

# BETA/PAK<sup>®</sup> COMBO KIT

## SAFETY DATA SHEET (SDS)

*Prepared in accordance with:*

- OSHA Hazard Communication Standard (29 CFR 1910.1200, HazCom 2012)
- Regulation (EC) No 1272/2008 (CLP)
- Regulation (EC) No 1907/2006 (REACH)
- UK REACH (post-Brexit)
- GHS (Globally Harmonized System of Classification and Labelling of Chemicals)
- TSCA (U.S. Toxic Substances Control Act) requirements, where applicable
- California Proposition 65 (where applicable)

*This SDS also supports compliance with:*

- Regulation (EU) 2017/746 (IVDR)
- ISO 13485:2016 Quality Management Systems
- FDA Quality Management System Regulation (21 CFR Part 820)

### SECTION 1: Identification of the Substance and Supplier

Product Name: BETA/PAK<sup>®</sup> Combo Kit

Catalog Number:

REF

101580

Product Contents:

- ADP Reagent, 1 vial (0.5 mL)
- Collagen Reagent, 1 vial (0.5 mL)
- Ristocetin Reagent, 1 vial (0.5 mL)

Relevant Identified Use:

IVD

In vitro diagnostic reagent used in light transmission platelet aggregation testing.

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## SECTION 2: Hazard Identification

Classification (EC 1272/2008):

Not classified as hazardous.

Label Elements (CLP/GHS):

No hazard pictogram, signal word, hazard, or precautionary statements required.

Other Hazards:

### ADP AND RISTOCETIN REAGENTS

Not considered hazardous under IVDR or CLP regulations. Use according to standard laboratory and professional practice.

### COLLAGEN REAGENT

Contains thimerosal at  $\leq 0.01\%$ , which in its neat form is classified as acutely toxic. At the concentration present in this finished formulation, it does not trigger mixture classification under CLP. Contains soluble collagen, which may cause mild mechanical irritation in sensitive individuals. No significant hazards are expected under normal laboratory use. Use according to standard laboratory and professional practice.

OSHA Classification (29 CFR 1910.1200 / HazCom 2012):

This product is not classified as hazardous under OSHA Hazard Communication Standard (HazCom 2012).

WHMIS Classification (Canada, 2015):

Not classified as hazardous under WHMIS 2015.

## SECTION 3: Composition / Information on Ingredients

### ADP REAGENT

Substance	CAS No.	EC No.	Function	Concentration	Classification
Adenosine-5'-diphosphate Sodium Salt	20398-34-9	—	Active Ingredient	85 mg/L (0.0002 M)	Not classified

Sodium Chloride	7647-14-5	231-598-3	Isotonicity agent	0.85% (w/v)	Not classified
Water, Purified (Reagent Grade)	7732-18-5	231-791-2	Solvent / vehicle	qs to 1 mL	Not classified

### COLLAGEN REAGENT

Substance	CAS No.	EC No.	Function	Concentration	Classification
Soluble Collagen, Calf Skin (Type I)	9007-34-5	232-697-4	Active Ingredient	Proprietary	Not classified
Sodium Chloride	7647-14-5	231-598-3	Isotonicity agent	0.85% (w/v)	Not classified
Mannitol	69-65-8	200-711-8	Stabilizer	≤ 1%	Not classified
Thimerosal	54-64-8	200-210-4	Preservative	≤ 0.01%	Not classified (based on final formulation)
Water, Purified (Reagent Grade)	7732-18-5	231-791-2	Solvent / vehicle	qs to 1 mL	Not classified

### RISTOCETIN REAGENT

Substance	CAS No.	EC No.	Function	Classification
Ristocetin A Sulphate	11140-99-1	215-770-5	Active Ingredient	Not classified
Sodium Chloride (0.85%)	7647-14-5	231-598-3	Isotonic agent	Not classified
Water, Purified (Reagent Grade)	7732-18-5	231-791-2	Solvent / vehicle	Not classified

### SECTION 4: First Aid Measures

General Advice: Not expected to pose a hazard. Use standard laboratory precautions.

Inhalation: Not an expected route of exposure.

Skin Contact: Wash with water. Seek medical attention if irritation persists.

Eye Contact: Rinse cautiously with water. Seek medical attention if needed.

Ingestion: Rinse mouth. Seek medical attention if symptoms occur.

## **SECTION 5: Fire-Fighting Measures**

Suitable Extinguishing Media: Water spray, CO<sub>2</sub>, dry chemical, or foam.

Special Hazards: Non-flammable.

Protective Equipment: Standard chemical fire PPE.

## **SECTION 6: Accidental Release Measures**

Personal Precautions: Wear gloves, eye protection.

Cleanup Methods: Absorb with inert material. Dispose in accordance with local regulations.

Environmental Precautions: Avoid runoff and prevent discharge into waterways.

## **SECTION 7: Handling and Storage**

### **ADP AND COLLAGEN REAGENTS**

Handling:

Use per standard laboratory practice. Avoid contamination. Reconstitute the ADP and Collagen Reagents using purified water.

Storage Conditions:

No temperature protection required during shipment.

Upon receipt, store at 2–8 °C in original packaging.

Once reconstituted, the reagent is stable for 30 days in a tightly capped vial at 2–8 °C.

Avoid light and repeated freeze-thaw cycles.

### **RISTOCETIN REAGENT**

Handling:

Use per standard laboratory practice. Avoid contamination. Reconstitute the Ristocetin Reagent using purified water.

Storage Conditions:

No temp protection required during shipment.

Upon receipt, store at 2 – 8°C in original packaging.

Once reconstituted, the reagent is stable for 7 days in tightly capped vial at 2 – 8°C.

