

PLANT LOCATION: South Plainfield NJ**PLAN TITLE: Shelf Stable Liquid Flavor Process****PLANT LOCATION:** South Plainfield NJ

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HAZARD ANALYSIS

Ingredient, Packaging or Process Step (Column 1)	FORESEEABLE Hazards introduced, increased, or controlled at this step? (Column 2)	Risk Assessment		Is this an Acceptable, Moderate, or High risk level?	Justification for Risk Level	What measures can be applied to prevent, eliminate, or reduce the hazards being addressed?	Is this step a PC or CCP? (Column 7)	Preventive Control			
		Severity	Likelihood								
1b. Receiving (Refrigerated items)	B	Salmonella, Listeria, Mold Spores	High Injury / Illness	Low Unlikely to Occur	12 Moderate	Supply Chain controls exist for items that potentially are susceptible to pathogens , and it is unlikely to introduce pathogens at receiving activities. The physical hazards will be addressed downstream in the process. The chemical hazards are low enough that a Process Control is not required: example- allergen labeling is a regulatory requirement for manufacturers so the label verification is part of our PRP. Supplier Approval process addresses radiological concerns, prior to receipt. Even though the score is low for quality due to the likely severity we feel this is the best step to control the risk by making this a QCCP, if an issue is not identified here it will result in an exception or non conformance of finished product.	Pre-Requisite Programs - Allergen Control Receiving and Inspection Bulk Receiving SOP Supplier Approval and Management GMP Training Sampling and Testing Program QUALITY QCCP1- Organoleptic evaluation SUPPLY CHAIN PC- Check Vendor CoFA for pathogen results on high risk items (based on FDA guidelines and risk assessment)	Yes PC-1	Process Control	PC	
	P	Brittle Plastic, Wood, Metal, insects	Medium Minor Discomfort	Very Low Practically Impossible	20 Low				Supply Chain		
	C	Allergens, Pesticides, Radiological	Very High Fatality	Very Low Practically Impossible	11 Moderate				Sanitation Control		QCCP 1
	Q	Temperature, Odor, Humidity	Low Customer / Consumer Complaint	Medium Could Occur	18 Low				Other Control		
									Allergen Control		
1c. Receiving	B	Salmonella, Mold Spores,	High Injury / Illness	Very Low Practically Impossible	16 Low	The ingredients will not support microbiological survival, though organisms could be introduced during receiving activities. The physical hazards will be addressed downstream in the process. The chemical hazards are low enough	Pre-Requisite Programs - Personal Hygiene Pest Control Allergen Control	NO	Process Control		
	P	Brittle Plastic, Wood, Metal, insects	Medium Minor Discomfort	Very Low Practically	20 Low				Supply Chain		
									Sanitation Control		

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		Severity	Likelihood					
(packaging)			Impossible		that a PC is not required: example- allergen labeling is a regulatory requirement for manufacturers so the label verification is part of our PRP. Supplier Approval process addresses radiological concerns, prior to receipt	Receiving and Inspection Supplier Approval GMP Training	NO	Other Control
	C Allergens, Pesticides, Radiological	Very High Fatality	Very Low Practically Impossible	11 Moderate				
	Q Odor, Humidity, wrong packaging, damaged	LOW Customer / Consumer Complaint	Medium Could Occur	18 Low				Allergen Control

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		Severity	Likelihood					
2. Returned Product	B Salmonella, Mold Spores,	High Injury / Illness	Very Low Practically Impossible	16 Low	Only sealed product is accepted. The physical hazards will be addressed downstream in the process. Even though the score is low for quality due to the likely severity we feel this is the best opportunity to control the risk by making this a QCCP, if an issue is not identified here it will result in an exception or non conformance of finished product.	Pre-Requisite Programs - Receiving and Inspection Pest Control Procedure GMP Training QUALITY QCCP1- Organoleptic evaluation	NO	Process Control
	P Brittle Plastic, Wood, Metal, insects	Medium Minor Discomfort	Very Low Practically Impossible	20 Low				Supply Chain
	C Allergens, Pesticides, Radiological	Very High Fatality	Very Low Practically Impossible	11 Moderate				Sanitation Control
								Other Control
								Allergen Control

