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Food Safety Plan and HACCP Plan 001: Juice and Liquid Products

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Technical Letter from N	National Food Laboratory, 13 Apr 200	6		2
Prepared By:	Summer Brockman, PCQI			
Approved By:	Kevin Asay	Signature:	Kevin ()	Cur
Position:	Senior Director of Quality Assurance & Regulatory Affairs	Date:	Kevin 9. 8 Nov 201	7





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Food Safety Plan and HACCP Plan 001: Juice and Liquid Products

Product Description and Dist	ribution		
Common or usual name?			
Juice and liquid products.			
Product Description			
Juice and liquid products with concentrates, fruit purees, natu acid, ascorbic acid, botanical extensions and acid, ascorbic acid, botanical extensions.	ral flavors, extracts, sweet	eners, and powder	
Raw or Pasteurized?			
Pasteurized			
Ready-to-consume or requires cook	ing		
Ready to consume			
Preservation method			
Pasteurized and Hot-Filled			
Package Description			
Glass, Aluminum, and Plastic I	Bottles		
Distribution Method			
Direct ship to independent prod	luct consultants and custor	ners	
Is product distributed frozen, refrig	gerated, or is it shelf stable?		
Shelf Stable			
Who will consume the product, and	what is the normal use of the	product by the intend	ed consumer?
General Population. See label			
Approved By:	Kevin Asay Director of Quality Assuranc	Signature:	Kui J. hug
D SCIIIOI	Director of Quality Assurance		▼

& Regulatory Affairs

Position:

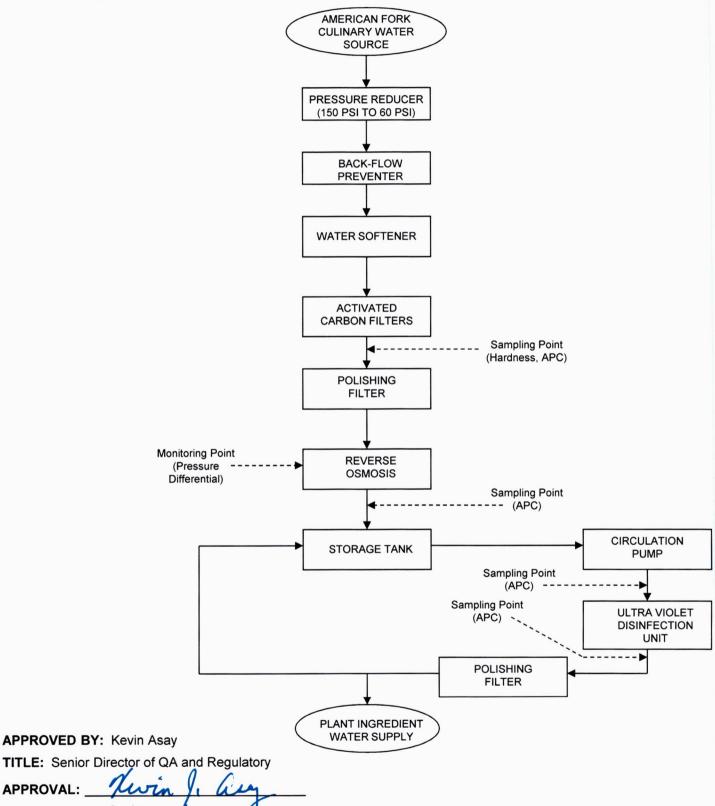
Date:

8 NOV 2017



APPROVAL:

DATE: ___

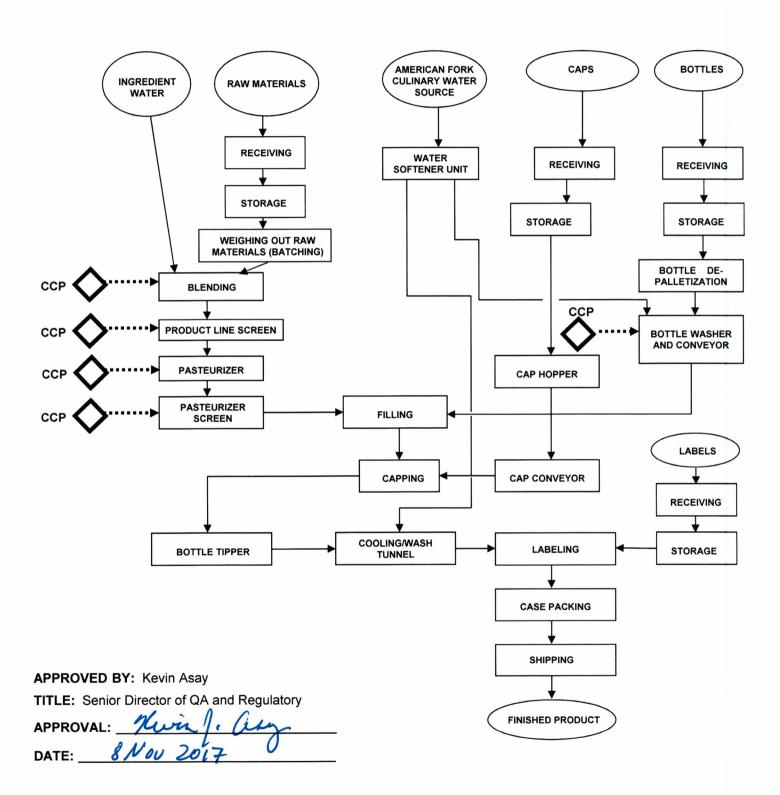






PROCESS FLOW DIAGRAM

Juice and Liquid Products



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Food Safety/HACCP Plan

Juice and Liquid Products Hazard Analysis Worksheet Product Description Dry Shelf and Direct Ship

Method of Storage & Distribution

See label for normal use instructions. General Public.

Intended Use & Consumer

			(3) Significant?			(6) CCP
(1) Processing Step	(2) Potential Hazards	Hazards	Yes/No	(4) Justify Decision	(5) Control Measures	Yes/No
	Biological None	one				
Water Pressure Reducer (150 PSI to 60 PSI)	Chemical None	one				
,	Physical None	one				
	Biological None	one				U1
Back-flow Preventer	Chemical None	one				1-(
	Physical None	one				Co C
	Biological None	one				nti op
Ingredient Water Softener Unit	Chemical None	one				rol Y
	Physical None	one				le

B-No

B-Flush weekly with Hydrogen Peroxide (5%)

solution.

B-Carbon filtration beds provide hospitable

B-Yes

Microbiological contamination

Biological

None

Physical

None

Biological

None

Chemical

Ingredient Water Polishing Filter None

Physical

None

Chemical

Activated Carbon Filters Ingredient Water

environment for bacteria, algae, and fungi.

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Hazard Analysis Worksheet

Product Description Juice and Liquid Products

Method of Storage & Distribution

Dry Shelf and Direct Ship

Intended Use & Consumer

See label for normal use instructions. General Public.

		(3) Significant?			(6) CCP
(1) Processing Step	(2) Potential Hazards	Yes/No	(4) Justify Decision	(5) Control Measures	Yes/No
	Biological None				
Ingredient Water Reverse Osmosis Unit	Chemical None		B , C , & P -Not likely to occur due to the nature of the reverse osmosis process.		
	Physical None				
	Biological		B- Not likely to occur. Water circulating		IJ1
Ingredient Water Storage	Microbiological contamination	B-N ₀	through this tank will go through the UV disinfection unit.		n-C
Tank	Chemical None				C)
	Physical None				nt or
	Biological		B-Not likely to occur. Water circulating		ro Y
	Microbiological	B-No	through this pump will go through the UV		
Ingredient water Circulation Pump	contamination		disinfection unit.		;
	Chemical None				
	Physical None				
	Biological		B- Microbial tests from samples taken at this		
Ingredient Water Ultra Violet Disinfection Unit	Pathogens, including E.coli and Salmonella species	B- No	point are routinely found to be within acceptable limits.		
	Chemical None				
	Physical None				
	Biological None				
Ingredient Water Polishing Filter	Chemical None				
I Ollolling I IIICI	Physical None				

