ADDITIVE FORMULA 3- dextrose monohydrate, trisodium citrate dihydrate, sodium chloride, sodium phosphate, monobasic, monohydrate, citric acid monohydrate, and adenine solution Terumo BCT, Ltd

---

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use ADDITIVE SOLUTION FORMULA 3 (AS-3) safely and effectively. See full prescribing information for ADDITIVE SOLUTION FORMULA 3 (AS-3).

ADDITIVE SOLUTION FORMULA 3 (AS-3)

Sterile Fluid
Polyolefin Bag

Initial U.S. Approval: 2002

INDICATIONS AND USAGE

Use only with Trima Accel red blood cell (RBC) apheresis collections. (1)

DOSAGE AND ADMINISTRATION

- AS-3 is added to tubing sets after apheresis collections, after the donor has been disconnected. (2)
- AS-3 may only be used with the Trima Accel apheresis device. For instructions on the use of the solution see the device operator's manual. (2.1)
- Follow the directions for connecting the AS-3 bag to the tubing set of a blood collection system. (2.2)

DOSAGE FORMS AND STRENGTHS

- 100 mL, 200 mL, or 350 mL sterile fluid in a Polyolefin bag. (3)

CONTRAINDICATIONS

- DO NOT INFUSE AS-3 DIRECTLY TO THE DONOR. (4)

WARNINGS AND PRECAUTIONS

- Verify that the AS-3 bag has been securely attached to the system tubing set. Use aseptic technique throughout all procedures to ensure product quality. (5)
- Do not reuse. Discard unused or partially used solution bags.

ADVERSE REACTIONS

Citrate reactions or toxicity may occur with the infusion of blood containing citrate. The recipient of the blood containing citrate should be monitored for the signs and symptoms of citrate toxicity. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Terumo BCT, Inc. at 1-877-339-4228 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch.*

Revised: 7/2018

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Use only with Trima Accel red blood cell (RBC) apheresis collections. *[See Dosage and Administration (2).]*

2 DOSAGE AND ADMINISTRATION

2.1 General Dosing Information

ADDITIVE SOLUTION FORMULA 3 (AS-3) is connected to the tubing set used for an apheresis RBC collection procedure after the collection has been completed.

- For automated RBC procedures, the recommended dose is determined by the apheresis device and metered into the tubing set by the apheresis device.
- To add the product manually, refer to the apheresis system operator's manual to determine the recommended dose.

For instructions on the use of the solution with the apheresis device and tubing set, see the device operator's manual.

2.2 Administration

Directions for connecting the* ADDITIVE SOLUTION FORMULA 3 (AS-3) *bag to the apheresis device.

Automated RBC additive solution procedures:

Connect ADDITIVE SOLUTION FORMULA 3 (AS-3) after the collection is over and the donor is disconnected. For automated addition of the product, the system will prompt you to connect the bag.

1. Remove the overwrap by pulling down at notch, and remove the AS-3 bag.
2. Before use, perform the following checks:
   - Ensure that the solution is the ADDITIVE SOLUTION FORMULA 3 (AS-3) and is within the expiration date.
   - Inspect the bag in good light. Do not use if the container is damaged, leaking or if there is any visible sign of deterioration. Check for leaks by gently squeezing the bag. If leaks are found, discard the bag.
   - Inspect the solution in good light. Use only if solution is clear and free of particulate matter. Bags showing cloudiness, haze, or particulate matter should not be used.
   - Protect from sharp objects.
3. Remove the protective cap from the port on the bag.
4. Connect the bag to the apheresis device tubing set using aseptic technique and hang the solution.
5. Break the frangible connector. When you break frangible connectors, bend them in both directions to ensure that you break them completely. Failure to do so may result in restricted flow.
6. Proceed according to the apheresis device operator's manual.

Manual RBC additive solution procedures:

Connect ADDITIVE SOLUTION FORMULA 3 (AS-3) after the collection is over and the donor is disconnected.

