



 **FSSC 22000**

AUDIT REPORT

1 ORGANIZATION DETAILS

1.1 ORGANIZATION PROFILE

Registered legal name	M&M Industries
Legal or official company registration number	-
Location/Address	4739 W. Jefferson St, 85043, Phoenix, United States
Contact person	Terry Iker
General description of audited organization	M&M Industries is a company dedicated to the manufacture of plastic pails and handles. It has injection and molding processes for products that serve as primary packaging for the food industry. It is located in the city of Phoenix, AZ. He obtained his FSSC 22000 V 5.0 certification in 2020, for this occasion he carried out his Surveillance 1 audit and the Upgrade to version 5.1 of FSSC 22000.
Significant changes since the previous audit	New injection equipment was installed. It was corroborated on the floor and it was observed operating.
Seasonal activities	N/A

1.2 HEAD OFFICE (WHERE APPLICABLE)

Registered legal name	
Location/Address	
Date and duration of head office audit	
Number of sites	
Overview of Head office functions	

1.3 OFF-SITE ACTIVITIES (WHERE APPLICABLE)

Site name	Location/Address	Date and duration of off-site activity audit/s	Activities at location

1.4 MULTI-SITES (WHERE APPLICABLE)

Registered legal name of the Group				
Legal or official company registration number				
Location/Address				
Date and duration of Central Functions audit	-			
Overview of Central Functions				
Number of sites in the group				
List of sites included, with addresses, date/s of audit and activity (scope)	Name	Address	Audit date	Activity (Scope)
			-	

AUDIT DETAILS

CB Name and office location	AIBI International 1213 Bakers way PO Box 3999, KS 66505- 3999, Manhattan, United States
Audit language	English
Audit objectives	<p>a) Determination of the conformity of the plant management system, or parts of it, with audit criteria;</p> <p>b) Evaluation of the ability of the management system to ensure the client organization meets applicable statutory, regulatory and contractual requirements;</p> <p>NOTE: A management system certification audit is not a legal compliance audit.</p> <p>c) Determination of the effectiveness of the management system to ensure the client organization can reasonably expect to meeting its specified objectives;</p> <p>d) As applicable, identification of areas for potential improvement of the management system.</p>
Audit criteria	FSSC 22000 V 5.1 (ISO22000:2018; ISO/TS22002-4:2013; FSSC 22000 Additional Requirements)
Audit type	Surveillance audit
Announced/Unannounced	Unannounced
Audit complexity	Standalone FSSC NONE
Audit delivery	Onsite
Audit dates	Onsite: 2022/05/26- 2022/05/27 Remote:-
Audit Duration (hours)	16
Deviation from audit duration	NONE
Addendums included as part of the audit	None

2.1 AUDIT SCOPE

Food chain sub-category	I
Scope statement	Manufacture of injection molding plastic pails and lids for the food industry.
Exclusions (when appropriate, including justification)	None
Verification of the scope	Yes

2.2 AUDIT PROGRAM AND PLAN

Deviation from audit program	None
Deviation from audit plan	None
ICT audit approach used due to a serious event	N/A
Serious event justification	N/A
Serious event justification explanation	N/A

2.3 AUDIT TEAM

Name	Function	Audit delivery method	Date(s)	Time
Fausto Ureña Montoya	Lead auditor	Onsite	2022/05/26	8 hours and 0 minutes
		Onsite	2022/05/27	8 hours and 0 minutes

2.4 PREVIOUS AUDIT

2.4.1 AUDIT DETAILS PREVIOUS AUDIT

Audit type	Surveillance audit
Announced / Unannounced	Announced
Audit date/s	2021/08/12
CB conducting previous audit if different to current CB	AIBI International
Actions taken on NCs raised at previous audit	Verification of the CAPA from the previous audit