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Juice and Liquid Products Hazard Analysis Worksheet Product Description Dry Shelf and Direct Ship Method of Storage & Distribution

Intended Use & Consumer

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(6) CCP Yes/No	² Un-			B -N _o		0N- 8
(5) Control Measures	B-Process Control = subsequent pasteurization step. Raw materials must always be accompanied by a Certificate of Analysis from the supplier. Raw materials used in food products could introduce pathogens, but our subsequent are accepted off the supplier COA. Raw materials used in dietary supplements are tested prior to acceptance and use unless they are qualified to accept on vendor COA (excluding identity testing).		P-Containers may be compromised. Incidental P-Check sanitation of container closure area. Confirm proper use contamination can take place during shipping of liners and seals. Inspect containers and reject if compromised. Reference SOP's.	B-Process Control = subsequent pasteurization step. Raw conditions, and prior handling procedures could introduce pathogens, but our subsequent are accepted off the supplier COA. Raw materials used in dietary pasteurization step can control the hazard. B-Process Control = subsequent pasteurization step. Raw materials used in food products accepted off the supplier. COA. Raw materials used in dietary supplements are tested prior to acceptance and use unless they are qualified to accept on vendor COA (excluding identity testing).		P-Containers may be compromised. Incidental P-Check sanitation of container closure area. Confirm proper use contamination can take place during shipping of liners and seals. Inspect containers and reject if compromised. Reference SOP's.
(4) Justify Decision	B-Possible closure/container failure, storage conditions, and prior handling procedures could introduce pathogens, but our subsequent pasteurization step can control the hazard.		P-Containers may be compromised. Incidental contamination can take place during shipping and storage	B-Possible closure/container failure, storage conditions, and prior handling procedures could introduce pathogens, but our subsequent pasteurization step can control the hazard.		P-Containers may be compromised. Incidental contamination can take place during shipping and storage
(3) Significant? Yes/No	B- Yes		P-Yes	B- Yes		P-Yes
(2) Potential Hazards	Biological $Pathogens, including E.coli$ and Salmonella species	Chemical None	Physical Contamination during shipping	Biological $egin{array}{ccc} & & & & & & & & & & & & & & & & & &$	Chemical None	Physical Contamination during shipping
(1) Processing Step	Raw Material Receiving - Fruit Juices, Juice Blends, Fruit Juice	Purees, Nectars		Raw Material Receiving - Other Liquid (Sweeteners, Flavors,	Extracts, Colors, etc.)	

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Food Safety/HACCP Plan

Hazard Analysis Worksheet

Juice and Liquid Products Product Description

Dry Shelf and Direct Ship Method of Storage & Distribution

Intended Use & Consumer

(1) Processing Step	(2) Potential Hazards	(3) Significant? Yes/No	(4) Justify Decision	(5) Control Measures	(6) CCP Yes/No
D	Biological				
Raw Material Receiving - Powders/Dry Ingredients	Pathogens, including <i>E. coli</i> and Salmonella species	B-Yes	B-Process Control = subsequent pasteurization step. Raw materials must always be accompanied by a Certificate of Analysis from the supplier. Raw materials used in food products are accepted off the supplier could introduce pathogens, but our subsequent pasteurization step can control the hazard. supplements are tested prior to acceptance use unless they are qualified to accept on vendor COA (excluding identity testing).	B-Process Control = subsequent pasteurization step. Raw materials must always be accompanied by a Certificate of Analysis from the supplier. Raw materials used in food products are accepted off the supplier COA. Raw materials used in dietary supplements are tested prior to acceptance and use unless they are qualified to accept on vendor COA (excluding identity testing).	Un-Contro
(sweeteners, acidulents, botanical extracts, preservatives, vitamins, minerals, gums, etc.)	Chemical Allergen - shellfish	C-Yes	C-Glucosamine may contain shellfish allergen that must be labeled to inform consumers. Allergen cross-contact must be prevented during shipping, storage, and use in production.	C-Allergen control - proper allergen labeling and sanitation control to prevent allergen cross-contact.	olled S
	Physical Contamination during shipping	P-Yes	P-Containers may be compromised. Incidental contamination can take place during shipping and storage B-Check sanitation of container closure area. Contamination can take place during shipping containers and reject if compromised. Reference SOP's.	B- Check sanitation of container closure area. Confirm proper use of liners and seals. Inspect containers and reject if compromised. Reference SOP's.	B -No

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Hazard Analysis Worksheet

Product Description Juice and Liquid Products

Method of Storage & Distribution

Dry Shelf and Direct Ship

Intended Use & Consumer

See label for normal use instructions. General Public.