1. Seal the RBC product lines as close to the cassette as possible.
2. Remove the overwrap by pulling down at notch, and remove the ADDITIVE SOLUTION FORMULA 3 bag.
3. Before use, perform the following checks:
   - Ensure that the solution is the ADDITIVE SOLUTION FORMULA 3 (AS-3) and is within the expiration date.
   - Inspect the bag in good light. Do not use if the container is damaged, leaking or if there is any visible sign of deterioration. Check for leaks by gently squeezing the bag. If leaks are found, discard the bag.
   - Inspect the solution in good light. Use only if solution is clear and free of particulate matter. Bags showing cloudiness, haze, or particulate matter should not be used.
   - Protect from sharp objects.
4. Remove the protective cap from the port on the bag.
5. Connect the bag to the apheresis device tubing set using aseptic technique and hang the solution.
6. Break the frangible connector. When you break frangible connectors, bend them in both directions to ensure that you break them completely. Failure to do so may result in restricted flow.
7. Proceed according to the apheresis device operator's manual.

3 DOSAGE FORMS AND STRENGTHS

100 mL, 200 mL and 350 mL ADDITIVE SOLUTION FORMULA 3 (AS-3) products are sterile solutions in a Polyolefin bag. Each 100 mL contains: Dextrose Monohydrate USP 1.10 g; Trisodium Citrate Dihydrate USP 0.59 g; Sodium Chloride USP 0.41 g; Monobasic Sodium Phosphate Monohydrate USP 0.28 g; Citric Acid Monohydrate USP 0.042 g; Adenine USP 0.03 g; and Water for Injection USP.

4 CONTRAINDICATIONS

DO NOT INFUSE ADDITIVE SOLUTION FORMULA 3 (AS-3) DIRECTLY TO THE DONOR.

5 WARNINGS AND PRECAUTIONS

- Verify that the AS-3 bag has been securely attached to the system tubing set. Use aseptic technique throughout all procedures to ensure product quality.
- Do not reuse. Discard unused or partially used solution bags.

6 ADVERSE REACTIONS

Citrate reactions or toxicity may occur with the infusion of blood products to patients. The recipient of the blood containing citrate should be monitored for the signs and symptoms of citrate toxicity. The signs and symptoms of citrate toxicity begin with paresthesia, a "tingling" sensation around the mouth or in the extremities, followed by severe reactions that are characterized by hypotension and possible cardiac arrhythmia. Citrate toxicity may occur more frequently in patients who are hypothermic, have impaired liver or renal function, or have low calcium levels because of an underlying disease.

8 USE IN SPECIFIC POPULATIONS

ADDITIVE SOLUTION FORMULA 3 (AS-3) has not been studied in controlled clinical trials with specific populations.

11 DESCRIPTION

ADDITIVE SOLUTION FORMULA 3 (AS-3) is designed to be added to packed RBC collected in apheresis procedures, and acts to preserve and extend the shelf life of packed RBC products for later transfusion to patients. The solution is intended to be metered by an apheresis device during apheresis procedures or added manually after a collection.

The solution is sterile and non-pyrogenic, and it contains no bacteriostatic or antimicrobial agents.

The formulas of the active ingredients are provided in Table 1.

Table 1: Active Ingredients

Ingredients	Molecular Formula	Molecular Weight
Dextrose Monohydrate USP	$C_6H_{12}O_6 \cdot H_2O$	198.17
Trisodium Citrate Dihydrate USP	$C_6H_9Na_3O_9$	294.10
Sodium Chloride USP	NaCl	58.44
Monobasic Sodium Phosphate Monohydrate USP	$NaH_2PO_4 \cdot H_2O$	137.99
Citric Acid Monohydrate USP	$C_6H_80_7 \cdot H_2O$	210.14
Adenine USP	$C_5H_5N_5$	135.13
Water for Injection USP	H_2O	18.00

Each 100 mL of ADDITIVE SOLUTION FORMULA 3 (AS-3) contains: Dextrose Monohydrate USP 1.10 g; Trisodium Citrate Dihydrate USP 0.59 g; Sodium Chloride USP 0.41 g; Monobasic Sodium Phosphate Monohydrate USP 0.28 g; Citric Acid Monohydrate USP 0.042 g; Adenine USP 0.03 g; and Water for Injection USP.

ADDITIVE SOLUTION FORMULA 3 is available in three volumes: 100 mL, 200 mL and 350 mL.

The 100 mL bags are individually wrapped with a clear plastic film. Six individually wrapped bags are then vacuum-sealed in a foil pouch, which serves as a vapor barrier to prevent water loss during storage. After you remove the individual solution bags from the foil pouch, you can either leave them in the clear plastic film or remove and discard it. Once the foil pouch has been opened, use all six of the solution bags within 2 weeks.

