

SAFETY DATA SHEET

NAME OF PRODUCT: **Lupus Anticoagulant Confirmation Reagent**

1: PRODUCT AND COMPANY IDENTIFICATION

1.1 Product Identifiers

PRODUCT NAME: Lupus Anticoagulant Confirmation Reagent, LACR,
SYNONYMS: Lupus Anticoagulant Confirmation Reagent, Platelet Extract Reagent (PER)
PRODUCT CODES: 102516

1.2 Details of the supplier of the safety data sheet

MANUFACTURER: Bio/Data Corporation
ADDRESS: 155 Gibraltar Road, Horsham, PA 19044, USA
PHONE: +1- 215-441-4000

1.3 Emergency information

EMERGENCY: Turn to nearest First Aid Station
EMERGENCY PHONE: +1-215-441-4000 (Bio/Data Corporation)

2: HAZARDS IDENTIFICATION

2.1 Environmental Protection Procedures: Spill response: Bio-hazard, Use Standard Precautions;
2.2 Waste Disposal Method: Dispose as Bio-hazard material in accordance with current regulations and policies.

3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Component: 5 x 1 mL of a Platelet phospholipids solution (<1%) from human blood; tested negative for HIV-1Ag, anti-HIC-1/2, Hepatitis B surface antigen, Hepatitis C antibody, Human T- Lymph tropic Type I and II (anti-HTLV I/II) and Negative by a serological test for Syphilis

Chemical Family: Biological
Formula: N/A

<u>CAS NO.</u>	<u>% WT</u>	<u>% VOL</u>	<u>CLASSIFICATION</u>
N/A	N/A	N/A	Not Regulated

Note: Reagents do not contain dangerous substances in quantities higher than limits reported by 67/548/EEC and 1999/45/EC directives, and following modifications and amendments, about classification, labeling and packaging of dangerous preparations.

4: FIRST AID MEASURES

- 4.1 Eye contact: flush eyes with water
- 4.2 Skin contact: wash off with water
- 4.3 Ingestion: seek medical advice
- 4.4 Direction for physician: symptomatic treatment by a physician

5: FIRE-FIGHTING MEASURES

N/A

6: ACCIDENTAL RELEASE MEASURES

- 6.1 **After spillage:** Bio-hazard, Use Standard Precautions, disinfect area
- 6.2 **Absorbent material:** no restriction
- 6.3 **Special measures:** Dispose as Bio-hazard material in accordance with current regulations and policies.

7: HANDLING AND STORAGE

- 7.1 Follow instructions on product insert and GLP. This product must be handled with the usual care for diagnostic reagents.

8: EXPOSURE CONTROLS/PERSONAL PROTECTION

- 8.1 **Respiratory protection:** none
- 8.2 **Eye protection:** use protective glasses
- 8.3 **Hand protection:** disposable gloves

9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

APPEARANCE	Flaky powder, un-reconstituted
COLOR	Clear to translucent colorless liquid
ODOR	None
pH	~7.4
BOILING POINT	N/A
MELTING POINT	N/A
IGNITION TEMPERATURE	N/A
FLASH POINT	Non-flammable
EXPLOSION LIMIT	N/A
VAPOR TENSION	N/A
DENSITY	N/A
VAPOR PRESSURE	N/A
SOLUBILITY IN WATER	Colloidal

10: STABILITY AND REACTIVITY

- 10.1 **STABILITY:** Stable
- 10.2 **CONDITIONS TO AVOID (STABILITY):** None
- 10.3 **INCOMPATIBILITY:** None
- 10.4 **HAZARDOUS DECOMPOSITION OR BY-PRODUCTS:** None
- 10.5 **HAZARDOUS POLYMERIZATION:** None
- 10.6 **CONDITIONS TO AVOID (POLYMERIZATION):** None

11: TOXICOLOGICAL INFORMATION

- 11.1 **LD50 oral:** not known.
- 11.2 **LD50:** not known.
- 11.3 **LD50 skin:** not known.
- 11.4 **LD50 inhalation:** not known.
- 11.5 Not identified as a carcinogen

12: ECOLOGICAL INFORMATION

No Data Available

13: DISPOSAL CONSIDERATIONS

- 13.1 Used reagents must be disposed of in accordance with local and federal regulations.

14: TRANSPORT INFORMATION

- 14.1 Not Regulated - This product is not subject to current regulations for transportation of hazardous goods.

15: REGULATORY INFORMATION

- 15.1 This Product does not require special labeling in accordance with the appropriate EEC directives.

16: OTHER INFORMATION

This product is intended for IN VITRO diagnostic use only.
NOT FOR USE IN HUMANS.

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.