AUDIT RESULTS

3.1 EXECUTIVE SUMMARY

Audit summary	<p>The UA Surveillance 2 audit was carried out considering the originally planned times 2 days on site were conducted. All the requirements included in the audit plan could be reviewed. The objective of the audit was met and as a result the organization's recertification proceeds once the non-conformities detected have been answered. It was verified that the internal audit process was carried out correctly and according to its procedure. The management review was conducted with the QA Manager, Plan Manager, QA Director considering all the elements of the ISO 22000:2018 standard. The corrective action process is carried out according to its procedure and in compliance with the ISO 22000: 2018 standard. As positive aspects, the controls that are in place for the entry and control of visitors are stated. Likewise, the commitment of the staff and knowledge regarding their applicable procedures was shown. During the tour, it was possible to talk with different people from operational areas to corroborate knowledge of the management system and how they carry out their operational activities. A tour was made of all the operational areas of the company. The plant was found in order. The system is effective, all the requirements of the standard are followed. The documentation is complete and simple. Applicable prerequisite programs based on ISO / TS 22002-1: 2009 and additional requirements of FSSC 22000 V. 5.1 were implemented and maintained. 1 minor non-conformity was raised that are described below: mNC1- Based on the requirement 4.2.6 Storage of ISO / TS 22002-4 which establishes that "All raw materials, intermediate products, chemicals and food packaging shall be stored in a manner to minimize the potential for contamination and with sufficient distance from the walls to allow inspection", a PP 25 Melt raw material was found open at the top (exposed to the environment).</p>
Confirmation that audit objectives have been fulfilled	Yes
Unresolved issues	N/A

3.2 SUMMARY OF AUDIT FINDINGS

# Critical nonconformities	0
# Major nonconformities	0
# Minor nonconformities	1

3.3 NONCONFORMITIES

CRITICAL NONCONFORMITIES

#	Requirement Reference (std., clause)	NC statement (incl objective evidence)	Root Cause Analysis (determine why it arose)	Corrective Action Plan (action to prevent repeat; person responsible, due date for completion)	Correction (to address the immediate issue)	Acceptance of correction, CAP and evidence (auditor and date)
1			Completed by client	Completed by client	Completed by client	
	Date of suspension: DD/MM/YYYY					
Follow-up Audit						
	Date of follow-up audit: DD/MM/YYYY					
	Objective Evidence reviewed to close out the NC: Provide detail of evidence reviewed to address and close out the NC					
	Result of Follow-up audit:			Lift suspension and reinstate certificate/withdraw certificate		

MAJOR NONCONFORMITIES

#	Requirement Reference (std., clause)	NC statement (incl objective evidence)	Root Cause Analysis (determine why it arose)	Corrective Action Plan (action to prevent repeat; person responsible; due date for completion)	Correction (to address the immediate issue)	Objective Evidence Reviewed (to close out the NC)	Acceptance of correction, CAP and evidence (auditor and date)
1			Completed by client	Completed by client	Completed by client	Indicate evidence reviewed to close the NC i.e. document name and number	
	Onsite close out:	Yes/No		Follow-up onsite audit date (where applicable)		DD/MM/YYYY	

MINOR NONCONFORMITIES

#	Requirement Reference (std., clause)	NC statement (incl objective evidence)	Root Cause Analysis (determine why it arose)	Corrective Action Plan (action to prevent repeat; person responsible; due date for completion)	Correction (to address the immediate issue)	Objective Evidence Reviewed (relating to the correction)	Acceptance of correction and CAP (auditor and date)
1	ISO/TS 22002-4:2013 - Food Packaging Manufacturing 4.2.6	Based on the requirement 4.2.6 Storage of ISO / TS 22002-4 which establishes that "All raw materials, intermediate products, chemicals and food packaging shall be stored in a manner to minimize the potential for contamination and with sufficient distance from the walls to allow inspection", a PP 25 Melt raw material was found open at the top (exposed to the environment).	Completed by client	Completed by client	Completed by client	Indicate evidence reviewed for the correction i.e. document name and number	Fausto Urena Montoya, Tuesday, June 21, 2022

3.4 AUDIT RECOMMENDATION

Recommendation	Certification maintained
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3.5 AUDIT DURATION