The 200 mL and 350 mL bags are individually wrapped with a clear plastic film. These larger volumes do not require the additional vapor barrier. Once the clear plastic film has been removed, use the solution within 2 weeks.

The Polyolefin bag is not made with natural rubber latex.

The bag is made from a multilayered film. It contains materials that have been tested to demonstrate the suitability of the container for storing pharmaceutical solutions. The bag is nontoxic and biologically inert. The bag-solution unit is a closed system and is not dependent upon entry of external air during administration.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

ADDITIVE SOLUTION FORMULA 3 acts to preserve and extend the shelf life of packed RBC products for later transfusion to patients. The following ingredients are key components of the solution:

- Adenine to support adenosine triphosphate (ATP) levels
- Citrate for membrane protection, anticoagulation and pH regulation

- Sodium (Sodium Chloride and Sodium Citrate) and dextrose for isotonicity
- Dextrose for RBC nutrition

This solution has no pharmacological effect.

14 CLINICAL STUDIES

The *in vivo* and *in vitro* quality of RBCs stored for 42 days in ADDITIVE SOLUTION FORMULA 3 (AS-3) storage solution has been assessed in three clinical studies.

In Vivo Recovery of Autologous Radiolabeled RBC

A single-arm, multicenter, *in vivo* study was conducted to assess the recovery of radiolabeled RBCs 24 hours post infusion. Acceptability of *in vivo* recovery was determined using established FDA-CBER acceptance criteria. Double collection RBCs (dRBC) were collected using the Trima Accel system and stored in ADDITIVE SOLUTION FORMULA 3 (AS-3) solution for 42 days, then radiolabeled with ^{51}Chromium, and transfused back to the original subject. Table 2 summarizes the *in vivo* recovery data. Of the 27 units transfused, 26 had > 75% RBC recovery.

Table 2: In vivo Radiolabeled RBC Recovery

Outcome Measure	Study Site (N)	Average (SD)	Min, Max
Overall Day 42 infused, 24-hour RBC Radiolabel Recovery (%)	Site 1 (12)	79.3 (5.6)	67.5, 86.5
	Site 2 (15)	87.1 (5.5)	79.0, 98.1

Abbreviations: Max= Maximum, Min= Minimum, N= Number of Units Transfused, RBC= Red Blood Cell, SD= Standard Deviation

FDA-CBER Criteria for Acceptable Recovery: Radiolabeled RBC recoveries should average at least 75%, with a standard deviation of at most 9%. In addition, the 95% one-sided lower confidence limit for the population proportion of successes should be > 70%, with success being defined as an individual red blood cell *in vivo* recovery of at least 75%. No more than 3 out of 24 data points may have less than 75% radiolabeled red cell recovery at 24 hours post infusion.

The primary outcome was met for RBCs collected on the Trima Accel system and stored in ADDITIVE SOLUTION FORMULA 3 (AS-3) storage solution.

In Vitro RBC Quality Studies

The *in vitro* quality of RBCs collected in single RBC collection (sRBC) and dRBC procedures using the Trima Accel system was assessed after 42 days of storage in ADDITIVE SOLUTION FORMULA 3 (AS-3) solution in a multicenter, paired study. *In vitro* quality was determined using established FDA-CBER acceptance criteria. The quality of RBCs stored in ADDITIVE SOLUTION FORMULA 3 (AS-3) solution (test) was compared to RBCs stored in plasma (control). Table summarizes the *in vitro* RBC quality data for collection on the Trima Accel system and storage in ADDITIVE SOLUTION FORMULA 3 (AS-3) solution.

Table 3: In Vitro Quality Measures for RBCs Collected using the Trima Accel System and Stored in ADDITIVE SOLUTION FORMULA 3 (AS-3)

Outcome Measure	Site (N)	Average (SD)	Min, Max
Day 42 Hemolysis for Single RBC Collection* (%)	Site 1 (32)	0.16 (0.06)	0.06, 0.33
	Site 2 (18)	0.34 (0.18)	0.12, 0.70
	Site 3 (18)	0.26 (0.11)	0.09, 0.47
Day 42 Hemolysis for Double RBC	Site 1 (25)	0.15 (0.05)	0.06, 0.29
	Site 2 (24)	0.29 (0.19)	0.16, 0.95

