Safety Data Sheet

CytoPure™ XF — Human Platelet Lysate, Fibrinogen-Depleted, Xeno-Free

Issued in accordance with the OSHA Hazard Communication Standard, 29 CFR 1910.1200, and the United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

Section 1. Identification

Product identifier	CytoPure™ XF — Human Platelet Lysate, Fibrinogen-Depleted, Xeno-Free
Catalog numbers	1909-C050 (50 mL) · 1909-C100 (100 mL) · 1909-C500 (500 mL)
Product form	Liquid, supplied frozen
Identified use	Cell culture supplement for laboratory research and cell therapy development. Research use only.
Uses advised against	Human or veterinary use; diagnostic or therapeutic procedures; food, drug, household, or any other non-laboratory use.
Supplier	Cytologics, Inc. 4231 Balboa Ave, Ste 3058, San Diego, CA, 92117, USA
Telephone	+1 (866) 298-6077 (Monday–Friday, 8:00 a.m.–5:00 p.m. Pacific Time)
Email	info@cytologicsbio.com
Emergency telephone	+1 (866) 298-6077 (Monday–Friday, 8:00 a.m.–5:00 p.m. Pacific Time)

Note This product is not classified as a hazardous chemical.

Section 2. Hazard identification

2.1 Classification of the substance or mixture

Not a hazardous substance or mixture under the OSHA Hazard Communication Standard, 29 CFR 1910.1200. No GHS hazard classes apply.

2.2 GHS label elements

None required. No signal word, hazard pictogram, hazard statement, or precautionary statement applies to this product.

2.3 Hazards not otherwise classified (HNOC)

This product is manufactured from pooled human platelets and must be treated as potentially infectious. Although every donor unit was tested and found non-reactive for the agents listed in Section 15, no testing method can completely exclude the presence of an infectious agent.

Caution Handle at Biosafety Level 2 or higher in accordance with the CDC/NIH publication Biosafety in Microbiological and Biomedical Laboratories. Observe universal precautions for materials of human origin.

Section 3. Composition / information on ingredients

3.1 Mixtures

Component	CAS No.	Concentration	GHS classification
Human platelet lysate (pooled human donor platelets, aqueous biological mixture)	Not assigned — biological mixture	Proprietary biological mixture / not applicable	Not classified

No animal-derived components are used at any stage of manufacture. Heparin is not used in the manufacture of this product.

No component of this product requires disclosure as hazardous under 29 CFR 1910.1200.

Section 4. First-aid measures

4.1 Description of first-aid measures

Inhalation	Remove the affected person to fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration and obtain medical attention.
Skin contact	Remove contaminated clothing and shoes. Wash the affected area with soap and water for at least 15 minutes. Obtain medical attention if irritation develops or if the skin was broken at the point of contact.
Eye contact	Rinse immediately with plenty of water for at least 15 minutes, holding the eyelids apart. Remove contact lenses if present and easy to do. Obtain medical advice.
Ingestion	Do not induce vomiting. Rinse the mouth with water if the person is conscious. Obtain medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No specific symptoms or effects are known. The principal concern is potential exposure to a material of human origin rather than chemical toxicity.

4.3 Indication of immediate medical attention and special treatment needed

Treat according to institutional procedures for exposure to human-derived material, including needlestick and mucous membrane exposure protocols where applicable. Show this Safety Data Sheet to the attending physician.

Section 5. Fire-fighting measures

5.1 Extinguishing media	Use any medium suitable for the surrounding fire: water spray, carbon dioxide, dry chemical, or alcohol-resistant foam. No restriction applies.
5.2 Special hazards	The product is aqueous and is not flammable. Combustion of the packaging may produce carbon oxides. No unusual fire or explosion hazard is associated with the product itself.
5.3 Advice for firefighters	Wear self-contained breathing apparatus and full protective equipment. Contain run-off and treat as potentially infectious material.

Section 6. Accidental release measures

6.1 Personal precautions	Wear gloves, eye protection, and a laboratory coat. Avoid generating aerosols or splashes. Restrict access to the area until decontamination is complete.

