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

Contents **Date:** November 7, 2017 **Number of Pages**

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Approved By: Kevin Asay **Signature:** Kevin J. Asay

Position: Senior Director of Quality Assurance & Regulatory Affairs **Date:** 8 Nov 2017

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

Product Description and Distribution

Common or usual name?

Juice and liquid products.

Product Description

Juice and liquid products with a pH less than 3.9. Typical ingredients include RO water, fruit juice concentrates, fruit purees, natural flavors, extracts, sweeteners, and powdered ingredients such as citric acid, ascorbic acid, botanical extracts, preservatives, and gums.

Raw or Pasteurized?

Pasteurized

Ready-to-consume or requires cooking

Ready to consume

Preservation method

Pasteurized and Hot-Filled

Package Description

Glass, Aluminum, and Plastic Bottles

Distribution Method

Direct ship to independent product consultants and customers

Is product distributed frozen, refrigerated, or is it shelf stable?

Shelf Stable

Who will consume the product, and what is the normal use of the product by the intended consumer?

General Population. See label for normal use instructions.

Approved By: Kevin Asay **Signature:** Kevin J. Asay

Position: Senior Director of Quality Assurance & Regulatory Affairs **Date:** 8 Nov 2017

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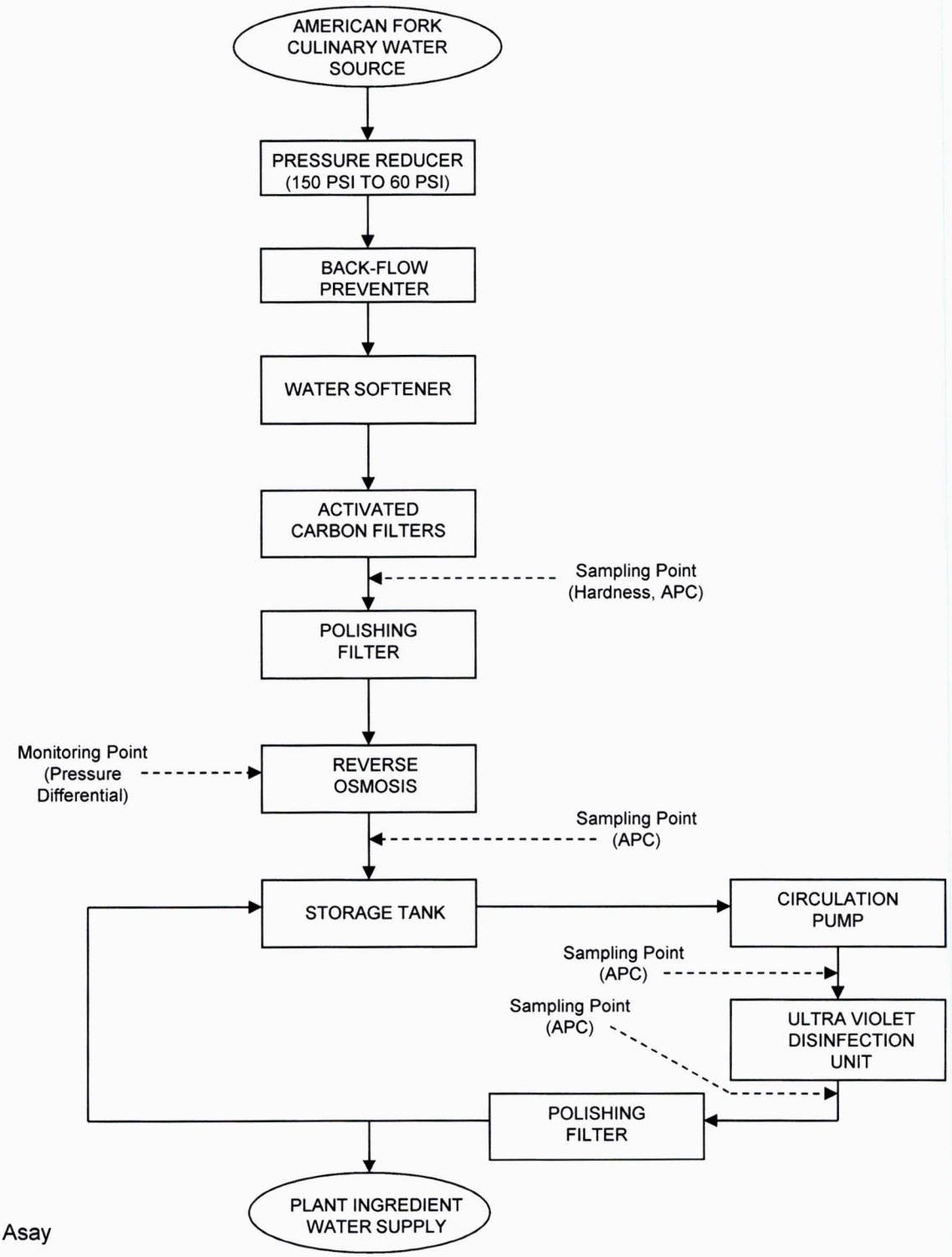
MORINDA