Collection* (%)	Site 2 (24)	0.39 (0.19)	0.16, 0.95
	Site 3 (21)	0.26 (0.12)	0.13, 0.61
Change in pH from Day 0 to Day 42 for Single RBC Collection†	Site 1 (31)	0.03 (0.02)	0.00, 0.08
	Site 2 (18)	0.03 (0.03)	0.00, 0.11
	Site 3 (16)	0.02 (0.02)	0.00, 0.07
Change in pH from Day 0 to Day 42 for Double RBC Collection†	Site 1 (23)	0.02 (0.02)	0.00, 0.05
	Site 2 (23)	0.02 (0.03)	0.00, 0.15
	Site 3 (19)	0.02 (0.02)	0.00, 0.08
Ratio of ATP Retention for Single Collection RBC Units (test/control)‡	All sites (65)	1.02 (0.18)	0.46, 1.47
Ratio of ATP Retention for Double Collection RBC Units (test/control)‡	All sites (65)	1.07 (0.19)	0.55, 1.51
Ratio of the Normalized Leaked Potassium for Single Collection RBC Units (test/control)§	All sites (65)	0.98 (0.07)	0.76, 1.13
Ratio of the Normalized Leaked Potassium for Double Collection RBC Units (test/control)§	All Sites (64)	1.00 (0.08)	0.85, 1.24

Abbreviations: HCT = hematocrit, HgB = hemoglobin, Max = Maximum, Min = Minimum, N = Number of Units, RBC = Red Blood Cell, SD = Standard Deviation

* Percent hemolysis was calculated from plasma free hemoglobin using the equation:
%Hemolysis = (100 – RBC Product HCT)* Plasma Hgb / (RBC Product Hgb).

† The difference in pH between Test and Control on Day 42 was calculated as:
$\Delta pH = |pHTest - pHControl| \leq 0.5$
where the difference was expected to be less than or equal to 0.5 pH units.

‡ ATP retention was determined for test and control units across all sites and calculated as ATP Level on Day 42 / ATP Level on Day 0.

§ Normalized potassium was calculated by determining the total number of millimoles of potassium leaked from the RBCs into the supernatant volume and dividing this by the total hemoglobin in the stored product.
Normalized Leaked Potassium = Volume*(1-Hct/100)*(d42[K+] – d0[K+]) / Total Hemoglobin

FDA-CBER Criteria for Acceptable Day 42 Hemolysis: Zero failures (hemolysis ≥ 1% after 42-day storage) out of 60 test units that were not excluded from analysis by the Extreme Studentized Deviate test with α=0.05, which satisfies the binomial distribution testing requirement that, with 95% probability and a one-sided 95% lower confidence limit, the post-storage hemolysis was less than 1% per unit.

There were 0/68 sRBC test units and 0/70 dRBC test units with Day 42 hemolysis ≥ 1%. No donors were excluded as hemolysis was < 1% for all test units. Therefore, the primary objective was met for RBCs stored in ADDITIVE SOLUTION FORMULA 3 (AS-3).

The *in vitro* quality of sRBC and dRBC units collected using the Trima Accel system was assessed after 42 days of storage in AS-3 solution in a multicenter study. The quality of RBCs was compared between sRBC and dRBC units, and between units A and B of the dRBC collection. Table summarizes the *in vitro* RBC quality data for collection using the Trima Accel system and storage in ADDITIVE SOLUTION FORMULA 3 (AS-3).

Table 4: In Vitro Quality Measures for RBCs Collected using the Trima Accel System and Stored in ADDITIVE SOLUTION FORMULA 3 (AS-3)

Outcome Measure*	Site	RBC Unit			P Value†	
		dRBC A	dRBC B	sRBC	dRBC A v dRBC B	sRBC v dRBC

