



SAFETY DATA SHEET

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

1.1 Product identifiers

Product name : **Lyophilized Platelets**

Product Number : REF **101258**

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

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 blood/ infectious 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

2.2 Label Elements: Not Applicable2.3 Other Hazards: None
Restricted to professional users**SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS**3.1 Substances

Not applicable the product is not a substance.

3.2 Mixtures**Hazardous ingredients**

This product does not contain substances to be mentioned according to EU Regulation No 1907/2006 (REACH), Annex II

3.3 Other information

Do not inject or ingest.

The preparation contains material of human origin which has been tested and found negative for HBSAg, anti-HIV and HCV. As with all materials of human origin, this product should be regarded as potentially hazardous to health. Therefore, it should be handled in compliance with appropriate laboratory safety procedures to minimize the risk of transmitting infectious pathogens.

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

If symptoms develop or when in doubt, seek medical attention.
Never give anything by mouth to an unconscious person. Do not leave victim unattended.

If inhaled	Remove victim to fresh air. Keep warm and at rest. If irritation occurs, seek medical attention.
In case of skin contact	Wash off immediately with plenty of soap and water. Take off immediately all contaminated clothing. Wash contaminated clothing before reuse. If skin reaction occurs, seek medical attention.
In case of eye contact	Rinse immediately with plenty of water for at least 15 minutes holding the eyelids open. If possible, remove contact lenses. Continue to rinse. Seek medical attention preferably an ophthalmologist.
If swallowed	Get immediately medical attention. Do not induce vomiting. Never give anything by mouth to an unconscious person.

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

No Data Available

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

No Data Available

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media:

Suitable extinguishing media

Product itself is non-combustible; adapt fire extinguishing measures to surrounding areas

Unsuitable extinguishing media

Water spray

5.2 Special hazards arising from the substance or mixture:

In the event of fire, the following can be released: Carbon dioxide (CO₂); Carbon monoxide (CO)

5.3 Advice for firefighters:

In the event of a fire: Wear protective equipment. Self-contained breathing apparatus. Do not allow extinguishing water to enter sewerage or any water course. Do not breathe fire/explosion fumes.

5.4 Further information:

No further information available

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:

Refer to protective measures listed in section 7 and 8. Avoid contact with skin, eyes and clothing
Avoid dust formation. Do not breathe gas/mist/vapors.

6.2 Environmental precautions:

Prevent further spillage if safe. Do not allow product to enter drains or any water course. Avoid release to the environment.

6.3 Methods and materials for containment and cleaning up:

Do not place spilled material back in the original container. Collect spilled material with absorbent material. Clean contaminated surfaces and devices in compliance with all applicable legal requirements and regulations. Transfer to suitable, closed and labelled containers for storage/disposal.

6.4 Reference to other sections:

For disposal see section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling:

Advice on safe handling

For safe product handling, select and apply appropriate prevention and control measures that will reduce to a minimum the intrinsic risk hazard. Design and operate processes, insofar as the state of technology permits, in such a way that dangerous substances may not be released / contact with the skin can be ruled out.

General protective and hygiene measures

Do not eat, drink or smoke during work time. Keep away from food, drink and animal feeding stuffs. Wash hands and skin before breaks and after work. Do not inhale vapors. Avoid contact with eyes and skin. Remove soiled or soaked clothing immediately.

Advice on protection against fire and explosion

No special measures necessary.

7.2 Conditions for safe storage, including any incompatibilities:

Technical measures and storage conditions

Keep container tightly closed in a cool, well-ventilated place.

Incompatible materials

No data available.

Recommended storage temperature

Value : 2- 8°C

Requirements for storage rooms and vessels

Containers which are opened must be carefully closed and kept upright to prevent leakage.

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:

Occupational exposure limit values

No parameters available for monitoring.

Biological limit values

No data available

8.2 Exposure controls:

Appropriate engineering controls:

Technical measures and appropriate working operations should be given priority over the use of personal protective equipment. Any measure taken shall comply with good hygiene practice.

Personal protective equipment:

During product handling, wear appropriate protective clothing in compliance with the applicable rules.

Eye/Face protection:

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection:

During handling, wear appropriate protective gloves. Prior to use, check in any case suitability of protective glove for the specific workplace conditions. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Protective gloves must be tested and approved under EN374 standard.

Replace protective gloves immediately when they become worn and damaged.

Body protection:

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 not required. Where protection from nuisance levels of dusts are necessary, 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:

Prevent further spillage/release of material if safe. Do not allow product to enter drains or any water course. Avoid release to the environment.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**9.1 Information on basic physical and chemical properties:**

a)	Appearance Form	:	Lyophilized Powder Color: White / Yellow
b)	Odor	:	No Data Available
c)	Odor Threshold	:	No Data Available
d)	pH	:	No Data Available
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)	:	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	:	No Data Available
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 REACTIVITY

10.1 Reactivity:

No dangerous reactions known if handled in compliance with applicable provisions/under normal conditions of use.

10.2 Chemical stability:

The preparation is stable if handled and stored as recommended under section 7.

10.3 Possibility of hazardous reactions:

None if used for the intended purpose.

10.4 Conditions to avoid:

None if used for the intended purpose.

10.5 Incompatible materials:

None known.

10.6 Hazardous decomposition products:

None if used for the intended purpose.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects:

Acute toxicity : 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 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.
	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	:	No Data Available

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>	:	Do not discharge product unmonitored into the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product:

Dispose of waste in compliance with national rules and consultation with environmental services. The waste code is established in consultation with your regional waste disposer.

Contaminated Packaging: Empty properly packaging. Completely emptied packaging or practically empty packaging containing residues shall be disposed of properly in consultation with your regional waste disposer.

SECTION 14: TRANSPORT INFORMATION

The product is not covered by international regulations on the transport of dangerous goods (IMDG, IATA, ADR/RID).

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|------|--------------------------------------|---|
| 14.1 | <u>UN number:</u> | ADR/RID: - IMDG: - IATA: - |
| 14.2 | <u>UN proper shipping name:</u> | ADR/RID: Not dangerous goods
IMDG: Not dangerous goods
US DOT: Not dangerous goods
IATA: Not dangerous goods |
| 14.3 | <u>Transport hazard class(es):</u> | ADR/RID: - IMDG: - IATA: - |
| 14.4 | <u>Packaging group:</u> | ADR/RID: - IMDG: - IATA: - |
| 14.5 | <u>Environmental hazards:</u> | ADR/RID: no IMDG Marine pollutant: no IATA: no |
| 14.6 | <u>Special precautions for user:</u> | No Data Available |
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SECTION 15: REGULATORY INFORMATION

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2008.

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|------|--|-------------------|
| 15.1 | <u>Safety, health and environmental regulations/legislation specific for the substance or mixture:</u> | No Data Available |
| 15.2 | <u>Chemical Safety Assessment:</u> | No Data Available |
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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 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

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.