Avoid light and repeated freeze-thaw cycles.

## **SECTION 8: Exposure Controls / Personal Protection**

Occupational Exposure Limits:

No occupational exposure limits are established for the components.

### Engineering Controls:

Use in a well-ventilated area or within a biosafety cabinet as appropriate.

### Personal Protective Equipment (PPE):

Eye/Face Protection: Safety goggles or face shield

Skin Protection: Laboratory gloves (e.g., nitrile or latex)

Body Protection: Standard laboratory coat

Respiratory Protection: Not required under normal use conditions

### Hygiene Measures:

Wash hands thoroughly after handling.

Avoid ingestion, inhalation, or contact with eyes and skin.

## **SECTION 9: Physical and Chemical Properties**

### **ADP AND COLLAGEN REAGENTS**

#### Physical State:

- Reagent: Lyophilized cake/pellet
- Reconstituted Reagent: Liquid

#### Appearance:

- Reagent (lyophilized): White lyophilized cake/pellet
- Reconstituted Reagent: Clear, colorless

Odor: Odorless

pH (reconstituted): Neutral

Melting/Freezing Point: Not applicable

Boiling Point: Not applicable

Flash Point: Not applicable

Solubility: Soluble in water

Vapor Pressure: Not applicable

Specific Gravity: Similar to water

### **RISTOCETIN REAGENT**

#### Physical State:

- Reagent: Lyophilized cake/pellet
- Reconstituted Reagent: Liquid

Appearance:

- Reagent (lyophilized): White lyophilized cake/pellet
- Reconstituted Reagent: Clear, colorless to pale yellow

Odor: Odorless

pH (reconstituted): 5.0 – 6.0

Melting/Freezing Point: Not applicable

Boiling Point: Not applicable

Flash Point: Not applicable

Solubility: Soluble in water

Vapor Pressure: Not applicable

Specific Gravity: Similar to water

## **SECTION 10: Stability and Reactivity**

Reactivity: No known reactivity hazards under normal conditions.

Chemical Stability: Stable under recommended storage and handling conditions.

Possibility of Hazardous Reactions: No hazardous polymerization or decomposition expected.

Conditions to Avoid: Excessive heat, light exposure, or repeated freeze-thaw cycles.

Incompatible Materials: Strong oxidizing agents.

Hazardous Decomposition Products: None under normal use.

## **SECTION 11: Toxicological Information**

Acute Toxicity: Not classified as acutely toxic; very low systemic toxicity expected at use concentrations.

Skin Corrosion/Irritation: Not expected to be irritating

Serious Eye Damage/Irritation: May cause mild mechanical irritation

Sensitization: No data available; not expected

Carcinogenicity / Mutagenicity / Reproductive Toxicity: Not classified based on available data

STOT – Single/Repeated Exposure: No data indicating specific target organ toxicity

## **SECTION 12: Ecological Information**

### **ADP AND RISTOCETIN REAGENT**

Ecotoxicity: Not expected to pose a significant environmental hazard

Persistence and Degradability: Expected to be biodegradable

Bioaccumulation Potential: Not expected to bioaccumulate

Mobility in Soil: High water solubility; likely to move with water

Other Adverse Effects: None known

## **COLLAGEN REAGENTS**

Ecotoxicity: No specific ecotoxicity data are available for this finished formulation. Based on the low concentration of components and intended laboratory use, this product is not expected to pose a significant environmental hazard.

Persistence and Degradability: No specific test data are available for the finished formulation. Based on the chemical nature of the components, they are expected to be biodegradable.

Bioaccumulation Potential: No data are available for the finished formulation. Bioaccumulation is not expected based on physicochemical properties and low environmental exposure.

Mobility in Soil: Due to the water solubility of the final formulation, components are expected to be mobile in soil.

Other Adverse Effects: None known.

## **SECTION 13: Disposal Considerations**

Waste Treatment Methods:

Dispose of unused reagent and contaminated packaging in accordance with local, regional, or national regulations.

Do not dispose of via sewage or regular waste.

Follow procedures for laboratory chemical disposal.

## **SECTION 14: Transport Information**

UN Number: Not regulated

Proper Shipping Name: Not regulated

Transport Hazard Class: Not applicable

Packing Group: Not applicable

Environmental Hazards: None

Special Precautions: None

ADR/RID/IMDG/IATA Status: Not regulated for ground, air, or sea

## **SECTION 15: Regulatory Information**

EU IVDR: CE-marked under Regulation (EU) 2017/746.

EU REACH: Exempt per Article 2(5).

EU CLP: Not classified as hazardous under Regulation (EC) 1272/2008.

UK REACH: Exempt; UK conformity assessment and UK Responsible Person requirements apply where applicable for in vitro diagnostic distribution.

U.S. FDA / OSHA: This product is not classified as hazardous under OSHA Hazard Communication Standard (HazCom 2012); complies with FDA Quality Management System Regulation (21 CFR Part 820).

U.S. TSCA (EPA): This product is exempt from TSCA inventory requirements as it is manufactured and distributed solely for FDA-regulated in vitro diagnostic use.

ISO / UKAS: This SDS supports documentation requirements for ISO 15189 and ISO 17025 accredited laboratories. UKAS accreditation does not apply directly to SDS content.

California Proposition 65: This product contains no chemicals known to the State of California to cause cancer, birth defects, or other reproductive harm.

## **SECTION 16: Other Information**

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QMS Cross-Reference: This SDS is supported by internal, controlled documentation including Material Specifications (MS), Process Specifications (PS), Formulation Procedures (FP), and the Instruction for Use (IFU) for the product. Refer to the current versions of these documents maintained under Bio/Data Corporation's Quality Management System.

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