

ISOPLATE SOLUTION - PLATELET ADDITIVE SOLUTION [PAS-F] Version 1**Globally Harmonized System of Classification and Labeling of Chemicals (GHS)
Safety Data Sheet (SDS)****SECTION 1 – CHEMICAL PRODUCT AND COMPANY IDENTIFICATION****PRODUCT NAME** Isoplate Solution – Platelet Additive Solution [PAS-F]**PRODUCT USE** Isoplate™ Solution Platelet Additive Solution [PAS-F] is an isotonic solution to replace a portion of the plasma to store Platelet Pheresis, Leukocytes Reduced PAS products collected using a hyperconcentrated collection on Terumo BCT's Trima Accel® System. The solution should never be infused directly to the patient. Platelet Pheresis, Leukocytes Reduced Platelet Additive Solution [PAS-F] products are stored in a mix of 65% Isoplate™ and 35% plasma. Platelets in Isoplate™ Solution can be stored at a concentration range of 500-2100 x 106/mL for up to 5 days at 20-24°C with continuous agitation in the bag.**SUPPLIER**

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SECTION 2 – HAZARDS IDENTIFICATION

Mixture is not hazardous as defined by the Globally Harmonized System of Classification and Labeling of Chemicals (GHS).

EMERGENCY OVERVIEW**CHEMICAL CLASSIFICATION**

None.

PRECAUTIONARY STATEMENTS

None needed.

STORAGE

Store in a cool, well-ventilated place.

SECTION 3 – COMPOSITION / INFORMATION ON INGREDIENTS

Per 100 mL

0.530	g	Sodium Chloride USP	CAS No. – 7647-14-5
0.370	g	Sodium Acetate Trihydrate USP	CAS No. – 6131-90-4
0.037	g	Potassium Chloride USP	CAS No. – 7447-40-7
0.030	g	Magnesium Chloride Hexahydrate USP	CAS No. – 7791-18-6
0.012	g	Dibasic Sodium Phosphate Heptahydrate USP	CAS No. – 10028-24-7
0.500	g	Sodium Gluconate USP	CAS No. – 527-07-1
0.00082	g	Monobasic Potassium Phosphate NF	CAS No. – 7778-77-0
99.5	g	Water for Injection USP	CAS No. – 7732-18-5

SECTION 4 – FIRST AID MEASURES

First aid is not generally required. If in doubt, contact a Poison Control Center or a doctor.

EYE

Rinse with water. First aid is generally not required. If in doubt, contact a Poison Control Center or a doctor.

SKIN

If skin contact of several minutes occurs, rinse with running water. First aid is generally not required. If in doubt, contact a Poison Control Center or a doctor.

INHALED

Inhalation is not a route of exposure.

SECTION 5 – FIRE FIGHTING MEASURES

Not Flammable

No Fire/Explosion Hazard

SECTION 6 – ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS

None.

EMERGENCY PROCEDURES

None.

METHODS AND MATERIALS FOR CONTAINMENT AND CLEANUP

If local regulations permit, mop up with plenty of water and run to waste, diluting greatly with running water. Otherwise, contain with sand and transfer to salvage container. Arrange removal by disposal company.

SECTION 7 – HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING

Keep bags securely sealed prior to use.
Use standard safe hygienic work practices.

CONDITIONS FOR SAFE STORAGE

Avoid physical damage to bags.
Avoid freezing conditions.
Store at up to 25°C.

STORAGE INCOMPATIBILITY

None.

SECTION 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

CONTROL PARAMETERS

NOTE: The information in the table below is relevant for each chemical in a concentration of 100%.

Chemical	Reference	PEL	STEL
Sodium Chloride	US OSHA	Not Established	Not Established
Sodium Acetate Trihydrate	US OSHA	Not Established	Not Established
Potassium Chloride	US OSHA	Not Established	Not Established
Magnesium Chloride Hexahydrate	US OSHA	Not Established	Not Established
Dibasic Sodium Phosphate Heptahydrate	US OSHA	Not Established	Not Established
Sodium Gluconate	US OSHA	Not Established	Not Established
Monobasic Potassium Phosphate	US OSHA	Not Established	Not Established

ENGINEERING CONTROLS

None needed.

PERSONAL PROTECTIVE EQUIPMENT

Eye/Face — None needed.

Hands — None needed.

Respirator — None needed.

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL PROPERTIES

Appearance — Colorless liquid.

Odor — None.

Odor threshold — Does not apply.

pH — 7.4

Melting Point/Range — Does not apply.

Boiling Point/Range — ~ 100°C (212°F) (Water).

Flash Point — None.

Evaporation Rate — Dilute aqueous solution.
Flammability — Not flammable.
Upper Explosive Limit — None.
Lower Explosive Limit — None.
Vapor Pressure (mmHg) — The highest known value is 2.3 kPa (at 20°C) (Water).
Vapor Density — Does not apply.
Relative Vapor Density — Does not apply.
Solubility — Does not apply.
Partition Coefficient: n-octanol/water — None.
Auto-ignition Temperature — None.
Decomposition Temperature — None.
Viscosity — Liquid.
Explosive properties — None.
Oxidizing properties — None.
Freezing Point — ~0°C (32°F) (Water).

SECTION 10 – STABILITY AND REACTIVITY

CONDITIONS CONTRIBUTING TO INSTABILITY

Reactivity — None.
Chemical Stability — Considered very stable.
Possibility of Hazardous Reactions — None.
Conditions to Avoid — None.
Incompatibility — None.
Hazardous Decomposition Products — None.

SECTION 11 – TOXICOLOGICAL INFORMATION

Mixture is not known to be toxic.

SECTION 12 – ECOLOGICAL INFORMATION

Product is not considered to have an impact if released to the environment.

SECTION 13 – DISPOSAL CONSIDERATIONS

Dispose of in a manner consistent with local regulatory requirements for non-hazardous material.

SECTION 14 – TRANSPORTATION INFORMATION

Does not meet the definition of *hazardous material* as defined by the United States Department of Transportation (U.S. DOT).

Does not meet the definition of *dangerous goods* as defined by the United Nations.

Does not meet the definition of *dangerous goods* as defined by the International Air Transport Association (IATA).

Not known as a marine pollutant.

Not environmentally hazardous according to the United Nations Model Regulations.

Special Precautions for User – None.

SECTION 15 – REGULATORY INFORMATION

Not known to be regulated by any other authority.

Not known to have any prohibitions or restrictions in any country.

Not subject to The *Montreal Protocol on Substances that Deplete the Ozone Layer*, the *Stockholm Convention on Persistent Organic Pollutants*, or the *Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade*.

SECTION 16 – OTHER INFORMATION

US OSHA — United States Occupational Safety and Health Administration

PEL — Permissible Exposure Limit

STEL — Short Term Exposure Limit

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