Hematocrit (%), mean (SD)	Site 1	54.4 (3.7)	53.9 (3.6)	55.8 (4.4)	0.132	0.253
	Site 2	56.0 (3.9)	53.3 (11.6)	58.4 (3.6)	0.398	0.149
pH, mean (SD)	Site 1	6.4 (0.04)	6.4 (0.05)	6.5 (0.08)	0.760	0.643
	Site 2	6.4 (0.1)	6.4 (0.1)	6.4 (0.1)	0.175	0.217
pCO_2, mean (SD)	Site 1	140 (8)	137 (8)	139 (12)	0.172	0.525
	Site 2	130.5 (11.7)	130.4 (12.4)	125.6 (11.1)	1.00	0.316
pO_2, mean (SD)	Site 1	46 (7)	47 (7)	46 (7)	0.104	0.825
	Site 2	52.0 (10.6)	51.4 (12.5)	46.2 (3.4)	0.878	0.157
ATP (µmols/g HB), mean (SD)	Site 1	2.6 (0.6)	2.6 (0.6)	2.9 (0.5)	0.759	0.306
	Site 2	3.0 (0.5)	3.0 (0.6)	2.6 (0.5)	0.845	0.110
K (mEq/L), mean (SD)	Site 1	46.5 (7.9)	47.5 (8.2)	49.3 (10.1)	0.396	0.620
	Site 2	40.5 (5.8)	41.1 (5.9)	44.7 (5.7)	0.575	0.128
Na (mEq/L), mean (SD)	Site 1	122 (7)	123 (6)	126 (17)	0.016	0.609
	Site 2	105.6 (5.4)	104.2 (5.5)	100.0 (5.5)	0.004	0.069
Total Hemoglobin (g/dL)	Site 1	60.5 (5.8)	60.0 (5.3)	61.0 (4.7)	0.546	0.627
	Site 2	58.5 (5.5)	59.6 (5.8)	60.3 (5.0)	0.264	0.747
Plasma Hemoglobin (mg/dL), mean (SD)	Site 1	149.9 (151.6)	141.2 (145.3)	152.7 (86.3)	0.034	0.815
	Site 2	139.0 (61.0)	126.7 (80.4)	135.5 (82.1)	0.241	0.790
Hemolysis (%), mean (SD)	Site 1	0.33 (0.34)	0.32 (0.34)	0.30 (0.15)	0.05	0.855
	Site 2	0.34 (0.13)	0.31 (0.16)	0.31 (0.19)	0.363	0.995
Osmotic Fragility‡	Site 1	20.0 (14.4)	19.6 (15.2)	31.0 (22.3)	0.885	0.152
	Site 2	0.51 (0.03)	0.51 (0.03)	0.49 (0.02)	0.935	0.009

Abbreviations: dRBC A = Unit A of the Double Red Blood Cell Collection, dRBC B = Unit B of the Double Red Blood Cell Collection, sRBC = Single Red Blood Cell Unit, SD = Standard Deviation

* All outcome measures are shown after 42 days of storage in AS-3 solution.

† All comparisons were performed using a Student's T-test. A 2-tailed paired comparison was performed for dRBC A v dRBC B. A 2- tailed, two sample, equal variance comparison was performed for sRBC v dRBC units.

‡ Osmotic fragility was measured as percent hemolysis in 0.55% saline at Site 1 and as the percent saline at ≥ 50% hemolysis at Site 2.

The primary outcome of this study was to demonstrate RBC collection, storage, and viability *in vitro*.

The sRBC and dRBC units collected were comparable. The hematocrits, blood gasses, ATP, potassium, total hemoglobin, and osmotic fragility were within acceptable ranges following storage. Two statistically significant differences were identified between the A and B units in the dRBC collection at Day 42 (sodium and plasma free hemoglobin), but these differences were not clinically significant. There was no difference between dRBC units in hemolysis following storage in ADDITIVE SOLUTION FORMULA 3 (AS-3). A statistically significant difference was identified in the osmotic fragility of RBCs stored in ADDITIVE SOLUTION FORMULA 3 (AS-3) following sRBC collection or dRBC collection at Day 42, but the difference was not clinically significant. All the RBC units collected averaged less than 1% hemolysis on Day 42. These results are consistent with US and

European guidelines for hemolysis on transfusion. ATP recovery was greater than 70% of all units, which is predictive of good *in vivo* viability, and potassium levels on Day 42 average less than 50 mEq/L indicating good RBC membrane stability over the storage period.

16 HOW SUPPLIED/STORAGE AND HANDLING

ADDITIVE SOLUTION FORMULA 3 (AS-3) is a clear solution supplied in sterile and non-pyrogenic Polyolefin bags.

SIZE	CATALOG NUMBER	NDC NUMBER	QUANTITY PER CASE
100 mL	40824	14537-824-10	36
200 mL	40826	14537-826-20	30
350 mL	40828	14537-828-35	24

STORAGE

Up to 25 °C.

Protect from freezing.

