

3.0 K

WARNING: NOT FOR PARENTERAL USE. Use of this Acid Concentrate without the associated bicarbonate concentrate may cause patient injury or death.

3.0 Ca



Citrasate[®] Dry

62.5 LITER MIX (16.5 GAL)

OFD3301-DA

NON-PYROGENIC

Dry Acid Concentrate For Bicarbonate Dialysis

Chemical Contents of Dry Acid Concentrate (A):		Ionic Contribution of Liquid Acid Concentrate (A): (Nominal-Dilution 1:44)		45X Final Dialysate Nominal Ionic Concentrations: Acid:Bicarb.:Water (1:1.72:42.28)	
NaCl	16.44 kg	SODIUM	100.3 mEq/L	SODIUM	137.3 mEq/L
KCl	0.629 kg	POTASSIUM	3.0 mEq/L	POTASSIUM	3.0 mEq/L
CaCl ₂ • 2H ₂ O	0.620 kg	CALCIUM	3.0 mEq/L	CALCIUM	3.0 mEq/L
MgCl ₂ • 6H ₂ O	0.286 kg	MAGNESIUM	1.0 mEq/L	MAGNESIUM	1.0 mEq/L
C ₂ H ₃ NaO ₂ • 3H ₂ O	0.115 kg	ACETATE	0.3 mEq/L	ACETATE	0.3 mEq/L
C ₆ H ₈ O ₇	0.432 kg	CITRATE	2.4 mEq/L	CITRATE	2.4 mEq/L
C ₆ H ₁₂ O ₆ • H ₂ O	3.09 kg	DEXTROSE	100 mg/dL	DEXTROSE	100 mg/dL
		CHLORIDE	107.0 mEq/L	CHLORIDE	107.0 mEq/L
				BICARBONATE	34.6 mEq/L
Total Wt:	21.6 kg				

DESCRIPTION FOR USE: For use with FMCNA 45X sodium bicarbonate with a three-stream hemodialysis machine set for 45X. This package configuration is designed to be mixed by trained operators using an FMCNA Dry Acid Dissolution Unit.

Nominal Dialysate Composition: When 1 part acid concentrate is mixed with 1.72 parts of bicarbonate concentrate and 42.28 parts of purified water, the ionic contribution in the Final Dialysate is: Sodium 137.3 mEq/L and Bicarbonate 34.6 mEq/L (post-reaction Bicarbonate). All other constituents remain as listed in the Ionic contribution of Acid Concentrate table.

CAUTION: Refer to instructions provided by the hemodialysis machine manufacturer. **Check conductivity and pH of final dialysate just prior to dialysis treatment and each time new concentrate is supplied to the machine.** Refer to manufacturer for nominal conductivity of final dialysate. Use only as directed. Federal law (USA) restricts this device to sale by or on order of a physician. **DO NOT USE IF PACKAGE IS OPEN OR DAMAGED.**

WARNING: This acid concentrate product is for use as one component in mixing dialysate bath. This product contains sodium acetate and citric acid and, after mixing, yields 0.3 milliequivalents per liter of acetate and 2.4 milliequivalents per liter of citrate in the dialysate. After diffusion across the dialyzer membrane, acetate and citrate are metabolized by the liver to serum bicarbonate and adds to the serum bicarbonate that separately results from the diffusion of dialysate bicarbonate across the dialyzer membrane. During dialysis, the dynamic of diffusion and concentration gradients prevent serum bicarbonate concentration from exceeding the dialysate bicarbonate concentration. The bicarbonate concentration of the dialysate is the "bicarbonate" setting on the dialysis machine, and is the bicarbonate dose prescribed by the physician. On Fresenius 2008 series hemodialysis machines, the bicarbonate dose may be set in a range between 20 and 40 milliequivalents per liter, but may be set in different ranges in other machines.

When the dialysis session terminates, acetate and citrate that have not yet metabolized may remain in the blood and will be converted to serum bicarbonate after diffusion ceases, without possibility of diffusion out of the blood. The post dialysis metabolism of acetate and citrate could thus briefly increase serum bicarbonate concentration above the prescribed bicarbonate concentration of the dialysate. Physicians should consider this possibility in prescribing bicarbonate dose.

Prescription of insufficient bicarbonate may contribute to metabolic acidosis; excessive bicarbonate may contribute to metabolic alkalosis. Both conditions are associated with poor patient outcomes, including increased mortality risk.

INSTRUCTIONS FOR DISSOLUTION

The contents may clump or harden which does not affect product chemical composition. Break clumps prior to mixing.

When fully dissolved, six (6) cases produce 375 liters (99 gals); Eight (8) cases make 500 liters (132 gals).

Refer to FMCNA Dry Acid Dissolution Unit Operator's manual for additional details.

- 1) Use only with water that meets or exceeds ANSI/AAMI RD62 or ISO 13959 hemodialysis water quality standards. Water temperature should be 20°–30° C for proper dissolution.
- 2) Perform a Rinse Cycle before starting the batch by pressing the Rinse Start button. Wait for cycle to complete before continuing.
- 3) Begin the batch by pressing the Dissolution Start button. Wait until ADD GRANULES light begins to flash
- 4) Add Dry Acid to Dissolution Unit. Verify all cases are the same catalog #, formulation and lot #.

IMPORTANT: Use entire contents of each bag (4) within this case. Do not use unless all (4) bags are present. The contents of the bags are different. All bags must be used. Label tank with contents and date prepared.

- 5) Continue with mixing procedure according to the FMCNA Dry Acid Dissolution Unit Operator's manual.
- 6) When mixing is complete, test for proper Specific Gravity according to the FMCNA Dry Acid Dissolution Unit Operator's manual. Filter with a nominal 1 micron filter during transfer. Keep container sealed. Label and date all storage containers.

AVOID EXCESSIVE TEMPERATURE. STORE IN A DRY LOCATION.

MANUFACTURER/DISTRIBUTOR:

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Citrasate[®] is a registered trademark of Advanced Renal Technologies.
U.S. patent 6,610,206 and others applied for.

FMCNA Cat. No.
OFD3301-DA



Exp. Date

Lot #