6.2 Environmental precautions	Do not allow the product to enter drains, surface water, or groundwater.
6.3 Containment and cleanup	Contain the spill immediately. Decontaminate the spill using an appropriate freshly prepared disinfectant effective against biological materials, such as sodium hypochlorite, in accordance with institutional biosafety procedures. Allow the required contact time specified for the disinfectant. Absorb the neutralized material with a suitable absorbent, place it in a labeled biohazard container, and dispose of it as regulated medical waste.
6.4 Reference to other sections	See Section 8 for personal protective equipment and Section 13 for disposal.

Section 7. Handling and storage

7.1 Precautions for safe handling	Handle in a Class II biological safety cabinet using aseptic technique. Do not eat, drink, or smoke in the handling area. Keep the container closed when not in use. Wash hands thoroughly after handling.
7.2 Conditions for safe storage	Store at ≤ –20°C on receipt. For storage beyond 12 months, –80°C is recommended. Keep in the original closed container.
7.3 Specific end uses	Cell culture supplement, research use only. Refer to CYT-HPL-1909 for directions for use.

Section 8. Exposure controls / personal protection

8.1 Control parameters

No occupational exposure limits have been established for this product or its components by OSHA, ACGIH, or NIOSH.

8.2 Engineering controls

Handle in a certified Class II biological safety cabinet when procedures may generate aerosols or splashes. Follow applicable institutional biosafety requirements.

8.3 Individual protection measures

Eye and face protection	Safety glasses with side shields, or chemical safety goggles where splashing is possible.
Skin protection	Disposable nitrile or latex gloves and a laboratory coat. Change gloves immediately if contaminated.
Respiratory protection	Not required under normal conditions of use when handled in a biological safety cabinet.
Thermal protection	Insulated cryogenic gloves when handling frozen product or dry ice.
Hygiene measures	Wash hands and exposed skin thoroughly with soap and water before breaks and on leaving the laboratory. Launder contaminated clothing before reuse.

Section 9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Property	Value
Appearance	Straw to amber liquid; frozen solid as supplied. May appear cloudy or contain flocculent material after thawing.
Odor	Mild or odorless

Property	Value
Odor threshold	Not determined
pH	7.0–7.8
Melting point / freezing point	Not determined
Initial boiling point / range	Not determined
Flash point	Not applicable — aqueous, not flammable
Evaporation rate	Not determined
Flammability (solid, gas)	Not applicable
Upper / lower flammability limits	Not applicable
Vapor pressure	Not determined; approximates water
Vapor density	Not determined
Relative density	Not determined
Solubility	Miscible with water
Partition coefficient (n-octanol/water)	Not applicable — aqueous biological mixture
Auto-ignition temperature	Not applicable
Decomposition temperature	Not determined
Viscosity	Similar to water
Explosive properties	Not explosive
Oxidizing properties	Not oxidizing

9.2 Other information

Osmolality 250–350 mOsm/kg; total protein 4.0–7.0 g/dL. Lot-specific values are reported on the Certificate of Analysis supplied with each lot.

Section 10. Stability and reactivity

10.1 Reactivity	Not reactive under normal conditions of use.
10.2 Chemical stability	Stable when stored frozen at ≤ –20°C in the original closed container.
10.3 Possibility of hazardous reactions	None known.
10.4 Conditions to avoid	Repeated freeze-thaw cycling; prolonged storage at 2–8°C; elevated temperature; direct sunlight.
10.5 Incompatible materials	Strong oxidizing agents; strong acids and bases.
10.6 Hazardous decomposition products	None under normal conditions. Thermal decomposition may produce carbon oxides and nitrogen oxides.

Section 11. Toxicological information

11.1 Information on toxicological effects

Endpoint	Information
Acute toxicity	No data available for this mixture
Skin corrosion / irritation	No data available
Serious eye damage / irritation	No data available
Respiratory or skin sensitization	No data available
Germ cell mutagenicity	No data available

Endpoint	Information
Carcinogenicity	Not listed by IARC, NTP, or OSHA
Reproductive toxicity	No data available
STOT — single exposure	No data available
STOT — repeated exposure	No data available
Aspiration hazard	No data available

The relevant hazard associated with this product is biological rather than toxicological. See Section 2.3.

