Safety Data Sheet

In accordance with OSHA's Hazard Communication Standard (29 CFR 1910.1200), Regulation (EC) No 1272/2008 - Classification, Labelling and Packaging of Substances and Mixtures (CLP), and the Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

Terumo - Platelet Additive Solution (T-PAS+)

SECTION 1: Identification

1.1 Product identifier

Trade name **Terumo - Platelet Additive Solution (T-PAS+)**

1.2 Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses T-PAS+ Solution is a platelet additive solution intended to partially replace plasma in the preparation and storage of a buffy coat-derived platelet concentrate or apheresis platelet units.

1.3 Details of the supplier of the safety data sheet

Terumo BCT
10811 West Collins Ave.
Lakewood, Colorado 80215
United States

e-mail: EHS@terumobct.com

1.4 Emergency telephone number

Emergency information service +1 (303) 231-4357

General Use: Safety Data Sheets are designed to protect the health and safety of people in the workplace by providing information on the hazards of drug products and how they should be safely used, stored, transported, and disposed of.

SECTION 2: Hazard(s) identification

2.1 Classification of the mixture

This product does not meet the criteria for classification in any hazard class according to Regulation 2 (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. However a safety data sheet is being supplied for it upon request as it contains mixture of different salts and water for injection.

2.2 Label elements

Labeling not required

2.3 Other hazards

Of no significance.

SECTION 3: Composition/information on ingredients

3.1 Substances

Not relevant (mixture)

3.2 Mixtures

Description of the mixture

Name of substance	CAS No	EC No	Wt%	Classification acc. to GHS
Purified water	7732-18-5	231-791-2	> 1	Not Applicable
Sodium chloride	7647-14-5	231-598-3	< 1	Acute Tox. 5 / H303 Acute Tox. 5 / H313 Acute Tox. 5 / H333

Name of substance	CAS No	EC No	Wt%	Classification acc. to GHS
Sodium citrate dihydrate	6132-04-3	612-118-5	< 1	Acute Tox. 5 / H313
Magnesium chloride hexahydrate	7791-18-6	616-575-1	< 1	Not Applicable
Potassium chloride	7447-40-7	682-118-8	< 1	Acute Tox. 5 / H303
Sodium dihydrogen phosphate dihydrate	13472-35-0	603-853-2	< 1	Acute Tox. 5 / H303 Acute Tox. 5 / H313
sodium acetate trihydrate	6131-90-4	612-115-9	< 1	Acute Tox. 5 / H303
Disodium hydrogen phosphate dodecahydrate	10039-32-4	600-088-6	< 1	Not Applicable

Remarks

For full text of abbreviations: see SECTION 16

SECTION 4: First-aid measures

4.1 Description of first-aid measures

Following inhalation

Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Immediately notify medical personnel and supervisor.

Following skin contact

Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.

Following eye contact

If easy to do, remove contact lenses, if worn. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs or persists, notify medical personnel and supervisor.

Following ingestion

If swallowed, call a physician immediately. Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor.

4.2 Most important symptoms and effects, both acute and delayed

Medical conditions aggravated by exposure: None known or reported. Treat symptomatically and supportively.

4.3 Indication of any immediate medical attention and special treatment needed

Supportive care should be provided based on clinical judgment and the patient's condition.

SECTION 5: Fire-fighting measures

5.1 Extinguishing media

Suitable extinguishing media

Use water spray (fog), foam, dry powder, or carbon dioxide as appropriate for surrounding fire and materials.

Unsuitable extinguishing media

No information is available.

5.2 Special hazards arising from the substance or mixture

May emit carbon monoxide, carbon dioxide, oxides of nitrogen, and other nitrogen-containing compounds.

5.3 Fire and Explosion Hazards

Not flammable. No fire/explosion hazard.

Special protective equipment for firefighters

In case of fire in the surroundings, use the appropriate extinguishing agent. Wear full protective clothing and an approved, positive pressure, self-contained breathing apparatus. Decontaminate all equipment after use.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

No specific protective equipment is required; follow general hygiene and safety practices.

6.2 Environmental precautions

Do not empty into drains. Avoid release to the environment.

6.3 Methods and material for containment and cleaning up

Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

Advice on how to clean up a spill

Contain and collect the spill using absorbent materials such as sand, earth, or inert material. Transfer the absorbed material into suitable containers for disposal. Prevent the material from entering drains or watercourses

6.4 Reference to other sections

Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Avoid contact with skin and eyes. Use appropriate personal protective equipment when handling. Handle in accordance with safety practices. Keep away from incompatible materials, sparks, open flames, and sources of heat. Prevent spills and leaks.

7.2 Conditions for safe storage, including any incompatibilities

Store at up to 25°C. Avoid excessive heat and protect from freezing.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limit values (Workplace Exposure Limits)

No occupational exposure limits are established for this mixture.

8.2 Exposure controls

Appropriate engineering controls

No special engineering controls are required. General ventilation is recommended to maintain good workplace hygiene practices.

Individual protection measures (personal protective equipment)

Eye and face protection

Wear safety glasses.

Skin and body protection

Wear proper gowning appropriate to the task.

Hand protection

Wear protective gloves when handling.

Wash hands in the event of contact with this substance, especially before eating, drinking, or smoking.

Respiratory protection

No specific respiratory protection is required for this product in its final form, except in case of aerosol formation. Use in well-ventilated areas.

Environmental exposure controls

Avoid release to the environment and operate within closed systems wherever practicable. Liquid emissions should be directed to appropriate pollution control devices. In case of spill, do not release to drains.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	Liquid
Color	Colorless
Odor	Odorless
Melting point	No data available
Freezing point	No data available
Boiling point or initial boiling point and boiling range	100 °C, 212 °F
Evaporation rate	No data available
Flammability proporties	It is a liquid with high water content containing no flammable substances.
Explosive properties	It is a liquid with high water content containing no explosive substances.
Lower and upper explosion limit	No data available
Flash point	No data available
Explosive limit	No data available
Flammability	No data available
Auto-ignition temperature	No data available
Decomposition temperature	No data available
pH (value)	7.1 – 7.5
Solubility(ies)	No data available
Partition coefficient n-Octanol/water (log KOW)	No data available
Vapor pressure	2.3 kPa at 20°C

9.2 Other information There is no additional information

SECTION 10: Stability and reactivity

10.1 Reactivity

Contact with incompatible materials. Exposure to heat.

10.2 Chemical stability

Stable under normal storage conditions.

10.3 Possibility of hazardous reactions

No known hazardous reactions.

10.4 Conditions to avoid

Contact with incompatible materials and exposure to heat.

10.5 Incompatible materials

Acids, bases, and oxidizers

10.6 Hazardous decomposition products

Not available.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Mixture is not known to be toxic.

Acute toxicity

No information is available for this product.

Acute toxicity of components

Name of substance	CAS No	Exposure route	Endpoint	Value	Species
Purified water	7732-18-5	oral	TDLo	42,860 $^{mg}/_{kg}$	Human (Man)
Magnesium chloride hexahydrate	7791-18-6	oral	LD50	8,100 $^{mg}/_{kg}$	Rat
Magnesium chloride hexahydrate	7791-18-6	oral	LD50	7,600 $^{mg}/_{kg}$	Mouse
Potassium chloride	7447-40-7	oral	LD50	2,600 $^{mg}/_{kg}$	Rat
Potassium chloride	7447-40-7	oral	LD50	1,500 $^{mg}/_{kg}$	Mouse
Potassium chloride	7447-40-7	oral	LD50	3,020 $^{mg}/_{kg}$	Rat
Sodium dihydrogen phosphate dihydrate	13472-35-0	oral	LD50	>2,000 $^{mg}/_{kg}$	Rat
Sodium citrate dihydrate	6132-04-3	oral	LD50	5,400 $^{mg}/_{kg}$	Mouse
Sodium chloride	7647-14-5	oral	LD50	3,000 $^{mg}/_{kg}$	Rat
Sodium chloride	7647-14-5	oral	LD50	4,000 $^{mg}/_{kg}$	Mouse
Sodium chloride	7647-14-5	oral	LD50	8,000 $^{mg}/_{kg}$	Rabbit
sodium acetate trihydrate	6131-90-4	oral	LD50	2,700 $^{mg}/_{kg}$	Rat

Skin corrosion/irritation

No information is available for this product.

Serious eye damage/eye irritation

No information is available for this product.

Respiratory or skin sensitization

No information is available for this product.

Germ cell mutagenicity

No information is available for this product.

Carcinogenicity

No information is available for this product.

Reproductive toxicity

No information is available for this product.

Specific target organ toxicity - single exposure

No information is available for this product.

Specific target organ toxicity - repeated exposure

No information is available for this product.

Aspiration hazard

No information is available for this product.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity (chronic) of components of the mixture

Name of substance	CAS No	EC No	Endpoint	Value	Species	Exposure time
Magnesium chloride hexahydrate	7791-18-6	616-575-1	EC50	>900 mg/l	*Daphnia magna*	3 h
Magnesium chloride hexahydrate	7791-18-6	616-575-1	EC10	321 mg/l	Water flea (Daphnia)	21 d
Potassium chloride	7447-40-7	682-118-8	EC50	>1,000 mg/l	Activated sludge	3 h
Sodium chloride	7647-14-5	231-598-3	EC50	2,430 mg/l	*Nitzschia species*	120 h
sodium acetate trihydrate	6131-90-4	612-115-9	EC50	7,200 mg/l	*Pseudomonas putida*	16 h

Aquatic toxicity (acute) of components of the mixture

Name of substance	CAS No	EC No	Endpoint	Value	Species	Exposure time
Magnesium chloride hexahydrate	7791-18-6	616-575-1	LC50	2,119 mg/l	*Pimephales promelas* (fathead minnow)	96 h
Magnesium chloride hexahydrate	7791-18-6	616-575-1	LC50	548.4 mg/l	*Daphnia magna*	48 h
Magnesium chloride hexahydrate	7791-18-6	616-575-1	EC50	>900 mg/l	(Top) predators	48 h
Potassium chloride	7447-40-7	682-118-8	LC50	1,250,000 µg/l	Chironomus tentans (Midge) size 1.56 mm, 1st instar	96 h
Potassium chloride	7447-40-7	682-118-8	LC50	880 mg/l	*Pimephales promelas* (fathead minnow)	96 h
Potassium chloride	7447-40-7	682-118-8	EC50	440 – 880 mg/l	*Daphnia magna*	48 h
Potassium chloride	7447-40-7	682-118-8	ErC50	>100 mg/l	*Desmodesmus subspicatus* (green algae)	72 h
Sodium citrate dihydrate	6132-04-3	612-118-5	LC50	>18,000 – 32,000 mg/l	Guppy (Poecilia reticulata)	96 h
Sodium citrate dihydrate	6132-04-3	612-118-5	EC50	655 mg/l	*Ceriodaphnia dubia* (water flea)	48 h
Sodium chloride	7647-14-5	231-598-3	EC50	1,000 mg/l	Water flea (Daphnia)	48 h
Sodium chloride	7647-14-5	231-598-3	LC50	5,840 mg/l	Bluegill (Lepomis macrochirus)	96 h
Sodium chloride	7647-14-5	231-598-3	LC50	874 mg/l	*Daphnia magna*	24 h
Sodium chloride	7647-14-5	231-598-3	LC50	4,136 mg/l	*Daphnia magna*	48 h
sodium acetate trihydrate	6131-90-4	612-115-9	LC50	>100 mg/l	Zebra fish (*Danio rerio*)	96 h
sodium acetate trihydrate	6131-90-4	612-115-9	EC50	>1,000 mg/l	*Daphnia magna*	48 h
sodium acetate trihydrate	6131-90-4	612-115-9	ErC50	>1,000 mg/l	*Skeletonema costatum*	72 h

12.2 Persistence and degradability

Degradability of components of the mixture					
Name of substance	**CAS No**	**EC No**	**Process**	**Degradation rate**	**Time**
sodium acetate tri-hydrate	6131-90-4	612-115-9	DOC removal	99 %	28 d

12.3 Bioaccumulative potential
No data available.

12.4 Mobility in soil
No data available.

12.5 Results of PBT and vPvB assessment
No data available.

12.6 Endocrine disrupting properties
No data available.

12.7 Other adverse effects
No data available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods
Dispose of any cleanup materials and waste residue according to prescribed federal, state, and local regulations.

SECTION 14: Transport information

14.1 UN number	Not assigned
14.2 UN proper shipping name	Not assigned
14.3 Transport hazard class(es)	None
14.4 Packing group	Not assigned
14.5 Environmental hazards	Non-environmentally hazardous acc. to the dangerous goods regulations

14.6 Special precautions for user
There is no additional information.

14.7 Transport in bulk according to IMO instruments
The cargo is not intended to be carried in bulk.

Information for each of the UN Model Regulations

Transport of dangerous goods by road or rail (49 CFR US DOT) - Additional information
Not subject to transport regulations.