(1) Ducoccing Ston	(2) Defential Hazanda	(3) Significant?	(4) Tuestife, Passision	Money Money	(6) CCP
dans Suissaan (1)	Biological	155/10	HOISTON (HORDS (4)		ON I COL
Raw Material Storage	Pathogens, including E.coli and Salmonella species	B-No	B-Not likely to occur.		
Frozen	Chemical None				J
	Physical				Jr
	Contamination during	P-No	P-Not likely to occur.		1-(
	storage				<u> </u>
	Biological				OT C
Daw Material Storage	Pathogens, including E. coli and Salmonella species	B -No	B-Not likely to occur.		itro py
Refrigerated	Chemical None				116
	Physical				
	Contamination during storage	P- No	P-Not likely to occur.		
	Biological				
Raw Material Storage	Pathogens, including E. coli and Salmonella species	B -N ₀	B-Not likely to occur.		
Dry Storage (Ambient)	Chemical None				
	Physical				
	Contamination during	P-No	P-Not likely to occur.		
	storage				

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Juice and Liquid Products Hazard Analysis Worksheet Product Description

Method of Storage & Distribution

Dry Shelf and Direct Ship

Intended Use & Consumer

See label for normal use instructions. General Public.

		(3) Significant?			(6) CCP	
(1) Processing Step	(2) Potential Hazards	Yes/No	(4) Justify Decision	(5) Control Measures	Yes/No	
	Biological None					
Packaging Receiving -	Chemical	ţ	C-Labels must declare allergens present in	C-Allergen Control - Label review for	2	
	Undeclared Allergens	C-Yes	the product.	allergen information is performed before labels are released for use.	0.1-0	
	Physical None					
	Biological None					1 T
Doolowing Day Ctorogo	Chemical None				1	n.
Packaging Dry Storage - Bottles, Caps, Labels	Physical None					_(
	Contamination during	P-N _o	P-Not likely to occur.		C	C)C
	storage				`() [
	Biological None				þ	ıt!
	Chemical None				y	(0
Bottle De-palletization	Physical		D Adressed in subsequent propessing sten			11
	Glass fragments and other	P-No	f-Addiesed in subsequent processing step (bottle washer).			e
	foreign matter					1
	Biological None					
Wash water softener unit Chemical	Chemical None					
	Biological None					
	Biological None					
	Chemical None					
Bottle Washer and	Physical		D Describle whee framents and other foreign	P-Water spray washing, drainage by		
	Glass fragments and other foreion matter	P-Yes	matter.	inversion, and covered conveyer following the washer.	P-Yes	
	TOTO BUT THERE I					

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Food Safety/HACCP Plan

 \mathbf{o} Page Product Description Juice and Liquid Products Hazard Analysis Worksheet