<i>On-site audit time calculation – refer Table B.1 in ISO/TS22003: 2013 and V5 Part 4, clause 4.3</i>				
D	H	MS	FTE	FSSC additional
1.0	0.0	0.25	0.5	0.5
Audit duration calculation (hours)		16		
Audit time reduction		No		
Audit duration ISO 9001		N/A		
Combined FSMS and QMS time (refer IAF MD11)		N/A		
Existing Management system certification in place		Yes/No – if yes specify		
Number of HACCP studies (linked to product groups)		1		
Number of employees (FTEs)		80		
Number of shifts		3		
Description of activities per shift if different from main shift		NA		
Employees per main shift (FTE)		36		

CHECKLISTS

ISO 22000:2018 - FOOD SAFETY MANAGEMENT SYSTEMS

Clause	Requirement	Grade (Yes / No)	Conform (Minor / Major / Critical)	if No – detail	NC#
4	Context of the organization				
4.1	Understanding the organization and its context	Yes			
4.2	Understanding the needs and expectations of interested parties	Yes			
4.3	Determining the scope of the food safety management system	Yes			
4.4	Food safety management system	Yes			
<p>Summary: Understanding the organization and its context Internal and external issues that impact the organization are included in the Risk assessment document. Some elements considered were Industry (market) changes, emergencies and incidents, government regulations, customer supply, customer loss, manpower, disruption to supply chain, financial. Additionally, a business risk assessment SWOT Analysis is carried out on April 12, 2022. Some examples of threats al labor shortage, resin supply, gas prices, gasket supply, cash, interest rates. Opportunities detected were research alternative vendors, additional facility, expanded product line, recycle, more automation, resin technology, additives, partnering with PCR group, reputation. Understanding the needs and expectations of interested parties The Quality Manual section 4.2 describes the needs and expectations of interested parties. The stakeholders contemplated are: External providers (suppliers), Finance, IT, Sales, Production / Manufacturing, Customers, Distributors, Contractors / Consultants, HR, Marketing, Product management, Community. All the needs and expectations of each interested party are identified. Determining the scope of the food safety management system The scope of the FSMS is included in FSSC 22000 and Quality Manual “Manufacture of injection molding plastic pails and lids for the food industry”. Food safety management system Legal requirements applicable to the company were identified. AS an example, a letter referring 49 CFR178.503. In this letter explain that in addition to the making of packaging under the mentioned section, the following conditions must be met: For packaging manufactured at other locations, a separate M number is required for identification purposes, notify this office of any change in facility name, address, ownership, management, equipment, or testing personnel within twenty days of the change. The FSMS has been planned by creating different documents associated with the requirements of ISO 22000: 2018, ISO / TS 22002-1: 2013 and Additional Requirements of FSSC 22000 V 5.1.</p>					

Clause	Requirement	Grade (Yes / No)	Conform (Minor / Major / Critical)	if No – detail	NC#
5	Leadership				
5.1	Leadership and commitment	Yes			
5.2	Policy	Yes			
5.2.1	Establishing the food safety policy	Yes			

5.2.2	Communicating the food safety policy	Yes			
5.3	Organizational roles, responsibilities and authorities	Yes			
5.3.1	Top management shall ensure that responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization	Yes			
5.3.2	The food safety team leader shall be responsible for: a) - d)	Yes			
5.3.3	All persons shall have responsibility to report problem(s) with regards to the FSMS to identified person(s)	Yes			

Summary: Leadership and commitment There is a management team that follows up on all resource needs, as well as actively participates in FSMS activities. The Director of Quality is kept informed through the auditing agency representing FSSC 22000, FDA, and local agencies of relevant legislative requirements. The plant manager will ensure that all aspects of the FSMS are being maintained. Policy There is a documented food safety policy, which is disseminated to the staff through visual aids, banners, meetings, and emails. Every Thursday a diffusion with the staff is carried out in which emphasis is placed on Food Safety culture, and the way in which it is achieved through daily activities. In these meetings, awareness of the elements of Food Safety that the staff must observe is carried out. Trainings have been carried out to promote the culture of food safety, supported with visual aids throughout the areas. Organizational roles, responsibilities, and authorities Organization chart is included in HACCP Plan 2022. Job descriptions are available. The job description of the Production operator is revised. GMP training provided, presentation shown. A slide is shown with guidelines such as Washing hands after using rest rooms and eating, hair protection an beard nets, No jewelry when working on the production floor although wedding band allowed, no eating, chewing gum on the production floor, no loose objects in shirts that can fall into pails, no personal belongings at the workstation, no personal belongings at the workstation, reporting common illnesses to supervisors (colds / flu), no false eyelashes - gloves must be worn over fake nails”.

