© August 2014		Introduction Type: New Item					Fir	nal Version		Date:	3/	3/16	
PRODUCT INFORMATION								SPECIAL HAN	NDLING AND S	TORAGE REQU	IREMENTS*		
Company Name: AvKARE, INC Application: ANDA							a. Temperature – Indicate the USP temperature range for this product.						
Application Number for	d Device:	202128				I. Freezer – between -25 and -10 C (-13° – 14° F)							
Rx Product/Proprietary Name: Potassium Chloride ER 10mEq (750mg) Capsule							II. Cold – between 2 and 8 C (36° – 46° F)						
NDC:	50268-0671-13		UPC:				III. Cool – between 8 and 15 C (46° – 59° F)						
CVX Code:			MVX Code:				x IV. Controlled Room – between 20 and 25 C (68° – 77° F)						
Description:	Potassium Chloride I	ER 10mEq (750r	ng) Capsule				allows for excursions between 15 and 30 C (59° – 86° F)						
										ove 40 C (>104°	F)		
Active ingredients:							L VI	. Other Tempe (write in)	erature Range I	Requirement		1	
URL for Additional Product Information:							VII. No Requirement						
Address: 615 North First Street			Address 2:				b. Contact for temperature excursion questions:						
City:	Pulaski		State: TN		Zip: 38478		Name:						
Key Contact:	Kim Bracey		Email:	kbracey@avk	kare.com		Number:						
Phone Number:	one Number: 931-908-0028		Fax: 931-292-6229			Is this product to be shipped to customers on ice?							
		FOR	R GENERIC DRUG PRODUC	CTS			Is this produc	ct to be shippe	ed to customer:	s on dry ice?			
I. Orange Book Rating:	AB		II. Brand Name:	potassium ch	loride								
III. Generic Equivalent for Brand: potassium chi							c. Special regu	lations for pro	oduct in certai	n states?			
	DRI	JG SUPPLY CH	AIN SECURITY ACT (DSCSA) INFORMATION				Special return	ns requirement	ts for this prod	uct?			
Does supplier meet DSCSA definition of manufacturer? Yes DUNS: 796560394							,					-	
Is product exempt from DSCSA? No							d. Store product (unit of sale) upright?						
If yes, select exemption:							Protect prod	duct (unit of s	ale) from light	?			
Other exemption - Write in:							-		-			_	
Is product repackaged? Yes If Yes, was original product purchased direct from mfr?						Yes	e. Shelf life:		Months				
Is product sold by manuf	facturer's exclusive d	stributor?	Yes		=		,	Initial shelf I	ife at launch (i	f different):		Months	
Are any waivers granted	for product ID/barcoo	le?	No	If yes, attach	documentation from FDA							='	
ADDITIONAL PRODUCT INFORMATION							ITEM AND PACKING INFORMATION						
Is the Product	Is the Product Direct and Drop Ship		ORDER INFORMATION		Ī	Weight Lbs.	Dimensions (US msmts.)			Volume	# Pieces:		
Legend Device?		No	Unit of Sale	What is the N	NDC selling unit?		weight Lbs.	Depth	Height	Width:	(Cube)	# Pieces:	
State Control?													
		No	Bottle	30 pills per bo	ox	Item:	0.3	2 00"	4 25"	3 25"		1	
ARCOS reportable?		No	x Box/Carton	10 boxes per	case	Item:	0.3	2.00"	4.25"	3.25"	(5)	1	
Co-Licensed?		No No	x Box/Carton Ampule	10 boxes per		Box/	0.3	2.00"	4.25"	3.25"		1	
Co-Licensed? Controlled Substance?		No	x Box/Carton Ampule Glass	10 boxes per (Write-in, e.g	case g. 1 Box of 10 Vials)			2.00"		3.25"			
Co-Licensed? Controlled Substance? Schedule No.?	tic)	No No	x Box/Carton Ampule Glass Tube	10 boxes per	case g. 1 Box of 10 Vials)	Box/	0.3	9.50"	4.25"	3.25" 6.50"	(5.5.5)	10	
Co-Licensed? Controlled Substance?		No No	x Box/Carton Ampule Glass	10 boxes per (Write-in, e.g	case g. 1 Box of 10 Vials)	Box/ Carton: Case:					(3.2.2)		
Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot	ode:	No No	x Box/Carton Ampule Glass Tube Vial Liquid Sgl	10 boxes per (Write-in, e.g	case p. 1 Box of 10 Vials) der quantity? Yes	Box/ Carton:							
Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Co Hazardous Material/Cyto	ode: otoxic Agent?	No No No	x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi	10 boxes per (Write-in, e.g	case J. 1 Box of 10 Vials) der quantity? Yes many of which package type? Each Inner/Carton/Pack	Box/ Carton: Case: Pallet:	3 Case:						
Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Co Hazardous Material/Cyto Is Item	ode: otoxic Agent? Unit Dose	No No No	x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql	10 boxes per (Write-in, e.g	case 1. 1 Box of 10 Vials) der quantity? Yes many of which package type? Each	Box/ Carton: Case:	3						
Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar of	ode: otoxic Agent? Unit Dose	No No No	X Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In	Minimum ord If Yes, how n	case_ j. 1 Box of 10 Vials) der quantity?	Box/ Carton: Case: Pallet: UPC:	3 Case:						
Co-Licensed? Controlled Substance? Schedule No.? (Incl. N for non-narcot Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar c hospital scanning?	ode: otoxic Agent? Unit Dose coded to unit dose for	No No No No Yes	X Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In	10 boxes per (Write-in, e.g Minimum ord If Yes, how n	case J. 1 Box of 10 Vials) der quantity? Yes many of which package type? Each Inner/Carton/Pack Case Other Product Informati	Box/ Carton: Case: Pallet: UPC:	3 Case: Carton:	9.50"		6.50"		10	
Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar of	ode: otoxic Agent? Unit Dose coded to unit dose for	No No No	X Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In	10 boxes per (Write-in, e.g Minimum ord If Yes, how n	case 1. 1 Box of 10 Vials) der quantity? Yes many of which package type? Each Inner/Carton/Pack Case Other Product Informat Size/Strength/Form:	Box/ Carton: Case: Pallet: UPC:	3 Case: Carton:	9.50" Per Unit of	4.50"	6.50"	Federal Ex	10	
Co-Licensed? Controlled Substance? Schedule No.? (Incl. N for non-narcot Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar of hospital scanning? Is it reverse numbered?	ode: toxic Agent? Unit Dose coded to unit dose for	No No No No Yes	X Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In PHARMACY ORDER Rec. self unit to custor	Minimum ord If Yes, how n 1 BILL UNIT	case J. 1 Box of 10 Vials) der quantity? Yes many of which package type? Each Inner/Carton/Pack Case Other Product Informat Size/Strength/Form: 30ct/750mg/capsule	Box/ Carton: Case: Pallet: UPC:	3 Case: Carton:	9.50" Per Unit of	4.50"	6.50"	Federal Ex	10	
Co-Licensed? Controlled Substance? Schedule No.? (Incl. N for non-narcot Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar c hospital scanning? Is it reverse numbered? WHOLE	ode: otoxic Agent? Unit Dose coded to unit dose for	No No No No Yes	X Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Sgl Vial Power Multi Vial Power Multi Other: Write In PHARMACY ORDER Rec. sell unit to custor (Write-in, e.g.	10 boxes per (Write-in, e.g. Minimum ord If Yes, how n 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	case J. 1 Box of 10 Vials) der quantity? Yes many of which package type? Each Inner/Carton/Pack Case Other Product Informat Size/Strength/Form: 30ct/1750mg/capsule Product Shape: capsule	Box/ Carton: Case: Pallet: UPC:	Case: Carton:	9.50" Per Unit of (\$)	4.50" COST INFO	6.50" ORMATION DIST (WAC) (\$)	Federal Ex	10	
Co-Licensed? Controlled Substance? Schedule No.? (Incl. N for non-narcot Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar c hospital scanning? Is it reverse numbered? ViHOLE Vendor #:	ode: toxic Agent? Unit Dose coded to unit dose for	No No No No Yes	A Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Powder Ndlti Other: Write In PHARMACY ORDER Rec. sell unit to custor (Write-in, e.g. Rx billing unit to pharn	10 boxes per (Write-in, e.g. Minimum ord If Yes, how n 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	case J. 1 Box of 10 Vials) der quantity? Yes many of which package type? Each Inner/Carton/Pack Case Other Product Informat Size/Strength/Form: 30ct/750mg/capsule	Box/ Carton: Case: Pallet: UPC:	3 Case: Carton:	9.50" Per Unit of (\$)	4.50" COST INFO	6.50"	Federal Ex	10	
