperature.

10.3 Possibility of Hazardous Reactions:

No Data Available

10.4 Conditions to Avoid:

ADP:
Sensitive to Moisture

Arachidonic Acid and Epinephrine:
Sensitive to exposure to air, moisture, and heat.

Collagen and Ristocetin:
No Further Relevant Information Available

10.5 Incompatible Materials:

ADP, Arachidonic Acid, Epinephrine, and Ristocetin:
Strong acids, oxidizing compounds, and various metals. Not to be expected for intended use.

Collagen:
No Further Relevant Information Available

10.6 Hazardous Decomposition Products:

Arachidonic Acid:
Carbon monoxide and carbon dioxide. In the event of fire, refer to Section 5.

ADP, Collagen, Epinephrine, and Ristocetin:
No dangerous decomposition products known. In the event of fire, refer to Section 5.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Acute Toxicity:

ADP	No Data Available
ARACHIDONIC ACID	DL50 intravenous - mouse - 39200 ug/kg
COLLAGEN	No Data Available
EPINEPHRINE	No Data Available
RISTOCETIN	DL50 intravenous - mouse - 1000 mg/kg Intraperitoneal – rat – 1500 mg/kg

Skin Corrosion/Irritation:

ADP	No Data Available
ARACHIDONIC ACID	No Data Available
COLLAGEN	Irritant and potentially harmful
EPINEPHRINE	No Data Available
RISTOCETIN	Non-irritant

Serious Eye Damage/Eye Irritation:

ADP	No Data Available
ARACHIDONIC ACID	No Data Available
COLLAGEN	No respiratory or skin sensitizing effects known.
EPINEPHRINE	No Data Available
RISTOCETIN	No Data Available

Respiratory or Skin Sensitization: No Data Available

<i>Germ Cell Mutagenicity:</i>	No Data Available
<i>Carcinogenicity:</i>	IARC, ACGIH, NTP or OSHA: 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. Substance is not listed.
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:

ADP, Collagen & Epinephrine:

RTECS: Not Available

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us. The substance is not subject to classification.

Arachidonic Acid:

RTECS: CE6675000

It may cause irritation. May be harmful by inhalation, ingestion, or skin absorption.

Ristocetin:

RTECS: VJ8650000

Promotes agglutination of normal platelets in plasma.

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>	

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.

12.6 Other Adverse Effects:

ADP, Collagen, Epinephrine, Ristocetin:

Do not dispose of the product unchanged in the environment.

Arachidonic Acid:

Water hazard class 1 (Self-assessment): slightly hazardous for water. Do not allow undiluted products to enter drains or sewer systems.

SECTION 13: DISPOSAL CONSIDERATIONS**13.1** Waste Treatment Methods*Product:*

Dispose of as a biohazardous waste in closed containers compliant to applicable regulations and laboratory policies. Do not allow the product to enter drains or sewer systems.

Contaminated Packaging:

Dispose of as an unused product.

SECTION 14: TRANSPORT INFORMATION**14.1** UN Number: ADR/RID: - IMDG: - IATA: -**14.2** UN Proper Shipping Name: 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

Non-environmentally hazardous according to the dangerous goods regulations

14.6 Special Precautions for User: No Data Available**14.7** Transport in bulk according to annex II of MARPOL 73/78 and the IBC-Code:

Not applicable, product is not intended to be transported in bulk.

SECTION 15: REGULATORY INFORMATION

This Safety Data Sheet complies with the requirements of Regulation (EC) No. 1907/2008.

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

No Data Available

15.2 Chemical Safety Assessment:

ADP, Collagen, Epinephrine, and Ristocetin:

For this product a chemical safety assessment was not carried out.

Arachidonic Acid:

For this product a chemical safety assessment was not carried out.

SARA 302

Components This material does not contain any components with a section 302 EHS TPQ

SARA 313

Components This material does not contain any chemical components with known CAS numbers that exceed the threshold (DeMinimis) reporting levels established by SARA Title III, Section 313

SARA 311/312 Hazards

No SARA Hazards

California Prop 65 COMPONENTS

This product does not contain any chemicals known to the State of California to cause cancer, birth defects or any other reproductive harm.

Massachusetts Right to Know Components

No components are subject to the Massachusetts Right to Know Act

New Jersey Right to Know Components

Arachidonic Acid, CAS No 506-32-1

Pennsylvania Right to Know Components

Arachidonic Acid, Cas No 506-32-1

SECTION 16: OTHER INFORMATION

Restrictions on use: No Data Available

Advice: No Data Available

Literary Reference: No Data Available

Preparation Date: June 1, 2024

Revision Level and Date: Revision -, June 1, 2024

Further information:

Epinephrine:

Full text of H-Statements referred to under sections 2 and 3.

H302	Harmful if swallowed.
H318	Causes serious damage to eyes Acute tox. Acute toxicity
H301+H331	Toxic if swallowed or if inhaled
H310	Fatal in contact with skin. Eye dam. serious damage to eyes
EUH031	Contact with acids liberates toxic gas

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.