Method of Storage & Distribution

Dry Shelf and Direct Ship

Intended Use & Consumer

(1) Processing Step	(2) Potential Hazards	(3) Significant? Yes/No	(4) Justify Decision	(5) Control Measures	(6) CCP Yes/No	
	Biological					
Weighing out Raw	Pathogens, including $E.coli$ and Salmonella species	B- Yes	B- Possible contamination and growth of pathogenic organisms.	B -Sanitation control - Zoning, maintaining environment and employee practices at appropriate hygiene level. Reference SSOP's.	B -No	
Materials (Batching)	Chemical		C-Material containing allergens	C. Allergen and Sanitation control - Droner		
	Allergens	C-Yes	(Glucosamine) is handled in the same environment.	cleaning between products.	C-N _o	TT
	Physical None					n-
	Biological					-C
	Pathogens, including E.coli and Salmonella species	B-Yes	B -Possible contamination and growth of pathogenic organisms.	B -Controlled by low pH and subsequent pasteurization or refrigeration.	Gop	onti
Blending	Chemical			C-Allergen and Sanitation control - Proper	y	col
	Cleaning Chemicals	C-Yes	C-Possible failure to properly drain system following CIP.	cleaning between products. Check tanks and lines for cleanliness and complete drainage of cleaning chemicals. Reference SSOP's.	C-No	lled
	Physical None					
	Biological None					
,	Chemical None		P-Foreign material can contaminate the			
Product Line Screen	Physical	ŝ	product.	P-Verify screen integrity.	P-Yes	
	Foreign material	P-Yes				
	Biological			B-Temperature and time. Process control -		
Pasteurizer	Pathogens, including E.coli and Salmonella species	B -Yes	B-Possible contamination and growth of pathogenic organisms.	Pasteuriztaion (based on National Food Lab time and temperature guidelines).	B-Yes	
	Chemical None					
	Physical None					

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Juice and Liquid Products **Hazard Analysis Worksheet Product Description** Dry Shelf and Direct Ship Method of Storage & Distribution

See label for normal use instructions. General Public.

Intended Use & Consumer

			P-Yes	Ut	1-(eakage Response		iti	ol y	led			P-No on capper.	
(5) Control Measures			P-Verify screen integrity			P-Follow SOP (Bottle Breakage Response SOD) for alace breakage on filler and filler	heads.					P-Follow SOP (Bottle Breakage Resnonse	SOP) for glass breakage on capper.	
(4) Justify Decision		P-Metal fatigue and worn and damaged	machine parts can cause contamination of the P-Verify screen integrity.	product.		D Descible breatenes on filler	r -r Ossiule of canage off filler.			B-Not likely to occur.			P-Possible breakage on capper.	
(3) Significant? Yes/No				P-Yes			D Voc	r-163		B-No			P-Yes	
(2) Potential Hazards	Biological None	Chemical None	Physical	Metal fragments and other foreign matter	Biological None	Chemical None	Physical	Broken glass	Biological	Pathogens, including E.coli and Salmonella species	Chemical None	Physical	Broken glass	Biological
(1) Processing Step	+		Pasteurizer Screen	·			giiiiig				Capping			

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B-No

B-Tipping brings all container inside surfaces

in contact with hot product.

pathogenic organisms on underlid and bottle

neck surfaces.

B-Possible contamination and growth of

B-Yes

Pathogens, including E.coli and Salmonella species

Bottle tipper

None None

Chemical **Physical**

Food Safety/HACCP Plan

Hazard Analysis worksneet	WOrksn	eer			Fage	ي ص	10	<i>ع</i>	Fages
Product Description		Juice and Liquid Products	Products						
Method of Storage & Distribution	e & Dist	tribution	Dry Shelf and Direct Ship	irect Ship					
Intended Use & Consumer	onsume		label for normal use	See label for normal use instructions. General Public.					
(1) Processing Step	(2) Pote	(2) Potential Hazards	(3) Significant? Yes/No	(4) Justify Decision)	(5) Control Measures	Measures		(6) CCP Yes/No
	Biological None	None							
Cooling/Wash Tunnel	Chemical	None							
	Physical	None							
	Biological	None							U
Labeling	Chemical	None							n-
	Physical	None							·C)
	Biological	None							OD Co
Case Packing	Chemical	None							p)
	Physical	None							J I
	Biological	None							
Shipping	Chemical	None							
	Physical	None							
							,		
Approved By:	; ;		Kevin Asay		Signature:	Hun	Hum/ R	7	
Position:	ü	Senior Dire	Senior Director of QA & Regul	Regulatory Affairs	Date:	Date: 8 Lov 2017	2017	0	