Section 12. Ecological information

12.1 Toxicity	No data available.
12.2 Persistence and degradability	No data available. No significant environmental hazard is anticipated under normal laboratory use.
12.3 Bioaccumulative potential	No data available. Bioaccumulation is not expected.
12.4 Mobility in soil	No data available.
12.5 Results of PBT and vPvB assessment	Not conducted.
12.6 Other adverse effects	None known.

Section 13. Disposal considerations

13.1 Waste treatment methods

Decontaminate the product and any contaminated materials before disposal, either by autoclaving or by chemical inactivation with sodium hypochlorite as described in Section 6.3. Dispose of decontaminated material as regulated medical waste in accordance with all applicable federal, state, and local requirements.

Do not dispose of untreated product to the sewer or to general refuse. Empty containers retain product residue and must be decontaminated before disposal.

Section 14. Transport information

	US DOT	IATA	IMDG
UN number	UN 3373	UN 3373	UN 3373
Proper shipping name	Biological Substance, Category B	Biological Substance, Category B	Biological Substance, Category B
Transport hazard class	6.2	6.2	6.2
Packing group	Not applicable	Not applicable	Not applicable
Packing instruction	P650	PI 650	P650

Special precautions: the product is shipped frozen. When dry ice is used as a refrigerant it must be declared separately as UN 1845, Carbon dioxide, solid (dry ice), Class 9, with the net quantity stated on the transport document.

Transport in bulk according to MARPOL Annex II and the IBC Code: not applicable.

Section 15. Regulatory information

15.1 Safety, health, and environmental regulations

OSHA	Not classified as hazardous under 29 CFR 1910.1200. Not subject to the OSHA Highly Hazardous Chemicals process safety standard, 29 CFR 1910.119.
OSHA Bloodborne Pathogens Standard	Material of human origin. Employers should consider the applicability of 29 CFR 1910.1030 to their handling of this product.
TSCA	Not applicable. The product is a biological material and is not a chemical substance subject to the Toxic Substances Control Act inventory.
SARA 311/312	No hazard categories apply.
SARA 313	No components are subject to reporting under Section 313.
State right-to-know	No components are listed on the Massachusetts, New Jersey, or Pennsylvania right-to-know lists.
California Proposition 65	No Proposition 65-listed substances are intentionally added to this product.
Donor testing	Source material was tested in accordance with 21 CFR Part 610 for: serologic test for syphilis; HBsAg; anti-HBc; HBV NAT; anti-HCV (EIA); HCV NAT; anti-HIV-1/2 (EIA), including HIV-1 subgroup O; HIV-1 NAT; anti-HTLV-I/II (EIA); WNV NAT; and anti-T. cruzi (Chagas disease). See CYT-VSD-009.

Section 16. Other information

Document number	CYT-SDS-1909
Revision	Rev 01
Effective date	16MAR2026
Reason for revision	Complete rewrite. Supersedes CYT.SDS-0017 Version 25.1, which was issued in the pre-2012 Material Safety Data Sheet format and under the former legal entity name. This revision adopts the 16-section GHS format, corrects the legal entity and address, and creates a separate Safety Data Sheet for each product in the CytoPure™ family.

Abbreviations

ACGIH American Conference of Governmental Industrial Hygienists · CAS Chemical Abstracts Service · GHS Globally Harmonized System · IARC International Agency for Research on Cancer · IATA International Air Transport Association · IMDG International Maritime Dangerous Goods · NIOSH National Institute for Occupational Safety and Health · NTP National Toxicology Program · OSHA Occupational Safety and Health Administration · PBT persistent, bioaccumulative and toxic · STOT specific target organ toxicity · TSCA Toxic Substances Control Act · vPvB very persistent and very bioaccumulative

Disclaimer

The information in this Safety Data Sheet is believed to be correct as of the effective date shown but does not purport to be all-inclusive and should be used only as a guide. It relates only to the specific material identified in Section 1 and may not be valid if that material is used in combination with any other material or in any process. Cytologics shall not be liable for any direct, indirect, consequential, or incidental damages arising from the use of, the results of the use of, the inability to use, or contact with this product. It is the responsibility of the user to determine the suitability of this material for their intended use and to comply with all applicable laws and regulations.

IMPORTANT For research use only. Not for use in diagnostic or therapeutic procedures. Not for human or animal use. This product contains human-derived material and must be handled as potentially infectious; observe universal precautions and handle at Biosafety Level 2 or higher.

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