Issued: July 18, 2018

Manufactured by
Terumo BCT, Inc.
Lakewood, CO 80215

PRINCIPAL DISPLAY PANEL - 100 mL Bag Pouch Carton Label

Additive Solution Formula 3 (AS-3)

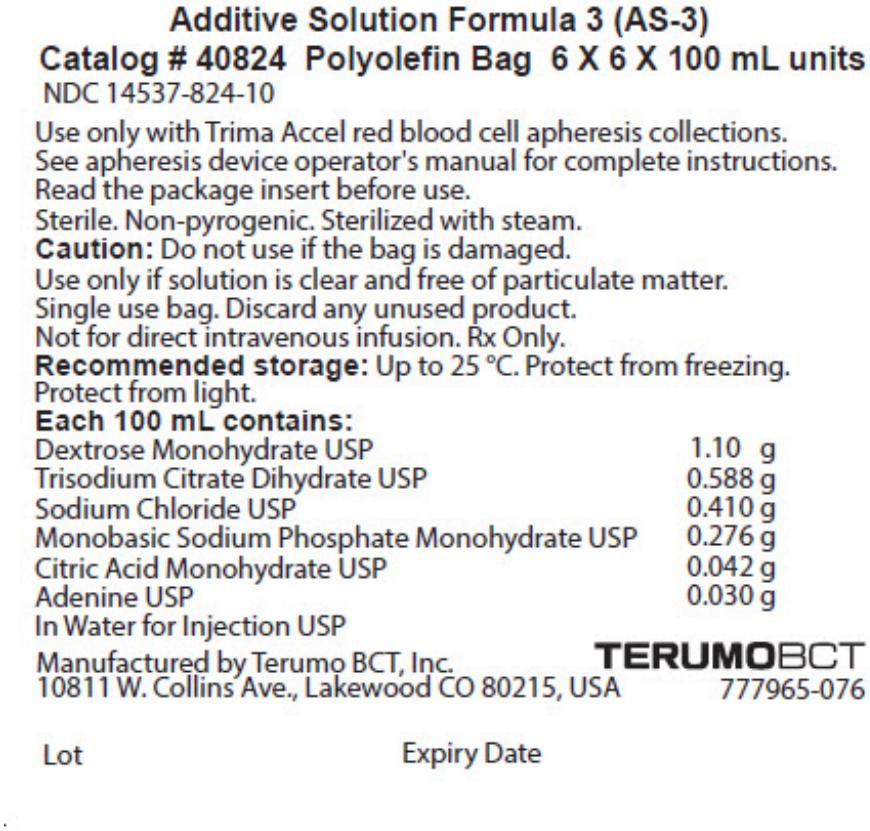
Catalog # 40824 Polyolefin Bag 6 X 6 X 100 mL units
NDC 14537-824-10

Use only with Trima Accel red blood cell apheresis collections.
See apheresis device operator's manual for complete instructions.
Read the package insert before use.
Sterile. Non-pyrogenic. Sterilized with steam.
Caution: Do not use if the bag is damaged.
Use only if solution is clear and free of particulate matter.
Single use bag. Discard any unused product.
Not for direct intravenous infusion. Rx Only.
Recommended storage: Up to 25 °C. Protect from freezing.
Protect from light.
Each 100 mL contains:
Dextrose Monohydrate USP
1.10 g
Trisodium Citrate Dihydrate USP
0.588 g
Sodium Chloride USP
0.410 g
Monobasic Sodium Phosphate Monohydrate USP

0.276 g
Citric Acid Monohydrate USP
0.042 g
Adenine USP
0.030 g
In Water for Injection USP

Manufactured by Terumo BCT, Inc.
TERUMOBCT
10811 W. Collins Ave., Lakewood CO 80215, USA
777965-076

Lot
Expiry Date



PRINCIPAL DISPLAY PANEL - 200 mL Bag Carton Label

Additive Solution Formula 3 (AS-3)

Catalog # 40826 Polyolefin Bag 30 X 200 mL units
NDC 14537-826-20

Use only with Trima Accel red blood cell apheresis collections.
See apheresis device operator's manual for complete instructions.
Read the package insert before use.
Sterile. Non-pyrogenic. Sterilized with steam.
Caution: Do not use if the bag is damaged.
Use only if solution is clear and free of particulate matter.
Single use bag. Discard any unused product.
Not for direct intravenous infusion. Rx Only.

