



SAFETY DATA SHEET

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

1.1 Product identifiers

Product name : **BETA/PAK**

Product Number : REF **101580**

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

Laboratory chemicals. Reagent for platelet aggregation tests

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

Follow Good Laboratory Practices Safety Protocol and
Follow laboratory blood/ infectious hazard protocol

Emergency Phone #: +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 IDENTIFICATION

 2.1 Classification of the substance or mixture:

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

 2.2 Label Elements: Not Applicable

 2.3 Other Hazards: None
 Restricted to professional users

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

 3.1 Substances

Synonyms:

ADP:	Adenosine-5'-Diphosphate
COLLAGEN:	Soluble Calf Skin, Type 1
RISTOCETIN:	AggRecetin, Ristocetin A Sulfate, Ristomycin, Ristomycin III, Ristomycin Monosulfate

Molecular weight: N / A

CAS-No.: N / A

EC-No.: N / A

 3.2 Mixtures

Component	Identifier	Concentration	Classification
ADP	Cas No.: 20398-34-9	N / A	Not Hazardous
Collagen	Cas No.: 9007-34-5 EC No.: 232-697-4	N / A	Not Hazardous
Ristocetin A Sulfate	Cas No.: 11140-99-1 Formula: C ₉₅ H ₁₁₀ N ₈ O ₄₄ -H ₂ SO ₄	≥90 %	Not Hazardous

No components need to be disclosed according to the applicable regulations. Please reference ADP, Collagen, and AggRecetin's Individual Safety Data Sheets for specific product related details.

SECTION 4: FIRST AID MEASURES4.1 Description of first-aid measures

If inhaled	Move person into fresh air. If not breathing, give artificial respiration. Consult a physician.
In case of skin contact	Wash off with soap and plenty of water.
In case of eye contact	Wash thoroughly eyes with plenty of water for at least 15 minutes. If irritation persist consult a physician.
If swallowed	Never give anything by mouth to an unconscious person. Rinse mouth with water.

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

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

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

No further information available

SECTION 5: FIREFIGHTING MEASURES5.1 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), Oxides of Sulfur.

5.3 Advice for firefighters:

Wear self-contained breathing apparatus for fire fighting if necessary.

5.4 Further information:

No further information available

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:

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

6.2 Environmental precautions:

Do not let product enter drains or sewers.

6.3 Methods and materials for containment and cleaning up:

Sweep up and shovel. Keep in suitable, closed containers for disposal. Follow laboratory policies for containing and cleaning up chemical spills.

6.4 Reference to other sections:

See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling:

Provide appropriate ventilation at places where dust is formed. Normal measures for preventive fire protection. For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities:

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

Store in cool place.

Recommended storage temperature 2-8 ° C.

Hygroscopic.

German storage class (TRGS 510): Solid incombustible

7.3 Specific end use(s):

Apart from the uses mentioned in section 1.2 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 users. General industrial hygiene and good laboratory practices. The usual precautionary measures for handling chemicals/reagents should be followed.

Personal protective equipment:

Eye/Face 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:

Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific work- place. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection:

Respiratory protection is not required. Where protection from nuisance levels of dusts are 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.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES9.1 Information on basic physical and chemical properties:

a)	Appearance Form	:	Lyophilized Powder Color: White to Light Yellow
b)	Odor	:	Interminate
c)	Odor Threshold	:	No Data Available
d)	pH	:	~7.4
e)	Melting point / freezing point	:	No Data Available
f)	Initial boiling point and boiling range	:	No Data Available No Data Available
g)	Flash point	:	No Data Available
h)	Evaporation rate	:	No Data Available
i)	Flammability (solid, gas)	:	Product is not flammable
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	:	Slowly Soluble
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 REACTIVITY10.1 Reactivity:

No Data Available

10.2 Chemical stability:

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions:

No Data Available

10.4 Conditions to avoid:

Sensitive to moisture

10.5 Incompatible materials:

Strong oxidizing agents

10.6 Hazardous decomposition products:

No data available. In the event of fire: see section 5

SECTION 11: TOXICOLOGICAL INFORMATION11.1 Information on toxicological effects:

<i>Acute toxicity</i>	:	DL50 intravenous - mouse - 1000 mg/kg Intraperitoneal – rat – 1500 mg/kg
<i>Skin corrosion/irritation</i>	:	Non-irritant
<i>Serious eye damage/eye irritation:</i>		Irritant and Potentially Harmful
<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. NTP (National Toxicology Program): Substance is not listed. OSHA-Ca (Occupational Safety & Health Administration): 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: 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.
		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>		PBT/vPvB assessment not available as chemical safety assessment not required/not conducted
12.6 <u>Other adverse effects</u>	:	Water hazard class 1 (Self-assessment): slightly hazardous for water. Do not allow undiluted product to enter sewage system.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product:

Dispose of as Biohazardous waste in accordance with applicable policies and regulations.

Contaminated Packaging: Dispose of as Biohazardous waste in accordance with applicable regulations and laboratory policies. Do not allow product to enter sewer system.

SECTION 14: TRANSPORT INFORMATION

- 14.1 UN number: ADR/RID: - IMDG: - IATA: -
- 14.2 UN proper shipping name: ADR/RID: Not dangerous goods
IMDG: Not dangerous goods
US DOT: Not dangerous goods
IATA: Not dangerous goods
- 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: No Data Available
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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:
No Data Available
- 15.2 Chemical Safety Assessment:
For this product a chemical safety assessment was not carried out.
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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

Abbreviations and Acronyms:

SDS:	Safety Data Sheet
PBT:	Persistence, Bioaccumulation, Toxicity
vPvB:	Very persistent and very bioaccumulative
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.