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Food Safety/HACCP Plan

Critical Control Points

Product Description

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Juice and Liquid Products

Method of Storage & Distribution

Dry Shelf and Direct Ship

Intended Use & Consumer

			Cantrol	led		
Records		Pressure at the beginning of each barch is recorded on the Batch Record.	Calibration of the pressure gauge is recorded in the Metrology Logbook.		The pH of each batch is recorded on the Batch Record.	Calibration of the pH meter is recorded in the pH Calibration Logbook.
Vorification		Calibration of the pressure gauge.	Physical inspection of spray nozzle settings.		Calibrate pH meter prior to start-up each production run.	
Corroctive Action(e)		Stop the line. Remove bottles past the washer.	Finished product manufactured outside of critical limits will be placed on QA Hold.	Disposition of finished product on QA Hold is determined by the Material Review Board.	Discard batch or, under R&D direction, adjust pH to appropriate level.	
	Who	Line Super- visor			Compounder	
Monitoring	Frequency	At the beginning of each batch			Each batch	
Moni	моН	Visual check of gauge			pH meter	
	What	Wash Pressure			Hd	
Critical Limits for each Preventive Measure		Main Line: ≥17 psi			Not greater than 3.90	
Significant	Hazard(s)	Bottle Washer Glass fragments and other foreign matter			Pathogens, including E. coli and Salmonella species	
Critical	Control Point (CCP)	Bottle Washer			Blending	

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Food Safety/HACCP Plan

Critical Control Points

Juice and Liquid Products

Product Description Juice and Liquid Produ

Method of Storage & Distribution Dry

Dry Shelf and Direct Ship

Intended Use & Consumer

Un-Controlled						
Records		The recording chart is filed with the Batch Record. Calibration records are located in the Metrology Logbook.				
Verification		Calibrate dial thermometers and continuous chart recorders annually as per SOP. Reference technical letter from The National Food Laboratory, Inc. and CFR 21 Part 114.3.				
Corrective Action(s)		If the product temperature in advance of the automatic control valves is below the critical limit, the valves will operate to divert the flow back to the balance tank. If the automatic control valves fail to operate properly, the pasteurizer is shut down and the automatic control valve temperature sensor is repaired or replaced. Disposition of finished product on QA Hold is determined by the Material Review Board.				
	Who	Pasteurizer				
oring	Frequency	Continuous				
Monitorin	ном	In-line temperature recording chart				
	What	Temperature				
Critical Limits for each Preventive Measure		For glass bottles: Every particle of product to be held at not less than 176°F (80°C) for not less than 0.062 seconds. For aluminum bottles: Every particle of product to be held at not less than 165°F (73.9°C) for not less than 0.89 seconds.				
Significant Hazard(s)		Pathogens, including E. coli and Salmonella species				
Critical Control Point (CCP)		Pasteurizer				

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Food Safety/HACCP Plan

Critical Control Points

Product Description Juice and Liquid Products

Method of Storage & Distribution

Dry Shelf and Direct Ship

Intended Use & Consumer

See label for normal use instructions. General Public.

Un-Controlled							
Records		Screen checks are recorded in the HACCP Logbook. Annual inspections are located in the Metrology Logbook.	Screen checks are recorded in the HACCP Logbook. Annual inspections are located in the Metrology Logbook.	SOP 210-046 Bottle Breakage Response			
Verification		Annual inspection of screen for general condition.	Annual inspection of screen including average hole size and general condition.	Line not restarted until corrective action completed (measurement or verification prerequisites for HACCP not available. Included in HACCP Plan only for reference).			
Corrective Action(s)		Product produced since previous screen inspection will be placed on QA hold. The screen will be repaired or replaced if found to be compromised.	Product produced since previous screen inspection will be placed on QA hold. The screen will be repaired or replaced if found to be compromised.	Filler operator stops the line, removes open bottles, and cleans all broken glass pieces according to the Bottle Breakage Response SOP.			
	Who	Sanitation	Sanitation	Filler Operator			
oring	Frequency		After each production run	Every time a bottle breaks in the filling room.			
Monitoring	How	Physical inspection	Physical inspection	Halt filling line and remove by hand.			
	What	Screen integrity and proper installation	Screen integrity and proper installa-tion	All open bottles removed (since monitoring glass in bottles is not possible).			
Critical Limits for each Preventive Measure		Screen must be intact at conclusion of run.	Screen must be intact at conclusion of run.	Zero Tolerance			
Significant	Hazard(s)	Foreign material	Metal fragments and other foreign matter	Pieces of broken glass in product			
Critical	Control Point (CCP)	Product Line Screen	Pasteurizer Screen	Glass Breakage in Filler Room (SOP included in HACCP Plan for reference)			

