

PLAN TITLE: Drymix Process

PLANT LOCATION: Edison, 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					
1a. Receiving (Raw Material)	B Salmonella, 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.	Pre-Requisite Programs - Personal Hygiene Pest Control Allergen Control Receiving and Inspection Supplier Approval 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
	P Brittle Plastic(sampling), Wood, Metal, insects,	Medium Minor Discomfort	Very Low Practically Impossible	20 Low				Supply Chain PC
	C Allergens, Pesticides, Radiological; Toxic, Non food products	Very High Fatality	Very Low Practically Impossible	11 Moderate				Sanitation Control Other Control QCCP 1
	Q Temperature, Odor, Humidity, mislabeling	Low Customer / Consumer Complaint	Medium Could Occur	18 Low				Allergen Control

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		Severity	Likelihood					
1b. Receive 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, no supply chain controls as it is our own product. 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	Very High Fatality	Very Low Practically Impossible	11 Moderate				Sanitation Control
								Other Control
								Allergen Control

QCCP 2

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		Severity	Likelihood					
					product.			
	Q Temperature, Odor, Humidity, mislabeling	Low Customer / Consumer Complaint	Medium Could Occur	18 Low				
1c. Receiving/Store (packaging)	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 is a regulatory requirement for manufacturers so the label verification is part of our PRP. Supplier Approval process addresses radiological concerns, prior to receipt	Pre-Requisite Programs - Personal Hygiene Pest Control Allergen Control Receiving and Inspection Supplier Approval GMP Training	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
	Q Odor, Humidity, wrong packaging, damaged	Low Customer / Consumer Complaint	Medium Could Occur	18 Low				Other Control Allergen Control

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		Severity	Likelihood					
2. 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 , Wood pieces from pallet, Metal/blades	Medium Minor Discomfort	Very Low Practically Impossible	20 Low				Supply Chain
	C Allergens (Soy, Milk, Tree nut)	High Injury / Illness	Very Low Practically Impossible	16 Low				Sanitation Control
	Q Temperature, Odor, Humidity	Low Customer / Consumer Complaint	Medium Could Occur	18 Low				Other Control Allergen Control

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		Severity	Likelihood					
3. Weighing / Staging /Re-packs/ Re-box	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 step where a Preventive control is needed for Sanitation Controls.		Process Control
	P	Zip Ties, plastic, metal scoops, jewelry, metal/blades	Medium Minor Discomfort	Medium Could Occur				Supply Chain
	C	Allergens:Soy, Milk, tree nuts	High Injury / Illness	Medium Could Occur				Sanitation Control
	Q	Sanitation, Odor,Calibration, mis-compounding	Low Customer / Consumer Complaint	Medium Could Occur				Other Control
4. Sifting (if particle size not appropriate)	B	Staph Aureus,	Medium Minor Discomfort	Very Low Practically Impossible	20 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.	Yes PC 2	Allergen Control
	P	vinyl, metal-blades,plastic liner, jewelry , zip tie	Medium Minor Discomfort	Very Low Practically Impossible				Sanitation Control

Pre-Requisite Programs -
Allergen Control
GMP
Sanitation
Training

Sanitation PC- Visual Inspection prior to weighing

PC

Pre-Requisite Programs
Annual testing by American Water Company
Annual testing by Ecolab
Quarterly Water Quality Testing

No

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		Severity	Likelihood					
6. Mixing					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 Pre-op inspection	No	Supply Chain
	P metal, gasket	Medium Minor Discomfort	Low Unlikely to Occur	17 Low				Sanitation Control
	C undeclared soy, Milk, tree nut from cross contact	High Injury / Illness	Medium Could Occur	8 Moderate				Other Control
	Q Cross contamination , environmental odor	Low Customer / Consumer Complaint	Medium Could Occur	18 Low				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.	Pre-Requisite Programs - Allergen Control Pallet Control Glass/Brittle Plastic Control Chemical Control Sanitation GMP Control QUALITY QCCP2- Organoleptic evaluation	NO	Process Control
	P sampling scoop,metal, plastic, paper , jewelry, zip ties	Medium Minor Discomfort	Very Low Practically Impossible	23 Low				Supply Chain
	C product cross cotnamination	Low Customer / Consumer Complaint	Medium Could Occur	18 Low				Sanitation Control
	Q Cross contamintaion off flavor /odor	Low Customer / Consumer Complaint	Medium Could Occur	18 Low				Other Control
								Allergen Control

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>At this stepth is best place to capture which products contain Allergens to ensure they are indentified 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-PC3	Process Control
	P	zip ties, stitching thread, paper,debris	Medium Minor Discomfort	Very Low Practically Impossible				Supply Chain
	C	Allergens:Soy, Milk, tree nuts	High Injury / Illness	Medium Could Occur				Sanitation Control
	Q	Cross contamination , environmental odor	Low Customer / Consumer Complaint	Medium Could Occur				Other Control
								Allergen Control

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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	
								Supply Chain	
	P	Zip Ties, plastic, metal scoops, metal/blades	Medium Minor Discomfort	Very Low Practically Impossible				20 Low	Sanitation Control
	C	Allergens:Soy, Milk, tree nuts	High Injury / Illness	Low Unlikely to Occur				12 Moderate	Other Control
	Q	Odor, Calculation of formula, mis-labeling	Low Customer / Consumer Complaint	Medium Could Occur	18 Low			Allergen Control	
10. Re-label	B	None			Minimal contact with product packaging; Label has to be checked for presence of allergen to ensure correct label is adhered.	Pre-Requisite Programs - GMP Label Control Training Shipping Inspection Allergen Control	NO	Process Control	
								Supply Chain	
	P	None						Sanitation Control	
	C	Mislabelling; Allergen, Milk, Soy	High Injury / Illness	Very Low Practically	16 Low	Allergen Containing ingredients are not re-		Other Control	

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			Severity	Likelihood					
		Tree nut	Impossible	Impossible		packed			Allergen Control
	Q	Mislabeled, 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 Wood, Forklift (puncture), Moisture	Medium Minor Discomfort	Medium Could Occur	13 Moderate				Supply Chain
	C none							Sanitation Control
	Q Temperature abuse; picking error; documentation, Moisture	Low Customer / Consumer Complaint	Medium Could Occur	18 Low				Other Control Allergen Control