Clause	Requirement	Grade (Yes / No)	Conform (Minor / Major / Critical)	if No – detail	NC#
6	Planning				
6.1	Actions to address risks and opportunities	Yes			
6.1.1	When planning for the FSMS, the organization shall consider the issues referred to in 4.1 and the requirements in 4.2 and 4.3 and determine the risks and opportunities that need to be addressed to: a) - d)	Yes			
6.1.2	The organization shall plan: a) - b)	Yes			
6.1.3	The actions taken by the organization to address risks and opportunities shall be proportionate to: a) - c)	Yes			
6.2	Objectives of the food safety management system and planning to achieve them	Yes			

6.2.1	The organization shall establish objectives for the FSMS at relevant functions and levels. The objectives of the FSMS shall: a) - f)	Yes			
6.2.2	When planning how to achieve its objectives for the FSMS, the organization shall determine: a) - e)	Yes			
6.3	Planning of changes	Yes			

Summary: Actions to address risks and opportunities Business risk assessment SWOT Analysis is carried out on April 12, 2022. Some examples of threats al labor shortage, resin supply, gas prices, gasket supply, cash, interest rates. Opportunities detected were research alternative vendors, additional facility, expanded product line, recycle, more automation, resin technology, additives, partnering with PCR group, reputation. Objectives of the food safety management system and planning to achieve them The 2022 goals for the FSMS are: 15 % decrease in corrective action companywide from 0.19 to 0.16 currently at 0.14. Complete 100% of internal corrective actions 40 % current. Complete 3 gage R&R testing trials (first one in process now for melt index) – 1 complete Finish product data spec sheets for all products (almost complete for website) – 95 % complete Complete electronic system for all print and HTL job spec sheets – Rolling out in AZ current. Continue to enhance Quiz data reporting to include component testing – Working on process control charting first meeting held 04/11/2022, will work on press 12 & 14 @ E14 for part wt. Planning of changes There is a management team that follows up on all the modifications that are made, taking care that other processes are not affected. And if changes or updates to documents are needed, or training depending on the changes. All changes are managed through the quality area and the FSMS, in order to evaluate that they do not have an impact on other processes, and the corresponding documentation is updated.

Clause	Requirement	Grade (Yes / No)	Conform (Minor / Major / Critical)	if No – detail	NC#
7	Support				
7.1	Resources	Yes			
7.1.1	General	Yes			
7.1.2	People	Yes			
7.1.3	Infrastructure	Yes			
7.1.4	Work environment	Yes			
7.1.5	Externally developed elements of the FSMS	Yes			
7.1.6	Control of externally provided processes, products or services	Yes			
7.2	Competence	Yes			
7.3	Awareness	Yes			
7.4	Communication	Yes			

7.4.1	General	Yes			
7.4.2	External communication	Yes			
7.4.3	Internal communication	Yes			
7.5	Documented information	Yes			
7.5.1	General	Yes			
7.5.2	Creating and updating	Yes			
7.5.3	Control of documented information	Yes			
7.5.3.1	Documented information required by the FSMS and by this document shall be controlled to ensure: a) - b)	Yes			
7.5.3.2	For the control of documented information, the organization shall address the following activities as applicable: a) - d)	Yes			

Summary: Resources There are support areas for resource management, such as administration, purchasing and maintenance. The facilities are observed in excellent condition, as well as the warehouse and operation areas. Adequate infrastructure is observed. There is enough personnel to carry out the operations, it is mentioned that due to the pandemic there was an area of opportunity with the number of personnel, but that it has currently been regularized. Regarding the work environment, adequate working conditions are observed. Sufficient ventilation, sufficient lighting, as well as adequate workspaces. Competence The records of the HACCP Online course (23-May-2022) of George Santiago and Lourdes Ortega are reviewed. Trainings for allergens were carried out through GMP's training, and these are evaluated through an exam (an example is shown). The records of said trainings are shown. There is a training program for staff. For each job position there is a training matrix that includes all the topics related to their operational activities. Awareness Meetings are held on a weekly basis where topics such as complaints, or special events that are going to happen are addressed. Likewise, there is a QC Board, where all the information corresponding to situations that impact quality and safety is posted. Quality Alerts are even generated that involve activities that, in case something goes wrong, are shown on said boards so that they know what should be done. Communication There are blackboards showing the characteristics of the processes and there are visual aids that include samples of the products being processed and, if necessary, specific instructions (e.g., no holder). There are weekly meetings to review matters related to the operation as well as the FSMS, which are used to communicate any eventuality that may arise. Documented information There is a document control procedure that establishes the controls to adequately identify the documents involved for the quality and food safety management systems. The documents are reviewed and approved for release and use in the areas. There is a control of the registers that are filled as a result of the execution of the activities of the different areas. The records that were required throughout the audit were shown, and were requested from the corresponding areas.

Clause	Requirement	Grade (Yes / No)	Conform (Minor / Major / Critical)	if No – detail	NC#
8	Operation				
8.1	Operational planning and control	Yes			

8.2	Prerequisite programmes (PRPs)	Yes			
8.2.1	The organization shall establish, implement, maintain and update PRPs to facilitate the prevention and/or reduction of contaminants (incl food safety hazards) in the products, product processing and work environment	Yes			
8.2.2	The PRPs shall be: a) - d)	Yes			
8.2.3	When selecting and/or establishing PRPs, the organization shall ensure that applicable statutory, regulatory and mutually agreed customer requirements are identified. The organization should consider: a) - b)	Yes			
8.2.4	When establishing PRPs the organization shall consider: a) - l)	Yes			
8.3	Traceability system	Yes			
8.4	Emergency preparedness and response	Yes			
8.4.1	General	Yes			
8.4.2	Handling of emergencies and incidents	Yes			
8.5	Hazard control	Yes			
8.5.1	Preliminary steps to enable hazard analysis	Yes			
8.5.1.1	General	Yes			
8.5.1.2	Characteristics of raw materials, ingredients and product contact materials	Yes			
8.5.1.3	Characteristics of end products	Yes			
8.5.1.4	Intended use	Yes			
8.5.1.5	Flow diagrams and description of processes	Yes			
8.5.1.5.1	Preparation of the flow diagrams	Yes			
8.5.1.5.2	On-site confirmation of the flow diagrams	Yes			
8.5.1.5.3	Description of processes and process environment	Yes			

8.5.2	Hazard analysis	Yes			
8.5.2.1	General	Yes			
8.5.2.2	Hazard identification and determination of acceptable levels	Yes			
8.5.2.2.1	The organization shall identify and document all food safety hazards that are reasonably expected to occur in relation to the type of product, type of process and process environment. The identification shall be based on: a) - e)	Yes			
8.5.2.2.2	The organization shall identify step(s) (e.g. receiving raw materials, processing, distribution and delivery) at which each food safety hazard can be present, be introduced, increase or persist. When identifying hazards the organization shall consider: a) - c)	Yes			
8.5.2.2.3	The organization shall determine the acceptable level in the end product of each food safety hazard identified, whenever possible. When determining acceptable levels, the organization shall: a) - c)	Yes			
8.5.2.3	Hazard assessment	Yes			
8.5.2.4	Selection and categorization of control measure(s)	Yes			
8.5.2.4.1	Based on the hazard assessment, the organization shall select an appropriate control measure or combination of control measures that will be capable of preventing or reducing the identified significant food safety hazard to defined acceptable levels	Yes			
8.5.2.4.2	In addition, for each control measure, the systematic approach shall include an assessment of the feasibility of: a) - c)	Yes			
8.5.3	Validation of control measure(s) and combination of control measures	Yes			
8.5.4	Hazard control plan (HACCP/OPRP plan)	Yes			
8.5.4.1	General	Yes			
8.5.4.2	Determination of critical limits and action criteria	Yes			