Approved By: Kevin Asay

Position:

Senior Director of QA & Regulatory Affairs

Date:

of

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Food Safety/HACCP Plan

Preventive Controls

Juice and Liquid Products **Product Description**

Method of Storage & Distribution

Dry Shelf and Direct Ship

Intended Use & Consumer

See label for normal use instructions. General Public.

		1		
Records		Label Inspection Form Corrective Action Recods	Article Inspection and Label Record or CC line checks. Corrective Action Records. Corrective Action Records	
Verification		QA Review of Label Inspection Form and Corrective Action records.	QC Review of First Article Inspection and Label Record. QC line checks.	
Corrective Action(s)		If label is incorrect, reject labels and return to supplier or detroy. Identify root cause and prevent recurrence.	If product is packaged with the invorrect label, segregate the product, inspect back to the last good check. Rework affected product into correct packagin or discard. Identify root cause and prevent recurrence.	
Monitoring	Who	QC Label Tech	Line	
	Frequency	Each receipt before release to production	Prior to beginning the production run	
	How	Visual check of label and carton to match Master Label Standard (which matches the product formula).	Visual inspection of the label and carton to confirm the correct part numbers are used	
	What	Ingredient listing and allergen declaration matches product	Confirm Correct that label and packaging carton item used numbers are matches the used on product products. specificatio n sheet	
Critical Limits		All finished product labels must declare the allergens present in the formula	Correct label and carton item numbers are used on products.	
Hazard(s)		Undeclared allergen - shellfish	Use of incorrect labels, cartons. Undeclared allergen (shellfish).	
Preventive Control (PC)		Allergen Control: Receiving packaging (labels and cartons)	Allergen Control: Label verification at Packaging	

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Food Safety/HACCP Plan

Juice and Liquid Products **Product Description Preventive Controls**

Dry Shelf and Direct Ship

Method of Storage & Distribution

See label for normal use instructions. General Public. Intended Use & Consumer

Sanitiation Preventive Controls (to address prevention of microbial contamination and allergen cross-contact):

Zoning and GMP Controls

product line, receiving, storage, and shipping areas. Signage and employee training are used to designate these areas. In these higher hygiene zones • The batching room (used for weighing raw materials), filling room, and pasteurizer area are maintained at a higher hygiene level than labeling, employees must put on clean smocks, hair nets, beard nets, and wash their hands before entering. Employees entering the batching room for weighing raw materials must wear clean gloves. See SOP 100-020 Personnel Sanitation.

Cleaning and Sanitation

- Batching tanks, pasteurizer, and processing lines are cleaned ad sanitized using a CIP (clean-in-place) process according to Sanitation Standard Operating Procedures. Equipment and utensils are cleaned and sanitized in the sanitation room before and after use in production. Refer to individual SSOPs.
- A Daily Sanitation Check to monitor the eight points of sanitation in 21 CFR 120.6 and ensure the facility is maintained in a clean and sanitary condition is conducted by production personnel prior to beginning production each day. Results are recorded on the Daily Sanitation Checklist (Form #180).
- ontrolled equipment is clean and completing the Daily Sanitation Checklist. The Daily Sanitation Checklist should be attached to the Batch Record of the first recorded in the Sanitation Logbook. After the room and equipment are confirmed to be in a clean and sanitary condition sign and date the "Cleaning multiple batches should be attached to the first batch of the day. Documentation of cleaning and sanitizing of equipment and processing lines is also batch of the day. Attach the Equipment Ready For Use tags filled out by Sanitation personnel to the Batch Record. Tags that are applicable to • Prior to beginning a new batch a cleaning clearance must be done. Perform a cleaning clearance by making sure the Batching Room and Clearance" line on the Blending Record.

Kevin Asay Approved By: Senior Director of QA & Regulatory Affairs

Signature: