

**PLAN TITLE: Base Blends**

**PLANT LOCATION: South Plainfield NJ**

Review Date 11/10/2021

## 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					
<b>1a. Receiving (Raw Material )</b>	B	Salmonella, Mold Spores,	High Injury / Illness	Low Unlikely to Occur	12 Moderate	<p>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.</p> <p>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.</p>	Yes PC-1	Process Control
	P	Brittle Plastic, Wood, Metal, insects	Medium Minor Discomfort	Very Low Practically Impossible	20 Low			Process Control
	C	Allergens, Pesticides, Radiological; toxic; non food products	Very High Fatality	Very Low Practically Impossible	11 Moderate			Supply Chain <b>PC</b>
	Q	Temperature, Odor, Humidity, mislabeling	Low Customer / Consumer Complaint	Medium Could Occur	18 Low			Sanitation Control
						<p><b>Pre-Requisite Programs -</b>            Personal Hygiene            Pest Control            Allergen Control            Receiving and Inspection            Supplier Approval            GMP Training            Sampling and Testing Program</p> <p><b>QUALITY QCCP1- Organoleptic evaluation</b></p> <p><b>SUPPLY CHAIN PC- Check Vendor CofA for pathogen results on high risk items (based on FDA guidelines and risk assessment)</b></p>		Other Control <b>QCCP 1</b>
								Allergen Control

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			Severity	Likelihood					
<b>1b. Receiving (Temperature Controlled items)</b>	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.	<b>Pre-Requisite Programs -</b> Allergen Control Receiving and Inspection Bulk Receiving SOP Supplier Approval and Management GMP Training Sampling and Testing Program  <b>QUALITY QCCP1- Organoleptic evaluation</b>  <b>SUPPLY CHAIN PC- Check Vendor CofA for pathogen results on high risk items (based on FDA guidelines and risk assessment)</b>	Yes PC-1	Process Control
	P	Brittle Plastic, Wood, Metal, insects	Medium Minor Discomfort	Very Low Practically Impossible	20 Low				Supply Chain <b>PC</b>
	C	Allergens, Pesticides, toxic, non food, Radiological	Very High Fatality	Very Low Practically Impossible	11 Moderate				Sanitation Control
	Q	Temperature, Odor	Low Customer / Consumer Complaint	Medium Could Occur	18 Low				Other Control <b>QCCP 1</b>
<b>1c. Receiving (packaging )</b>	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 that a PC is not required: example- allergen labeling	<b>Pre-Requisite Programs -</b> Personal Hygiene Pest Control Allergen Control Receiving and Inspection Supplier Approval	NO	Allergen Control
	P	Brittle Plastic, Wood, Metal, insects	Medium Minor Discomfort	Very Low Practically Impossible	20 Low				Sanitation Control

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		Severity	Likelihood					
					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	Supplier Approval GMP Training		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	Low Unlikely to Occur	12 Moderate	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 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 - Receiving and Inspection Pest Control Procedure GMP Training  QUALITY QCCP2- 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; non food; toxic	Very High Fatality	Very Low Practically Impossible	11 Moderate				Sanitation Control
								Other Control
								Allergen Control