QCCP 1

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		Severity	Likelihood					
	Q Temperature, Odor, Humidity, mislabeling	LOW Customer / Consumer Complaint	Medium Could Occur	18 Low				
3a. Storage-Ambient	B None				Pre-requisite Programs are in place to mitigate moderate risks.	Pre-Requisite Programs - GMP Sanitation Chemical Control Glass/Brittle Plastic Control Allergen Control Personal Hygiene Training	NO	Process Control
	P Plastic from sampling tools or process, Wood pieces from pallet, Metal, spray insulation	Medium Minor Discomfort	Very Low Practically Impossible	20 Low				Supply Chain
	C Allergens (tree nut-Coconut, Almond; Mustard Oil)	High Injury / Illness	Very Low Practically Impossible	16 Low				Sanitation Control
								Other Control
	Q Temperature, Odor, Humidity	LOW Customer / Consumer Complaint	Medium Could Occur	18 Low				Allergen Control

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		Severity	Likelihood					
3b. Storage - Refrigerated	B	None			Containers are sealed. The risk concerning the identified hazards is low enough that it does not need to be addressed using a PC. Pre-requisite Programs are also in place to mitigate moderate risks.	Pre-Requisite Programs - GMP Training Pest Control Sanitation Chemical Control Glass/Brittle Plastic Control Allergen Control Personal Hygiene	NO	Process Control
	P	Plastic from sampling tools , Wood pieces from pallet, Metal	Medium Minor Discomfort	Low Unlikely to Occur				Supply Chain
	C	Allergens (tree nut Coconut, Almond; Mustard oil)	High Injury / Illness	Very Low Practically Impossible				Sanitation Control
	Q	Temperature, Odor,	Low Customer / Consumer Complaint	Medium Could Occur				Other Control Allergen Control

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			Severity	Likelihood					
4. Weighing / compounding Ingredients/ Re-pack	B	Staph Aureus,	Medium Minor Discomfort	Very Low Practically Impossible	20 Low	The risk concerning the identified hazards is low enough that it does not need to be addressed using a CCP or a Preventive Control. Pre-requisite Programs are in place to mitigate low to moderate risk. Even though the risk is moderate, we believe this is the area where a Preventive control is needed for Sanitation Controls.	Pre-Requisite Programs - Allergen Control GMP Sanitation Training Sanitation PC- Visual Inspection prior to weighing	Yes PC 2	Process Control
	P	parafilm, plastic, metal scoops, jewelry, hair covers	Medium Minor Discomfort	Very Low Practically Impossible	20 Low				Supply Chain
	C	Allergen-(tree nut Coconut, Almond; mustard oil), Cleaning residue	Medium Minor Discomfort	Medium Could Occur	13 Moderate				Sanitation Control PC
	Q	Sanitation, ,Odor Calibration, mis-compounding	Low Customer / Consumer Complaint	Medium Could Occur	18 Low				Other Control Allergen Control
5. Municipal Water	B	Microbes/Coliforms	Medium Minor Discomfort	Low Unlikely to Occur	16 Low	The ingredient can support microbiological survival, though finished products intrinsic factors mitigate the hazard. The chemical hazards are low enough that a PC is not required, but is monitored by a PRP.	Pre-Requisite Programs Monthly testing by American Water Company Quarterly Water Quality Testing	No	Process Control
	P	None							Supply Chain
	C	Heavy Metals,	High Injury /	Low Unlikely	12 Moderate				Sanitation Control

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		Severity	Likelihood					
	chlorine	Illness	to Occur	12 Moderate				Other Control
	Q Taste(Chlorine)	Low Customer / Consumer Complaint	Medium Could Occur	18 Low				Allergen Control
6. Mixing	B None				Physical hazards are addressed at a later step. Only food grade lubricants used and would be incidental amount in large quantity of product so low risk.	Pre-Requisite Programs - Personal Hygiene Tool and Container Inspection Pallet Control Chemical Control Preventive Maintenance Ingredient Allergen Labeling Training GMP	No	Process Control
	P Paint chips	Medium Minor Discomfort	Low Unlikely to Occur	17 Low				Supply Chain
	C Lubricant from mixer, Allergen-(tree nut Coconut, Almond; mustard oil)from cross contact	Medium Minor Discomfort	Medium Could Occur	13 Moderate				Sanitation Control
	Q Cross contamination dirty sample rod	Low Customer / Consumer Complaint	Medium Could Occur	18 Low				Other Control Allergen Control