Recommended storage: Up to 25 °C. Protect from freezing.
Protect from light.
Each 100 mL contains:
Dextrose Monohydrate USP
1.10 g
Trisodium Citrate Dihydrate USP
0.588 g
Sodium Chloride USP
0.410 g
Monobasic Sodium Phosphate Monohydrate USP
0.276 g
Citric Acid Monohydrate USP
0.042 g
Adenine USP
0.030 g
In Water for Injection USP

Manufactured by Terumo BCT, Inc.
TERUMOBCT
10811 W. Collins Ave., Lakewood CO 80215, USA
777965-078

Lot
Expiry Date

Additive Solution Formula 3 (AS-3)
Catalog # 40826 Polyolefin Bag 30 X 200 mL units
NDC 14537-826-20
Use only with Trima Accel red blood cell apheresis collections.
See apheresis device operator's manual for complete instructions.
Read the package insert before use.
Sterile. Non-pyrogenic. Sterilized with steam.
Caution: Do not use if the bag is damaged.
Use only if solution is clear and free of particulate matter.
Single use bag. Discard any unused product.
Not for direct intravenous infusion. Rx Only.
Recommended storage: Up to 25 °C. Protect from freezing.
Protect from light.
Each 100 mL contains:

Dextrose Monohydrate USP	1.10 g
Trisodium Citrate Dihydrate USP	0.588 g
Sodium Chloride USP	0.410 g
Monobasic Sodium Phosphate Monohydrate USP	0.276 g
Citric Acid Monohydrate USP	0.042 g
Adenine USP	0.030 g

In Water for Injection USP
Manufactured by Terumo BCT, Inc. TERUMOBCT
10811 W. Collins Ave., Lakewood CO 80215, USA 777965-078

Lot Expiry Date

PRINCIPAL DISPLAY PANEL - 350 mL Bag Carton Label

Additive Solution Formula 3 (AS-3)

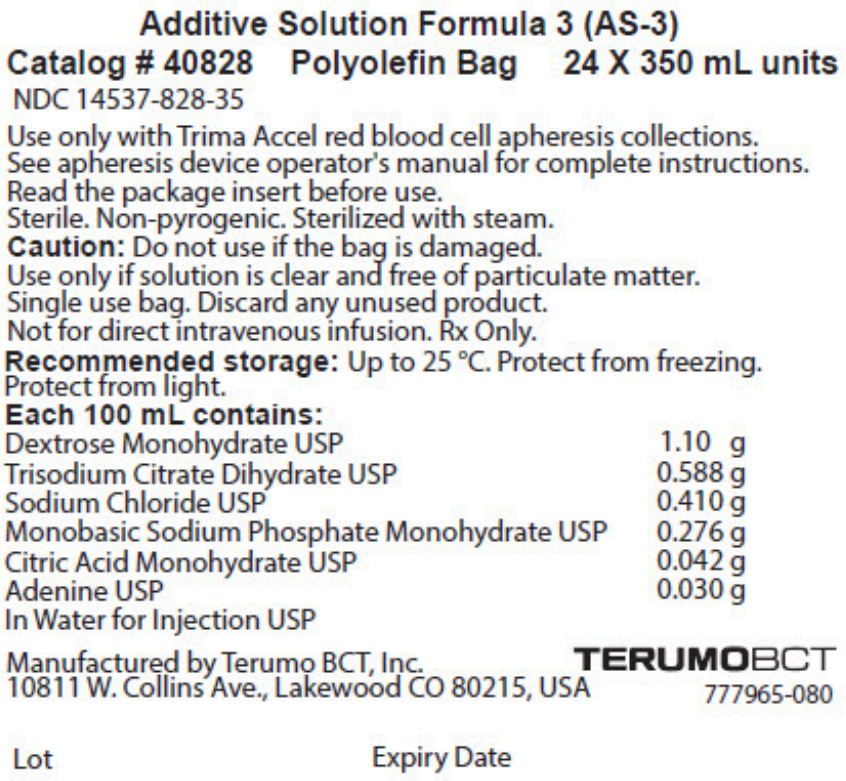
Catalog # 40828 Polyolefin Bag 24 X 350 mL units
NDC 14537-828-35

