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ARACHIDONIC ACID REAGENT
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: Arachidonic Acid Reagent

Catalog Number:

REF 101297

Product Contents:

- Arachidonic Acid, 3 vials (0.5 mL each)

Relevant Identified Use:

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

Manufacturer / Supplier:	Bio/Data Corporation
Address:	155 Gibraltar Road, Horsham, PA 19044 USA
Telephone:	+1 215-441-4000
Website:	www.biodatacorp.com
Email:	customer.service@biodatacorp.com
Emergency Contact:	+1 215-441-4000 (Available Monday–Friday, 8:30 AM – 5:00 PM EST)

SECTION 2: Hazard Identification

Classification (EC 1272/2008):
Based on the concentration present in the finished in vitro diagnostic formulation, this product is not classified as hazardous.

Label Elements (CLP/GHS):
No hazard pictogram, signal word, hazard, or precautionary statements required.

Other Hazards:
Contains arachidonic acid, which in its neat form may cause skin and eye irritation. In this finished formulation at working concentrations, 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

Substance	CAS No.	EC No.	Function	Concentration	Classification
Arachidonic Acid	506-32-1	208-033-4	Active Ingredient	1.0 g/vial (lyoph.)	Not classified (based on final formulation)
Sodium Carbonate	497-19-8	207-838-8	Buffering agent	2.121 g/g AA	Not classified
Water, Purified (Reagent Grade)	7732-18-5	231-791-2	Solvent / vehicle	qs to 0.5 mL	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_2, 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

Handling:
Use per standard laboratory practice. Avoid contamination. Reconstitute the Arachidonic Acid Reagent 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 24 hours in a 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

Physical State:

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

Appearance:

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

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

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

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 available for the finished formulation. Bioaccumulation is not expected based on physicochemical properties and low environmental exposure.
Mobility in Soil: Due to 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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Prepared by: Regulatory Affairs & Quality Assurance Department
Bio/Data Corporation
Email: customer.service@biodatacorp.com
Telephone: +1 215-441-4000

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.