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		Severity	Likelihood						
7. Sample / Retain	B	Staph Aureus,	Medium Minor Discomfort	Very Low Practically Impossible	20 Low	Physical hazards are addressed at a later step. The risk concerning the identified hazards is low enough that it does not need to be addressed using a CCP or a Preventive Control. Pre-requisite Programs are in place to mitigate low to moderate risk. Even though the score is low for quality due to the likely severity we feel this is the best opportunity to control the risk by making this a QCCP, if an issue is not identified here it will result in a complaint.	NO	Process control	
	P	Dipstick	Medium Minor Discomfort	Very Low Practically Impossible	23 Low			Supply Chain	
	C	Cross contamination through sampling	Low Customer / Consumer Complaint	Medium Could Occur	18 Low			Sanitation Control	
	Q	Cross contamination dirty sample rod	Low Customer / Consumer Complaint	Medium Could Occur	18 Low			Other Control	
						Pre-Requisite Programs - Allergen Control Pallet Control Glass/Brittle Plastic Control Chemical Control Sanitation GMP Control QUALITY QCCP2- Organoleptic evaluation		Allergen Control	
									QCCP 2

QCCP 2

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		Severity	Likelihood					
8. Package Product / Label	B	Mold, Listeria	Medium Minor Discomfort	Low Unlikely to Occur	<p>17 Low</p> <p>The risk concerning the identified hazards is low enough that it does not need to be addressed using a CCP or a Preventive Control. Pre-requisite Programs are in place to mitigate low to moderate risk.</p> <p>This step is best place to capture which products contain Allergens to ensure they are identified correctly for customer and ensures that vessels and equipment are identified for verification activities to prevent cross contact.</p>	<p>Pre-Requisite Programs -</p> <ul style="list-style-type: none"> GMP Training Glass and Brittle Plastic Control Allergen Control Personal Hygiene Environmental Monitoring Program sanitation program <p>ALLERGEN PC- Verifying batch sheet to label</p>	Yes- PC- 3	Process Control
	P	Gasket, seals, metal, dust, debris	Medium Minor Discomfort	Very Low Practically Impossible				Supply Chain
	C	Allergens(tree nut Coconut, Almond; Mustard Oil)	Medium Minor Discomfort	Medium Could Occur				Sanitation Control
	Q	Cross contamination dirty sample rod	Customer / Consumer Complaint	Medium Could Occur				Other Control
								Allergen Control

PC

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		Severity	Likelihood					
9. Rework	B	None			Product is sealed; no exposure after packaging. Final finished product shipping labels applied to prevent misbranding. Pre-requisite Programs are in place to mitigate low to moderate risk.	Pre-Requisite Programs - GMP Label Control Training Shipping Inspection Allergen Control Rework Control	No	Process Control
	P	Wood pieces from pallet, Metal, spray insulation Medium Minor Discomfort	Very Low Practically Impossible	20 Low				Supply Chain
	C	Allergens (tree nut Coconut, Almond) High Injury / Illness	Low Unlikely to Occur	12 Moderate				Sanitation Control
	Q	Cross contamination organoleptic Customer / Consumer Complaint	Medium Could Occur	18 Low				Other Control Allergen Control

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		Severity	Likelihood					
10. Ship	B	None			Product is sealed; no exposure after packaging. Final finished product shipping labels applied to prevent misbranding.	Pre-Requisite Programs - GMP Label Control Training Shipping Inspection Allergen Control	No	Process Control
	P	None						Supply Chain
	C	none						Sanitation Control
								Other Control
								Allergen Control
	Q	Mislabeled (shipping address); temperature abuse; picking error; documentation	Low Customer / Consumer Complaint	Medium Could Occur	18 Low			