PROCESS FLOW DIAGRAM

INGREDIENT WATER



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TITLE: Senior Director of QA and Regulatory

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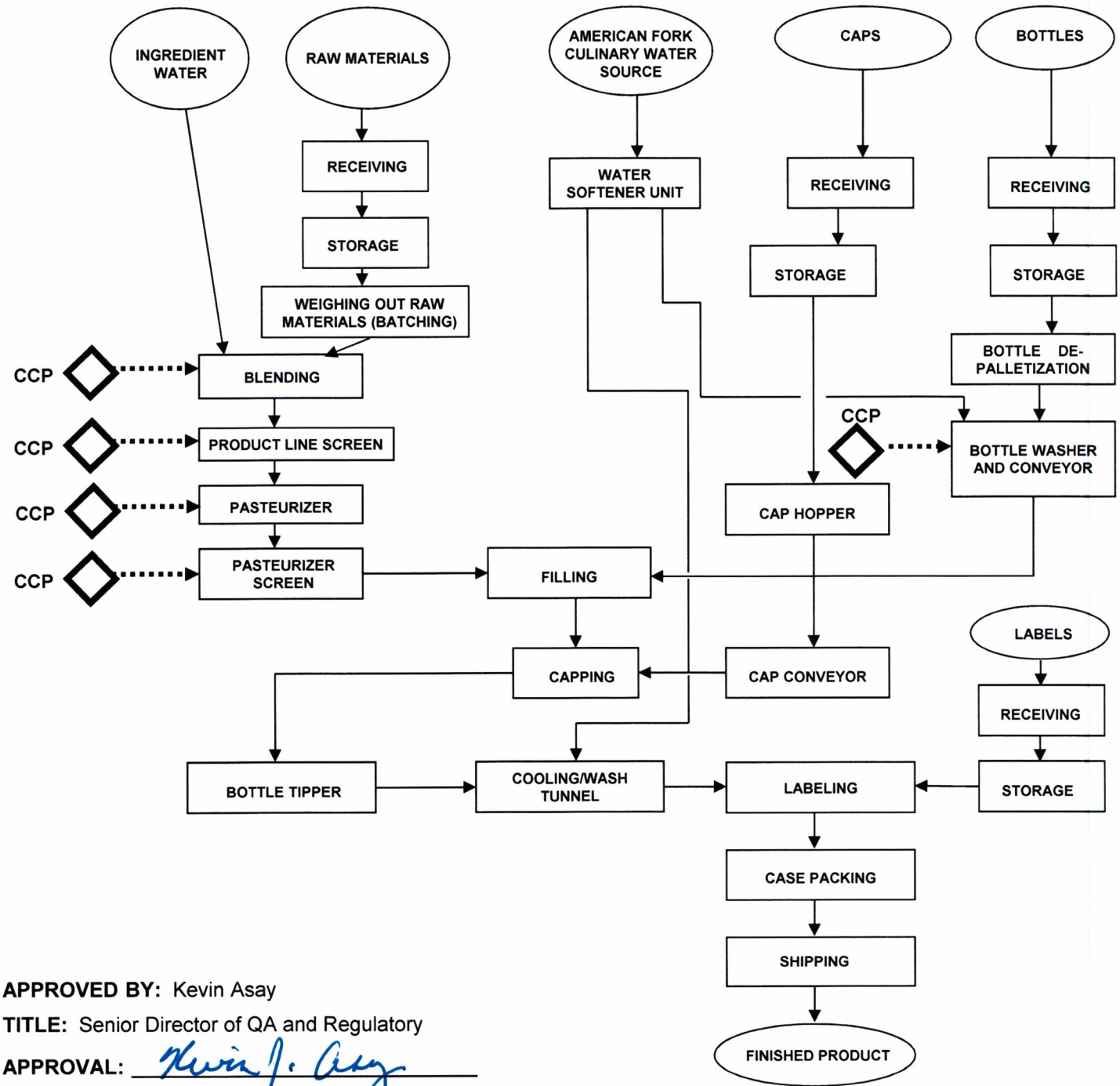
MORINDA

PROCESS FLOW DIAGRAM

Juice and Liquid Products



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Food Safety/HACCP Plan

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) Processing Step	(2) Potential Hazards	(3) Significant? Yes/No	(4) Justify Decision	(5) Control Measures	(6) CCP Yes/No
Water Pressure Reducer (150 PSI to 60 PSI)	**Biological** None				
	Chemical None				
	Physical None				
Back-flow Preventer	**Biological** None				
	Chemical None				
	Physical None				
Ingredient Water Softener Unit	**Biological** None				
	Chemical None				
	Physical None				
Ingredient Water Activated Carbon Filters	**Biological** Microbiological contamination	**B**-Yes	**B**-Carbon filtration beds provide hospitable environment for bacteria, algae, and fungi.	**B**-Flush weekly with Hydrogen Peroxide (5%) solution.	**B**-No
	Chemical None				
	Physical None				
Ingredient Water Polishing Filter	**Biological** None				
	Chemical None				
	Physical None				

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Ingredient Water Reverse Osmosis Unit	**Biological** None		**B, C, & P**-Not likely to occur due to the nature of the reverse osmosis process.		
	Chemical None				
	Physical None				
Ingredient Water Storage Tank	**Biological** Microbiological contamination	**B**-No	**B**-Not likely to occur. Water circulating through this tank will go through the UV disinfection unit.		
	Chemical None				
	Physical None				
Ingredient Water Circulation Pump	**Biological** Microbiological contamination	**B**-No	**B**-Not likely to occur. Water circulating through this pump will go through the UV disinfection unit.		
	Chemical None				
	Physical None				
Ingredient Water Ultra Violet Disinfection Unit	**Biological** Pathogens, including *E.coli and Salmonella species*	**B**-No	**B**-Microbial tests from samples taken at this point are routinely found to be within acceptable limits.		
	Chemical None				
	Physical None				
Ingredient Water Polishing Filter	**Biological** None				
	Chemical None				
	Physical None				

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Raw Material Receiving - Fruit Juices, Juice Blends, Fruit Juice Concentrates, Fruit Purees, Nectars	**Biological** Pathogens, including *E.coli and Salmonella species*	**B**-Yes	**B**-Possible closure/container failure, storage conditions, and prior handling procedures could introduce pathogens, but our subsequent pasteurization step can control the hazard.	**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).	**B**-No
	Chemical None				
	Physical Contamination during shipping	**P**-Yes	**P**-Containers may be compromised. Incidental contamination can take place during shipping and storage	**P**-Check sanitation of container closure area. Confirm proper use of liners and seals. Inspect containers and reject if compromised. Reference SOP's.	**B**-No
Raw Material Receiving - Other Liquid (Sweeteners, Flavors, Extracts, Colors, etc.)	**Biological** Pathogens, including *E.coli and Salmonella species*	**B**-Yes	**B**-Possible closure/container failure, storage conditions, and prior handling procedures could introduce pathogens, but our subsequent pasteurization step can control the hazard.	**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).	**B**-No
	Chemical None				
	Physical Contamination during shipping	**P**-Yes	**P**-Containers may be compromised. Incidental contamination can take place during shipping and storage	**P**-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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(1) Processing Step	(2) Potential Hazards	(3) Significant? Yes/No	(4) Justify Decision	(5) Control Measures	(6) CCP Yes/No
Raw Material Receiving - Powders/Dry Ingredients (sweeteners, acidulents, botanical extracts, preservatives, vitamins, minerals, gums, etc.)	**Biological** Pathogens, including *E.coli and Salmonella species*	**B**-Yes	**B**-Possible closure/container failure, storage conditions, and prior handling procedures could introduce pathogens, but our subsequent pasteurization step can control the hazard.	**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).	**B**-No
	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.	**C**-No
	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. Confirm proper use of liners and seals. Inspect containers and reject if compromised. Reference SOP's.	**B**-No

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Food Safety/HACCP Plan

Hazard Analysis Worksheet

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Raw Material Storage - Frozen	**Biological** Pathogens, including *E.coli and Salmonella species*	**B**-No	**B**-Not likely to occur.		
	Chemical None				
	Physical Contamination during storage	**P**-No	**P**-Not likely to occur.		
Raw Material Storage - Refrigerated	**Biological** Pathogens, including *E.coli and Salmonella species*	**B**-No	**B**-Not likely to occur.		
	Chemical None				
	Physical Contamination during storage	**P**-No	**P**-Not likely to occur.		
Raw Material Storage - Dry Storage (Ambient)	**Biological** Pathogens, including *E.coli and Salmonella species*	**B**-No	**B**-Not likely to occur.		
	Chemical None				
	Physical Contamination during storage	**P**-No	**P**-Not likely to occur.		

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(1) Processing Step	(2) Potential Hazards	(3) Significant? Yes/No	(4) Justify Decision	(5) Control Measures	(6) CCP Yes/No
Packaging Receiving - Bottles, Caps, Labels	**Biological** None				
	Chemical Undeclared Allergens	**C**-Yes	**C**-Labels must declare allergens present in the product.	**C**-Allergen Control - Label review for allergen information is performed before labels are released for use.	**C**-No
	Physical None				
Packaging Dry Storage - Bottles, Caps, Labels	**Biological** None				
	Chemical None				
	Physical None Contamination during storage	**P**-No	**P**-Not likely to occur.		
Bottle De-palletization	**Biological** None				
	Chemical None				
	Physical Glass fragments and other foreign matter	**P**-No	**P**-Addressed in subsequent processing step (bottle washer).		
Wash water softener unit	**Biological** None				
	Chemical None				
	Biological None				
Bottle Washer and Conveyor	**Biological** None				
	Chemical None				
	Physical Glass fragments and other foreign matter	**P**-Yes	**P**-Possible glass fragments and other foreign matter.	**P**-Water spray washing, drainage by inversion, and covered conveyer following the washer.	**P**-Yes

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(1) Processing Step	(2) Potential Hazards	(3) Significant? Yes/No	(4) Justify Decision	(5) Control Measures	(6) CCP Yes/No
Weighing out Raw Materials (Batching)	**Biological** 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
	Chemical Allergens	**C**-Yes	**C**-Material containing allergens (Glucosamine) is handled in the same environment.	**C**-Allergen and Sanitation control - Proper cleaning between products.	**C**-No
	Physical None				
Blending	**Biological** 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.	**B**-Yes
	Chemical Cleaning Chemicals	**C**-Yes	**C**-Possible failure to properly drain system following CIP.	**C**-Allergen and Sanitation control - Proper cleaning between products. Check tanks and lines for cleanliness and complete drainage of cleaning chemicals. Reference SSOP's.	**C**-No
	Physical None				
Product Line Screen	**Biological** None		**P**-Foreign material can contaminate the product.	**P**-Verify screen integrity.	**P**-Yes
	Chemical None				
	Physical Foreign material	**P**-Yes			
Pasteurizer	**Biological** Pathogens, including *E.coli and Salmonella species*	**B**-Yes	**B**-Possible contamination and growth of pathogenic organisms.	**B**-Temperature and time. Process control - Pasteuriztaion (based on National Food Lab time and temperature guidelines).	**B**-Yes
	Chemical None				
	Physical None				

