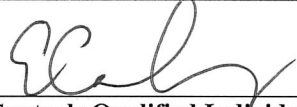


Santa Cruz Nutritionals

Preventive Controls Hazard Analysis

(1)	(2)		(3)	(4)	(5)	(6)	(7)
Ingredient / Processing Step	Potential Food Safety Hazard		Requires Preventive Control	Justification for Decision	Is this step a Critical Control Point (CCP)?	Preventive Control	Is the Preventive Control Applied at this Step?
Raw Material Receiving – Corn Syrup	Biological	Microbiological pathogens	Yes	<p>Possible inadequate or no preventive control at the supplier level for the prevention of pathogen contamination.</p> <p>Refer to “Microbial Testing Statement” white paper located in the justification section. Additionally, microbiological testing is completed on raw materials, on an ongoing basis, per raw material specifications. Preventive Controls are also in place to control the hazard.</p>	No	<p><u>Supply-Chain Control</u>: Have a Qualified status under the SCN Supplier Qualification Program</p> <p><u>Supply-Chain Control</u>: Verification of Supplier COA</p>	Yes
	Chemical	Allergen cross-contamination of ingredient at the supplier level	Yes	There is a possibility of allergen cross-contamination of ingredients at the supplier level if an inadequate allergen control program is in place.	No	<u>Supply-Chain Control</u> : Verification of Supplier’s Allergen Control Program through the Supplier Qualification Program	Yes
	Physical	Foreign Objects	Yes	<p>Physical contaminants such as metal objects may pose a potential problem when not addressed.</p> <p>cGMP, and use of in-line finger magnets and in-line basket strainers are used to remove foreign material. Preventive Control is also in place to control the hazard.</p>	No	<u>Process Control</u> : Subsequent metal detection	No



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(1)	(2)		(3)	(4)	(5)	(6)	(7)
Ingredient / Processing Step	Potential Food Safety Hazard		Requires Preventive Control	Justification for Decision	Is this step a Critical Control Point (CCP)?	Preventive Control	Is the Preventive Control Applied at this Step?
Raw Material – Bulk Sugar	Biological	None Identified					
	Chemical	Allergen cross-contamination of ingredient at the supplier level	Yes	There is a possibility of allergen cross-contamination of ingredients at the supplier level if an inadequate allergen control program is in place.	No	<u>Supply-Chain Control:</u> Verification of Supplier's Allergen Control Program through the Supplier Qualification Program	Yes
	Physical	Foreign Objects	Yes	Physical contaminants such as metal objects may pose a potential problem when not addressed. cGMP, and use of in-line finger magnets and in-line basket strainers are used to remove foreign material. Preventive Control is also in place to control the hazard.	No	<u>Process Control:</u> Subsequent metal detection	No


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(1)	(2)		(3)	(4)	(5)	(6)	(7)
Ingredient / Processing Step	Potential Food Safety Hazard		Requires Preventive Control	Justification for Decision	Is this step a Critical Control Point (CCP)?	Preventive Control	Is the Preventive Control Applied at this Step?
Raw Material Receiving – Into Warehouse	Biological	Microbiological pathogens	Yes	<p>Possible inadequate or no preventive control at the supplier level for the prevention of pathogen contamination.</p> <p>Improper handling of product may potentially cause microbial contamination.</p> <p>Refer to “Microbial Testing Statement” white paper located in the justification section. Additionally, microbiological testing is completed on raw materials, on an ongoing basis, per raw material specifications. Preventive Controls are also in place to control the hazard.</p>	No	<p><u>Supply-Chain Control</u>: Have a Qualified status under the SCN Supplier Qualification Program.</p> <p><u>Supply-Chain Control</u>: Verification of COA</p>	Yes
	Chemical	Allergen cross-contamination of ingredient at the supplier level	Yes	There is a possibility of allergen cross-contamination of ingredients at the supplier level if an inadequate allergen control program is in place.	No	<u>Supply-Chain Control</u> : Verification of Supplier’s Allergen Control Program through the Supplier Qualification Program	Yes
	Physical	Foreign Objects	Yes	<p>Physical contaminants such as metal objects may pose a potential problem when not addressed.</p> <p>cGMP, and use of in-line finger magnets and in-line basket strainers are used to remove foreign material. Preventive Control is also in place to control the hazard.</p>	No	<u>Process Control</u> : Subsequent metal detection	No

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Ingredient / Processing Step	Potential Food Safety Hazard	Requires Preventive Control	Justification for Decision	Is this step a Critical Control Point (CCP)?	Preventive Control	Is the Preventive Control Applied at this Step?
Raw Material – Water	Biological	No	Annual city water report, as well as weekly and monthly water testing is completed.			
	Microbiological pathogens (Water received from an un-potable source or un-validated source may lead to pathogen contamination)					
	Chemical					
	None Identified					
	Physical					
	None Identified					
	Biological					
Warehouse	Chemical					
	None Identified					

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(1)	(2)	(3)	(4)	(5)	(6)	(7)
Ingredient / Processing Step	Potential Food Safety Hazard	Requires Preventive Control	Justification for Decision	Is this step a Critical Control Point (CCP)?	Preventive Control	Is the Preventive Control Applied at this Step?
Warehouse	Physical	Yes	Improper use of equipment (such as fork lifts) and improper handling (pallets, containers) may introduce foreign objects. Good housekeeping practices are followed in the raw material storage area to minimize opportunity for contamination with potential foreign objects. Preventive Control is also in place to control the hazard.	No	Process Control: Subsequent metal detection	No
Starch	Biological	No	Refer to "Microbial Testing Statement" white paper located in justification section. Additionally, microbiological testing is completed on starch on an ongoing basis.			
	Chemical	None Identified				
	Physical	Foreign Objects	Physical contaminants such as metal objects may pose a potential problem when not addressed.	No	Process Control: Subsequent metal detection	No
		Yes	Starch travels through 3 screens: 3-SCRN03190, 30 mesh screen 3-600/51 TYPE "B" to remove foreign material. Preventive Control is also in place to control the hazard.			

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(1)	(2)	(3)	(4)	(5)	(6)	(7)
Ingredient / Processing Step	Potential Food Safety Hazard	Requires Preventive Control	Justification for Decision	Is this step a Critical Control Point (CCP)?	Preventive Control	Is the Preventive Control Applied at this Step?
Staging Lower Kitchen	Biological	None Identified				
	Chemical	Potential for cross-contamination of ingredients	No	Products that are staged for use in the lower kitchen are stored in sealed containers, off of the floor.		
	Physical	Foreign Objects	Yes	Physical contaminants such as metal objects may pose a potential problem when not addressed. During the process, there are in-line finger magnet and in-line basket strainers to remove foreign material. Preventive Control is also in place to control the hazard.	Process Control: Subsequent metal detection	No

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Ingredient / Processing Step	Potential Food Safety Hazard	Requires Preventive Control	Justification for Decision	Is this step a Critical Control Point (CCP)?	Preventive Control	Is the Preventive Control Applied at this Step?
Processing Lower Kitchen	Microbiological pathogens	Yes	There is a potential for microbial contamination via handling and the environment. Refer to "Microbial Testing Statement" white paper justification section. There is also subsequent ongoing finished product testing. Preventive Control is also in place to control the hazard.	No	Sanitation Control: GMP and Sanitation Controls	Yes
	Food Grade Lubricant	Yes	Food-grade lubricant is utilized on the equipment in LK processing.	No	Other Control: Regularly scheduled preventive maintenance programs are used to prevent the likelihood of chemical contamination from equipment used in the manufacturing process.	Yes
	Chemical	No	Products that are staged for use in the lower kitchen are stored in sealed containers, off of the floor.			
	There is a potential for incorrect supplement to be added during processing.	No				
	Physical	Yes	Physical contaminants such as metal objects may pose a potential problem when not addressed.	No	Process Control: Subsequent metal detection	No
	Foreign Objects					

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Ingredient / Processing Step	Potential Food Safety Hazard	Requires Preventive Control	Justification for Decision	Is this step a Critical Control Point (CCP)?	Preventive Control	Is the Preventive Control Applied at this Step?
Mogul Depositing	Biological	None Identified				
	Chemical	None Identified				
	Physical	Yes	Improperly maintained equipment may lead to foreign object contamination.			
			Starch is cycled through an AZO screen, a starch sifting screen, and passes over three magnets during conditioning. Preventive Control is also in place to control the hazard.	No	Process Control: Subsequent metal detection	No
Mogul Discharge Process	Biological	None Identified				
	Chemical	None Identified				

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Ingredient / Processing Step	Potential Food Safety Hazard	Requires Preventive Control	Justification for Decision	Is this step a Critical Control Point (CCP)?	Preventive Control	Is the Preventive Control Applied at this Step?
Mogul Discharge Process	Foreign Objects	Yes	Improperly maintained equipment may introduce foreign objects. Metal from LK/UK process may be introduced into the product stream.	No	<u>Process Control</u> : Subsequent metal detection <u>Other Control</u> : Regularly scheduled Preventive Maintenance programs are used to prevent the likelihood of foreign object contamination from equipment used in the manufacturing process.	No
	Physical					Yes
	Biological	None Identified				
	Chemical	None Identified				
Temco Discharge Process	Foreign Objects		Improperly maintained equipment may lead to foreign object contamination.		<u>Process Control</u> : Subsequent metal detection	
	Physical	Yes	In-line strainer baskets and finger magnets are in place. Preventive Control is also in place to control the hazard.	No		No

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Ingredient / Processing Step	Potential Food Safety Hazard	Requires Preventive Control	Justification for Decision	Is this step a Critical Control Point (CCP)?	Preventive Control	Is the Preventive Control Applied at this Step?
Curing Room	Biological	No	Refer to "Microbial Testing Statement" white paper located in justification section. Finished product testing completed to validate the presence of yeast and mold. Cure time/temps are product specific.			
	Chemical	None Identified				
	Physical	None Identified				
Dry Room	Microbiological pathogens		Inappropriate handling of the product after drying may potentially contaminate the product with pathogens.		Sanitation Control: GMP and Sanitation Controls	
	Biological	Yes	Employees handling product directly are required to wear clean gloves. Employees wear clean outer garments when working in food contact areas. Temperature and humidity of dry rooms are monitored. Preventive Control is also in place to control the hazard.	No		Yes

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(1)	(2)		(3)	(4)	(5)	(6)	(7)
Ingredient / Processing Step	Potential Food Safety Hazard		Requires Preventive Control	Justification for Decision	Is this step a Critical Control Point (CCP)?	Preventive Control	Is the Preventive Control Applied at this Step?
Dry Room	Chemical	None Identified					
	Physical	Foreign Objects	Yes	Inappropriate handling of the product after dry may potentially become contaminated with foreign material.	No	Process Control: Subsequent metal detection	No
Starch Reclaim		Microbiological pathogens	No	Inappropriate handling of the starch may potentially contaminate the starch with pathogens. Refer to "Microbial Testing Statement" white paper located in justification section. Ongoing microbial testing completed on starch.			
	Biological						
	Chemical	None Identified					
	Physical	Foreign Objects	Yes	Inappropriate handling of the starch may potentially contaminate the starch with foreign material. Starch travels through 3 screens: 3-SCRN-03190, 30 mesh screen 3-600/51 TYPE "B" to remove foreign material. Preventive Control is also in place to control the hazard.	No	Process Control: Subsequent metal detection	No

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Ingredient / Processing Step	Potential Food Safety Hazard	Requires Preventive Control	Justification for Decision	Is this step a Critical Control Point (CCP)?	Preventive Control	Is the Preventive Control Applied at this Step?
Packing – TNAs, Flow Wrapper, Lee Line, Hand Table, ABL, Bottling Line	Microbiological pathogens	Yes	Inappropriate handling of the product after drying may potentially contaminate the product with pathogens. Employees handling the product directly, are required to wear clean gloves. Employees wear clean outer garments when working in a food contact area. Preventive Control is also in place to control the hazard.	No	Sanitation Control: GMP and Sanitation Controls	Yes
	Chemical	None Identified				
	Physical	Foreign Objects	Improperly maintained equipment may introduce foreign objects. There is a possibility of metal from all other points in the process.	Yes	Process Control: Metal detection at packing phase. Metal detectors are challenged with 3 standards: 2.0mm FE, 2.5mm Non-FE, and 3.0mm SS.	Yes

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Ingredient / Processing Step	Potential Food Safety Hazard	Requires Preventive Control	Justification for Decision	Is this step a Critical Control Point (CCP)?	Preventive Control	Is the Preventive Control Applied at this Step?
Packaging	Biological	None Identified				
	Chemical	Contaminated packaging materials	Use of packaging materials, ink or dyes, manufactured from unapproved chemicals has the potential to contaminate product.	No	Supply-Chain Control: Have a Qualified status under the SCN Supplier Qualification Program. A letter of guarantee is obtained from the supplier or manufacturer of the packaging materials.	No
	Physical	None Identified				

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(1)	(2)	(3)	(4)	(5)	(6)	(7)
Ingredient / Processing Step	Potential Food Safety Hazard	Requires Preventive Control	Justification for Decision	Is this step a Critical Control Point (CCP)?	Preventive Control	Is the Preventive Control Applied at this Step?
Rework	Microbiological pathogens	Yes	Inappropriate handling of the product after drying may potentially contaminate the product with pathogens.	No	Sanitation Control: GMP and Sanitation Controls	Yes
	Biological	Yes	Employees handling the product directly, are required to wear clean gloves. Employees wear clean outer garments when working in a food contact area. Preventive Control is also in place to control the hazard.	No		
	Chemical	None Identified				
	Physical	Foreign Objects	Inappropriate handling of the product after drying may potentially contaminate the product with foreign material.	No	Process Control: Subsequent metal detection	No

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