



SAFETY DATA SHEET

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

1.1 Product identifiers

Product name : **Lupus Anti-Coagulant Confirmation Reagent
(LACR)**

Product Number : REF **102516**

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.

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

Emergency Phone #: Follow laboratory chemical hazard protocol
+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 IDENTIFICATION2.1 Classification of the substance or mixture:

Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008 on classification, labeling and packaging of substances and mixtures (CLP).

2.2 Label Elements: Not Applicable2.3 Other Hazards: Restricted to professional users

All chemicals are potentially dangerous. They are therefore only to be handled by specially trained personnel using necessary care and precautions.

The product contains human platelet membrane fragments derived from platelet concentrate plasmas that have been tested according to current FDA guidelines for the detection of antibodies to HIV and HCV, Hepatitis Surface Antigen, HIV-1 RNA, HBV DNA, WNV RNA, and Syphilis. A licensed NAT test for Babesia has been performed and found non-reactive for blood collected in those states where testing is required by the FDA. Each donor has been tested according to FDA guidelines for T. Cruzi (Chagas). All units yielded non-reactive/negative results for each test performed. All blood was collected in the United States from human donors at FDA licensed centers. All tests are performed using FDA approved test kits.

This product, as with all human based specimens, should be regarded as potentially infectious and handled following proper laboratory safety procedures for the use and disposal of biological material.

The product does not contain any components in concentrations of 0.1% or above, which are classified either as PBT or vPvB.

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS3.1 Substances

Synonyms: Lupus Anticoagulant Confirmation Reagent, LACR,
Platelet Extract Reagent (PER)

Molecular weight: N / A

CAS-No.: N / A

EC-No.: N / A

No components need to be disclosed according to the applicable regulations.

3.2 Mixtures

Component / Name of Substance	Identifier	Concentration (% by Weight)	Classification	Hazard Pictogram	Specific Concentration Limits
Reagent/ Lecithin	Cas No.: 8002-43-5	Formulation dependent	Not Hazardous	N / A	N / A
Reagent / Human Platelet Lysate	Cas No.: N / A	N / A	N / A	N / A	N / A
Buffer / Imidazole	Cas No.: 288-32-4	>10%	Not Hazardous	N / A	>10%
Buffer Preservative / Sodium azide	EC No.: 247-852-1 Cas No: 26628-22-8 Idx No.: 011-004-00-7	<0.001%	Acute Tox. Oral, Cat.2, Acute aquatic tox. Cat. 1, chronic aquatic tox. Cat 1, Kat. 1; H300*, H410*	N / A	>0.001%

SECTION 4: FIRST AID MEASURES

4.1 Description of first-aid measures



General

Remove contaminated clothes.

If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact

Wash affected area immediately with soap or mild detergent and plenty of water until mixture is completely gone. Seek medical advice if irritation continues.

In case of eye contact

Wash immediately with plenty of water or normal saline for at least 15 minutes. Keep eyelid open with finger. Seek medical advice if irritation continues.

If swallowed

If swallowed, rinse mouth with plenty of water provided person is conscious. Do not induce vomiting. Seek medical advice if adverse symptoms appear. mouth with water. Consult a physician.

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

Toxic symptoms and effects are not known. 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 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:

Nature of decomposition products not known.

5.3 Advice for firefighters:

Protective actions:

Water jets can be used successfully to cool containers exposed to the fire and disperse fumes

Equipment for self-protection:

Breathing apparatus (SCBA), flame and chemical resistant clothing (boots, gloves, overalls, eye and face protection Equipment must conform to national/international standards and used in the highest condition of protection on the basis of the information reported above.

5.4 Further information:

No further information available

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:

Use protective glasses, disposable gloves, and lab coat. Avoid dust formation. Avoid breathing vapors, mist or gas. For personal protection see section 8.

6.2 Environmental precautions:

Limit access to required personnel during formulation process. Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up:

Bio-Hazard, Use Standard Precautions, Disinfect Area

Collect spilled material with an inert absorbent material and clean with laboratory disinfectant.

Keep in suitable, closed containers for disposal.

6.4 Reference to other sections:

For disposal see section 13. Dispose as Bio-hazard material in accordance with current regulations and policies.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling:

Advice on protection against fire and explosion

Handle in a well-ventilated place, and away from sparkles and flames. Keep the mixture away from drains, surface or ground waters.

Hygiene measures

General industrial hygiene practice. For precautions see section 2.2.

Wear suitable Personal Protection Equipment (see section 8). Do not eat, drink and smoke in the working areas. Wash hands with soap and water after handling the mixture. Remove contaminated clothing and protective equipment before entering eating areas.

7.2 Conditions for safe storage, including any incompatibilities:

Avoid light exposure and keep away from heat sources. Work in a well-ventilated workplace. Keep containers tightly closed and labelled with the name of the product. Avoid environmental release. Keep away from food and drinks. Recommended storage temperature 2-8 ° C.

7.3 Specific end use(s):

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated. The product is intended for in-vitro diagnostic use by qualified laboratory personnel. Read and understand safety notes as given in the IFU. Use the product in accordance with the Good Laboratory Practice (GLP).

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Ingredients with workplace control parameters:

Workplace exposure limit values are not established.

8.2 Exposure controls:

Workplace exposure limit values are not established.

Appropriate engineering controls:

Restricted to professional users. General industrial hygiene practice.

Change contaminated clothing. Wash hands after working with substance.

Appropriate risk management measures, that must be adopted at the workplace, have to be selected and applied, following the risks assessment carried out by the employer, in connection with his working activity. If the results of this evaluation show that the general and collective prevention measures are not sufficient to reduce the risk, and if you cannot prevent exposure to the mixture by other measures, adequate personal protective equipment must be adopted, complying with relevant technical national/international standards.

Personal protective equipment:

Eye/Face protection:

Wear Safety Glasses. 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. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface). Wash and dry hands. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. 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	:	Flaky Powder, Un-reconstituted Color: White to Light Tan
b)	Odor	:	None
c)	Odor Threshold	:	None
d)	pH	:	~ 7.4
e)	Melting point / freezing point	:	No Data Available
f)	Initial boiling point and boiling range	:	No Data Available
g)	Flash point	:	Non-Flammable
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	:	Colloidal
o)	Partition coefficient - n-octanol/water	:	No Data Available
p)	Autoignition temperature	:	No Data Available
q)	Decomposition temperature	:	Thermal decomposition or combustion may include toxic and hazardous fumes of (CO _x , NO _x).
r)	Viscosity	:	No Data Available
s)	Explosive properties	:	Not classified as explosive
t)	Oxidizing properties	:	Avoid oxidizing agents, strong acid agents and strong alkaline agents.

9.2 Other safety information:

No Other Data Available

SECTION 10: STABILITY AND REACTIVITY10.1 Reactivity:

None

10.2 Chemical stability:

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions:

No Data Available

10.4 Conditions to avoid:

No Data Available

10.5 Incompatible materials:

Strong oxidizing agents

10.6 Hazardous decomposition products:Thermal decomposition or combustion may include toxic and hazardous fumes of (CO_x, NO_x). In the event of fire: see section 5.

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

<i>Acute toxicity</i>	:	Oral:	No Data Available
		Inhalation:	No Data Available
		Dermal:	No Data Available
<i>Skin corrosion/irritation</i>	:		No Data Available
<i>Serious eye damage/eye irritation:</i>			No Data Available
<i>Respiratory or skin sensitization :</i>			No Data Available
<i>Germ cell mutagenicity</i>	:		No Data Available

<i>Carcinogenicity</i>	:	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	:	No Data Available
11.2 Additional Information	:	RTECS: No Data Available To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

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>	:	No Data Available

SECTION 13: DISPOSAL CONSIDERATIONS13.1 Waste treatment methods

Product: Used reagents must be disposed of in accordance with local and federal regulations.

Contaminated Packaging: Dispose of as unused product.

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

Not classified as dangerous in the meaning of transport regulations.

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

SECTION 16: OTHER INFORMATION

Restrictions on use: No Data Available

Advice: No Data Available

Literary Reference: No Data Available

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 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**H300 Fatal if swallowed.****H410 Very toxic to aquatic life with long lasting effects.**

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.