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(1) Processing Step	(2) Potential Hazards	(3) Significant? Yes/No	(4) Justify Decision	(5) Control Measures	(6) CCP Yes/No
Pasteurizer Screen	**Biological** None		**P**-Metal fatigue and worn and damaged machine parts can cause contamination of the product.	**P**-Verify screen integrity.	**P**-Yes
	Chemical None				
	Physical Metal fragments and other foreign matter	**P**-Yes			
Filling	**Biological** None		**P**-Possible breakage on filler.	**P**-Follow SOP (Bottle Breakage Response SOP) for glass breakage on filler and filler heads.	**P**-Yes
	Chemical None				
	Physical Broken glass	**P**-Yes			
Capping	**Biological** Pathogens, including *E.coli and Salmonella species*	**B**-No	**B**-Not likely to occur.		
	Chemical None				
	Physical Broken glass	**P**-Yes	**P**-Possible breakage on capper.	**P**-Follow SOP (Bottle Breakage Response SOP) for glass breakage on capper.	**P**-No
Bottle tipper	**Biological** Pathogens, including *E.coli and Salmonella species*	**B**-Yes	**B**-Possible contamination and growth of pathogenic organisms on underlid and bottle neck surfaces.	**B**-Tipping brings all container inside surfaces in contact with hot product.	**B**-No
	Chemical None				
	Physical None				

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Food Safety/HACCP Plan

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Cooling/Wash Tunnel	**Biological** None				
	Chemical None				
	Physical None				
Labeling	**Biological** None				
	Chemical None				
	Physical None				
Case Packing	**Biological** None				
	Chemical None				
	Physical None				
Shipping	**Biological** None				
	Chemical None				
	Physical None				

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Approved By: Kevin Asay **Signature:** Kevin J. Asay

Position: Senior Director of QA & Regulatory Affairs **Date:** 8 Nov 2017

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.

Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Preventive Measure	Monitoring				Corrective Action(s)	Verification	Records
			What	How	Frequency	Who			
Bottle Washer	Glass fragments and other foreign matter	Main Line: ≥17 psi	Wash Pressure	Visual check of gauge	At the beginning of each batch	Line Super-visor	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.	Calibration of the pressure gauge. Physical inspection of spray nozzle settings.	Pressure at the beginning of each batch is recorded on the Batch Record. Calibration of the pressure gauge is recorded in the Metrology Logbook.
Blending	Pathogens, including *E. coli* and *Salmonella* species	Not greater than 3.90	pH	pH meter	Each batch	Compounder	Discard batch or, under R&D direction, adjust pH to appropriate level.	Calibrate pH meter prior to start-up each production run.	The pH of each batch is recorded on the Batch Record. Calibration of the pH meter is recorded in the pH Calibration Logbook.

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Food Safety/HACCP Plan

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Method of Storage & Distribution Dry Shelf and Direct Ship

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

Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Preventive Measure	Monitoring				Corrective Action(s)	Verification	Records
			What	How	Frequency	Who			
Pasteurizer	Pathogens, including *E. coli* and *Salmonella* species	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.	Temperature	In-line temperature recording chart	Continuous	Pasteurizer Operator	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.	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.	The recording chart is filed with the Batch Record. Calibration records are located in the Metrology Logbook.

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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.

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

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Position: Senior Director of QA & Regulatory Affairs **Date:** 6 Nov 2017

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Food Safety/HACCP Plan

Preventive Controls

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.

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

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Food Safety/HACCP Plan

Preventive Controls

Product Description Juice and Liquid Products

Method of Storage & Distribution Dry Shelf and Direct Ship

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

Zoning and GMP Controls

• The batching room (used for weighing raw materials), filling room, and pasteurizer area are maintained at a higher hygiene level than labeling, product line, receiving, storage, and shipping areas. Signage and employee training are used to designate these areas. In these higher hygiene zones 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).

• Prior to beginning a new batch a cleaning clearance must be done. Perform a cleaning clearance by making sure the Batching Room and equipment is clean and completing the Daily Sanitation Checklist. The Daily Sanitation Checklist should be attached to the Batch Record of the first 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 multiple batches should be attached to the first batch of the day. Documentation of cleaning and sanitizing of equipment and processing lines is also 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 Clearance" line on the Blending Record.

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Position: Senior Director of QA & Regulatory Affairs **Date:** 8 Nov 2017