Use only with Trima Accel red blood cell apheresis collections.
See apheresis device operator's manual for complete instructions.
Read the package insert before use.
Sterile. Non-pyrogenic. Sterilized with steam.
Caution: Do not use if the bag is damaged.
Use only if solution is clear and free of particulate matter.
Single use bag. Discard any unused product.
Not for direct intravenous infusion. Rx Only.
Recommended storage: Up to 25 °C. Protect from freezing.
Protect from light.
Each 100 mL contains:
Dextrose Monohydrate USP
1.10 g
Trisodium Citrate Dihydrate USP
0.588 g
Sodium Chloride USP
0.410 g
Monobasic Sodium Phosphate Monohydrate USP
0.276 g
Citric Acid Monohydrate USP
0.042 g
Adenine USP
0.030 g
In Water for Injection USP

Manufactured by Terumo BCT, Inc.
TERUMOBCT

10811 W. Collins Ave., Lakewood CO 80215, USA
777965-080

Lot
Expiry Date



ADDITIVE FORMULA 3

dextrose monohydrate, trisodium citrate dihydrate, sodium chloride, sodium phosphate, monobasic, monohydrate, citric acid monohydrate, and adenine solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:14537-824
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Dextrose Monohydrate (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	Dextrose Monohydrate	1.1 g in 100 mL
Trisodium Citrate Dihydrate (UNII: B22547B95K) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	0.59 g in 100 mL
Sodium Chloride (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698, SODIUM CATION - UNII:LYR4M0NH37)	Sodium Chloride	0.41 g in 100 mL
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN) (PHOSPHATE ION - UNII:NK08V8K8HR, SODIUM CATION - UNII:LYR4M0NH37)	SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE	0.28 g in 100 mL
Citric Acid Monohydrate (UNII: 2968PHW8QP) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	0.042 g in 100 mL
Adenine (UNII: JAC85A2161) (Adenine - UNII:JAC85A2161)	Adenine	0.03 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:14537-824-10	6 in 1 CARTON		
1		6 in 1 POUCH		
1		100 mL in 1 BAG; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	BN001214	05/29/2002	

ADDITIVE FORMULA 3

dextrose monohydrate, trisodium citrate dihydrate, sodium chloride, sodium phosphate, monobasic, monohydrate, citric acid monohydrate, and adenine solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:14537-826
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Dextrose Monohydrate (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	Dextrose Monohydrate	1.1 g in 100 mL
Trisodium Citrate Dihydrate (UNII: B22547B95K) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	0.59 g in 100 mL
Sodium Chloride (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698, SODIUM CATION - UNII:LYR4M0NH37)	Sodium Chloride	0.41 g in 100 mL
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN) (PHOSPHATE ION - UNII:NK08V8K8HR, SODIUM CATION - UNII:LYR4M0NH37)	SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE	0.28 g in 100 mL
Citric Acid Monohydrate (UNII: 2968PHW8QP) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	0.042 g in 100 mL
Adenine (UNII: JAC85A2161) (Adenine - UNII:JAC85A2161)	Adenine	0.03 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14537-826-20	30 in 1 CARTON		
1		200 mL in 1 BAG; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	BN001214	05/29/2002	

ADDITIVE FORMULA 3

dextrose monohydrate, trisodium citrate dihydrate, sodium chloride, sodium phosphate, monobasic, monohydrate, citric acid monohydrate, and adenine solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:14537-828
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Dextrose Monohydrate (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	Dextrose Monohydrate	1.1 g in 100 mL
Trisodium Citrate Dihydrate (UNII: B22547B95K) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	0.59 g in 100 mL
Sodium Chloride (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698, SODIUM CATION - UNII:LYR4M0NH37)	Sodium Chloride	0.41 g in 100 mL
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN) (PHOSPHATE ION - UNII:NK08V8K8HR, SODIUM CATION - UNII:LYR4M0NH37)	SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE	0.28 g in 100 mL
Citric Acid Monohydrate (UNII: 2968PHW8QP) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	0.042 g in 100 mL
Adenine (UNII: JAC85A2161) (Adenine - UNII:JAC85A2161)	Adenine	0.03 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:14537-828-35	24 in 1 CARTON		
1		350 mL in 1 BAG; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	BN001214	05/29/2002	

Labeler - Terumo BCT, Ltd (233649834)

Establishment

Name	Address	ID/FEI	Business Operations
Terumo BCT, Ltd		233649834	LABEL(14537-824, 14537-826, 14537-828) , ANALYSIS(14537-824, 14537-826, 14537-828) , STERILIZE(14537-824, 14537-826, 14537-828) , MANUFACTURE(14537-824, 14537-826, 14537-828)

Revised: 4/2019 Terumo BCT, Ltd