International Maritime Dangerous Goods Code (IMDG) - Additional information
Not subject to IMDG.

International Civil Aviation Organization (ICAO-IATA/DGR) - Additional information
Not subject to ICAO-IATA.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations specific for the product in question

National regulations (United States)

Toxic Substance Control Act (TSCA) Not all ingredients are listed (ACTIVE)

TSCA Inventory, identified by Chemical Abstract Service (CAS) Registry Number

Name of substance	CAS No	Status
Purified water	7732-18-5	ACTIVE
Sodium chloride	7647-14-5	ACTIVE
Potassium chloride	7447-40-7	ACTIVE

Superfund Amendment and Reauthorization Act (SARA TITLE III)

The List of Extremely Hazardous Substances and Their Threshold Planning Quantities (EPCRA Section 302, 304)

None of the ingredients are listed.

Specific Toxic Chemical Listings (EPCRA Section 313)

None of the ingredients are listed.

Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)

List of Hazardous Substances and Reportable Quantities (CERCLA section 102a) (40 CFR 302.4)

Name of substance	CAS No	Statutory code	Final RQ pounds (Kg)
Disodium hydrogen phosphate dodecahydrate	10039-32-4	1	5000 (2270)

Legend

1 "1" indicates that the statutory source is section 311(b)(2) of the Clean Water Act

Clean Air Act

None of the ingredients are listed.

Right to Know Hazardous Substance List

Cleaning Product Right to Know Act Substance List (CA-RTK)

None of the ingredients are listed.

Name of substance	CAS No	De Minimis Concentration Threshold
Disodium hydrogen phosphate dodecahydrate	10039-32-4	1.0 %

Hazardous Substances List (MN-ERTK)

None of the ingredients are listed.

Hazardous Substance List (NJ-RTK)

None of the ingredients are listed.

Hazardous Substance List (RI-RTK)

None of the ingredients are listed.

California Environmental Protection Agency (Cal/EPA): Proposition 65 - Safe Drinking Water and Toxic Enforcement Act of 1987

None of the ingredients are listed.

15.2 Chemical Safety Assessment

Chemical safety assessments for substances in this mixture were not carried out.

15.3 Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH)

Water - Exempt (Annex IV). Listed in REACH Annex IV as a substance of minimal risk.
Sodium chloride - Exempt (Annex V- natural origin).
Sodium citrate dihydrate - Registered.
Magnesium chloride hexahydrate - Registered.
Potassium chloride - Exempt (Annex V).
Sodium dihydrogen phosphate dihydrate - Registered (via anhydrous form).
Sodium acetate trihydrate -Registered.
Disodium hydrogen phosphate dodecahydrate - Registered (via anhydrous form).

SECTION 16: Other information, including date of preparation or last revision

Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
49 CFR US DOT	49 CFR U.S. Department of Transportation
Acute Tox.	Acute toxicity
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
DGR	Dangerous Goods Regulations (see IATA/DGR)
EC50	Effective Concentration 50 %. The EC50 corresponds to the concentration of a tested substance causing 50 % changes in response (e.g. on growth) during a specified time interval
EC No	The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identifier of substances commercially available within the EU (European Union)
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
ErC50	≡ EC50: in this method, that concentration of test substance which results in a 50 % reduction in either growth (EbC50) or growth rate (ErC50) relative to the control
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods Code
LC50	Lethal Concentration 50%: the LC50 corresponds to the concentration of a tested substance causing 50 % lethality during a specified time interval
LD50	Lethal Dose 50 %: the LD50 corresponds to the dose of a tested substance causing 50 % lethality during a specified time interval
NLP	No-Longer Polymer
PBT	Persistent, Bioaccumulative and Toxic
vPvB	Very Persistent and very Bioaccumulative

Classification procedure

Physical and chemical properties: The classification is based on tested mixture.
Health hazards, Environmental hazards: The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

List of relevant phrases (code and full text as stated in section 2 and 3)

List of relevant phrases (code and full text as stated in section 2 and 3)

Code	Text
H303	May be harmful if swallowed.
H313	May be harmful in contact with skin.
H333	May be harmful if inhaled.

Disclaimer

Disclaims any express or implied warranty as to the accuracy of the information contained herein and shall not be held liable for any direct, incidental, or consequential damages resulting from reliance on the information.