**QCCP 2**

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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.	<b>Pre-Requisite Programs -</b> 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, soy, milk)	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 - Temperature	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.  <b>Pre-requisite Programs</b> are also in place to mitigate moderate risks.	<b>Pre-Requisite Programs -</b> 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, soy, milk)	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					
<b>4. Weighing / compounding Ingredients/ Re-pack</b>	B	Staph Aureus,	Medium Minor Discomfort	Very Low Practically Impossible	20 Low	<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. Even though the risk is moderate, we believe this is the are where a Preventive control is needed for Sanitation Controls.</p> <p><b>Pre-Requisite Programs -</b> Allergen Control GMP Sanitation Training</p> <p><b>Sanitation PC- Visual Inspection prior to weighing</b></p>	<b>Yes PC 2</b>	Process Control
	P	plastic, metal scoops, jewelry, hair covers,	Medium Minor Discomfort	Very Low Practically Impossible	20 Low			Supply Chain
	C	Allergen-tree nut, Cleaning residue	High Injury / Illness	Medium Could Occur	8 Moderate			Sanitation Control <b>PC</b>
	Q	Sanitation, ,Odor, Scale calibration, mis-compounding	Low Customer / Consumer Complaint	Medium Could Occur	18 Low			Other Control Allergen Control
<b>5. Municipal Water</b>	B	Microbes/Coliforms,	Medium Minor Discomfort	Low Unlikely to Occur	16 Low	<p>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.</p> <p><b>Pre-Requisite Programs</b> Monthly testing by American Water Company Quarterly Water Quality Testing</p>	No	Process Control
	P	None						Supply Chain
	C	Heavy Metals, chlorine	High Injury /	Low Unlikely	12 Moderate			Sanitation 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. <b>Pre-requisite Programs</b> are in place to mitigate low to moderate risk.	<b>Pre-Requisite Programs -</b> Allergen Control Pallet Control Glass/Brittle Plastic Control Chemical Control Sanitation GMP Control  <b>QUALITY QCCP2- Organoleptic evaluation</b>	NO	Process Control	<b>QCCP 2</b>
	P	Plastic from sampling cup, jewelry	Medium Minor Discomfort	Very Low Practically Impossible	23 Low				Supply Chain	
	C	Cross contamination/Contact 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				
						Allergen Control				

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		Severity	Likelihood					
8. Package Product / Label	B	Mold, Listeria	Medium Minor Discomfort	Low Unlikely to Occur	17 Low	<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><b>Pre-Requisite Programs -</b>  GMP Training  Glass and Brittle Plastic Control  Allergen Control  Personal Hygiene  Environmental Monitoring Program  sanitation program</p> <p><b>ALLERGEN PC-</b> Verifying batch sheet to label</p>	<p>Process Control</p> <p>Supply Chain</p> <p>Sanitation Control</p> <p>Other Control</p> <p>Allergen Control</p>
	P	Gasket, seals, metal, dust, debris	Medium Minor Discomfort	Very Low Practically Impossible	20 Low			
	C	Allergen tree nut,	High Injury / Illness	Medium Could Occur	8 Moderate			
	Q	Cross contamination dirty sample rod	Low Customer / Consumer Complaint	Medium Could Occur	18 Low			

**Yes-PC3**

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. <b>Pre-requisite Programs</b> are in place to mitigate low to moderate risk.	<b>Pre-Requisite Programs -</b> 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				Supply Chain
	C	Allergens (tree nut, mustard oil)	High Injury / Illness	Low Unlikely to Occur				Sanitation Control
	Q	Cross contamination organoleptic	Low Customer / Consumer Complaint	Medium Could Occur				Other Control
10. Re-Label / Re-pack	B	Staph Aureus,	Medium Minor Discomfort	Very Low Practically Impossible	Minimal contact with product; Single use item used for sampling and clean metal scoop used for weighing. Label has to be checked for presence of allergen to ensure correct label is adhered.	<b>Pre-Requisite Programs -</b> GMP Label Control Training Shipping Inspection Allergen Control  <b>QUALITY QCCP2- Organoleptic evaluation</b>	NO	Allergen Control
	P	Metal Scoop for weighing, plastic scoop for sampling	Medium Minor Discomfort	Low Unlikely to Occur				Other Control
	C	Mislabeling; Allergen, Tree nut(Coconut, Almond)	Medium Minor Discomfort	Very Low Practically Impossible				Other Control

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			Severity	Likelihood					
	Q	Mislabeling, Shelf life	Low Customer / Consumer Complaint	Medium Could Occur	18 Low				

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			Severity	Likelihood					
11. 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
	Q	Mislabeling(shipping address); temperature abuse; picking error; documentation	Low Customer / Consumer Complaint	Medium Could Occur	18 Low				Allergen Control