Co-Licensed? Controlled Substance? Schedule No.? (Incl. N for non-narcot Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar o hospital scanning? Is it reverse numbered? WHOLE Vendor #:	ode: toxic Agent? Unit Dose coded to unit dose for	No No No No Yes	Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In PHARMACY ORDER Rec. sell unit to custor (Write-in, e.g. Rx billing unit to pharn	10 boxes per (Write-in, e.g. Minimum ord If Yes, how n 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	case J. 1 Box of 10 Vials) der quantity? Yes many of which package type? Each Inner/Carton/Pack Case Other Product Informat Size/Strength/Form: 30ct/750mg/capsule Product Shape: Capsule Dilue	Box/ Carton: Case: Pallet: UPC:	Case: Carton:	9.50" Per Unit of (\$)	4.50" COST INFO	6.50" ORMATION DIST (WAC) (\$)	Federal Ex	10	
Co-Licensed? Controlled Substance? Schedule No.? (Incl. N for non-narcot Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar c hospital scanning? Is it reverse numbered? Viriols Vendor #:	ode: toxic Agent? Unit Dose coded to unit dose for	No No No No Yes	X Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In PHARMACY ORDER Rec. sell unit to custor (Write-in, e.g. Rx billing unit to pharn Each Gram	10 boxes per (Write-in, e.g. Minimum ord If Yes, how n 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	case J. 1 Box of 10 Vials) der quantity? Yes many of which package type? Each Inner/Carton/Pack Case Other Product Informati Size/Strength/Form: 30ct/750mg/capsule Product Shape: capsule	Box/ Carton: Case: Pallet: UPC:	Case: Carton:	9.50" Per Unit of (\$)	4.50" COST INFO Invoice Co	6.50° ORMATION Dest (WAC) (\$)	Federal Ex	10	
Co-Licensed? Controlled Substance? Schedule No.? (Incl. N for non-narcot Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar o hospital scanning? Is it reverse numbered? WHOLE Vendor #: Whisl. Code #:	ode: toxic Agent? Unit Dose coded to unit dose for SALER USE ONLY:	No N	Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Powder Sql Vial Powder Sql Vial Powder Multi Other: Write In PHARMACY ORDER Rec. sell unit to custor (Write-in, e.g. Rx billing unit to pharn Each Gram Milliliter	10 boxes per (Write-in, e.g. Minimum ord If Yes, how n 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	case 1. 1 Box of 10 Vials) der quantity? Yes many of which package type? Each Inner/Carton/Pack Case Other Product Informat Size/Strength/Form: [30ct/750mg/capsule Product Shape: Product Color: blue Product Imprint: amneal;542	Box/ Carton: Case: Pallet: UPC:	Gase: Carton:	9.50" Per Unit of (\$) .97	4.50" COST INFO Invoice Co	6.50" ORMATION DIST (WAC) (\$)	Federal Ex	10	
Co-Licensed? Controlled Substance? Schedule No.? (Incl. N for non-narcot Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar o hospital scanning? Is it reverse numbered? Vendor #: Whole Vendor #: While Code:	ode: Unit Dose Unit dose for SALER USE ONLY:	No N	Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Powder Sql Vial Powder Sql Vial Powder Multi Other: Write In PHARMACY ORDER Rec. sell unit to custor (Write-in, e.g. Rx billing unit to pharn Each Gram Milliliter	10 boxes per (Wite-in, e.g. Minimum ord If Yes, how n 1 1 1 Vial) hacy:	case j. 1 Box of 10 Vials) der quantity? many of which package type? Each Inner/Carton/Pack Case Other Product Informat Size/Strength/Form: 30ct/750mg/capsule Product Shape: capsule Product Color: Product Imprint: amneal;542	Box/ Carton: Case: Pallet: UPC:	3 Case: Carton: Regular Cost Sale \$119 OF PRODUCT PAGE	9.50" Per Unit of (\$) .97	4.50" COST INFO Invoice Co	6.50° ORMATION Dest (WAC) (\$)	Federal Ex	10	
Co-Licensed? Controlled Substance? Schedule No.? (Incl. N for non-narcot Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar o hospital scanning? Is it reverse numbered? WHOLE Vendor #: Whisl. Code #:	ode: Unit Dose Unit dose for SALER USE ONLY:	No N	Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Powder Sql Vial Powder Sql Vial Powder Multi Other: Write In PHARMACY ORDER Rec. sell unit to custor (Write-in, e.g. Rx billing unit to pharn Each Gram Milliliter	10 boxes per (Wite-in, e.g. Minimum ord If Yes, how n 1 1 1 Vial) hacy:	case 1. 1 Box of 10 Vials) der quantity? Yes many of which package type? Each Inner/Carton/Pack Case Other Product Informat Size/Strength/Form: [30ct/750mg/capsule Product Shape: Product Color: blue Product Imprint: amneal;542	Box/ Carton: Case: Pallet: UPC:	Gase: Carton:	9.50" Per Unit of (\$) .97	4.50" COST INFO Invoice Co	6.50° ORMATION Dest (WAC) (\$)	Federal Ex	10	