8.5.4.3	Monitoring systems at CCPs and for OPRPs	Yes			
8.5.4.4	Actions when critical limits or action criteria are not met	Yes			
8.5.4.5	Implementation of the hazard control plan	Yes			
8.6	Updating the information specifying the PRPs and the hazard control plan	Yes			
8.7	Control of monitoring and measuring	Yes			
8.8	Verification related to PRPs and the hazard control plan	Yes			
8.8.1	Verification	Yes			
8.8.2	Analysis of results of verification activities	Yes			
8.9	Control of product and process nonconformities	Yes			
8.9.1	General	Yes			
8.9.2	Corrections	Yes			
8.9.2.1	The organization shall ensure that when critical limits at CCPs and/or action criteria for OPRPs are not met, the products affected are identified and controlled with regard to their use and release	Yes			
8.9.2.2	When critical limits at CCPs are not met, affected products shall be identified and handled as potentially unsafe products (see 8.9.4)	Yes			
8.9.2.3	Where action criteria for an OPRP are not met, the following shall be carried out: a) - c)	Yes			
8.9.2.4	Documented information shall be retained to describe corrections made on nonconforming products and processes, including a) - c)	Yes			
8.9.3	Corrective actions	Yes			
8.9.4	Handling of potentially unsafe products	Yes			
8.9.4.1	General	Yes			
8.9.4.2	Evaluation for release	Yes			

8.9.4.3	Disposition of nonconforming products	Yes			
8.9.5	Withdrawal/recall	Yes			

Summary: Operational planning and control Se cuenta con un programa de producción el cual incluye product description, cust name, W/O, SKU #, MOLD #, Total, Stack, Pallet qty, Color AR#, Resin #, PKG, Pallet Size, Special Instructions. Prerequisite programmes (PRPs) See ISO/TS 22002-4 check list of this document. Traceability system Traceability exercises are carried out once a year in January. The last traceability exercise (including the mock recall), was carried out on January 5, 2022 for the product 500630 5.0 M4 WH C/W PAIL, and date of manufacture July 23, 2021. The time that the exercise took was 45 minutes. 100% of the product involved was identified. During audit the following traceability exercise was carried out: Product Name 3.5 LL WH Pail Line produced on Line 6 (A00603308) Product shelf life 3 years A letter of shelf life of HDPE and PP containers for customers that explain that shelf life will vary depending upon storage conditions. Product Reference Number 500155 Date of Manufacture / Code 2022-03-10 Work order 0075369 Pack Date / Code 2022-04-06 Order # 063756 Total batches produced 2,743 pieces Total expected units – (line loss) 2,743 pieces Total units packaged 13 full pallet (2,652 pieces) Recipe Information / batching SOP Resin, color, cardboard tray, plastic handle, label and pallet. Label declaration A label is generated for the finished product that is placed on the product pallet which contains the following information: Product description, Item #, Machine number, Resin used, Mold used, Inspection carried out by, Production date and time, Facility, Customer item, Quantity, License of product. Label verification There is an operational supervisor who is the one who checks that the information on the label is correct for its use. Product description requirements/ COA A COA is generated for the finished product it contains. 1st Ingredient Resin 08452N-6 Melt. Approved supplier DOW Chemical Company There is an approved vendor list where the vendor was listed on 2017-10-19. Receiving Records trailer inspection and amount received It was received on March 1, 2022. COA / COC Certified of analysis – Polyethylene 08452N High Density Order number 113489508 – 188900.00 lbs Date shipped 2022-02-18 Shipment 40448135 Manufacturing date 2022-02-13 Melt index and density. 1st packaging material Cardboard tray Approved supplier Cactus container – There is an approved vendor list where the vendor was listed on 2016-06-01. Receiving Records trailer inspection and amount received The receiving order tally report records for March 4, 2022 are displayed. COA / COC Currently no COA is received for this type of material, the material reception area checks that the materials come in clean and correct operating conditions. Out bound finished product trailer inspection and amount shipped There is a packing slip of the shipped product. This one shipped on May 26, 2022. When the product is shipped, a photograph is taken of the conditions in which it was shipped, the photograph of the product shipped on May 26, 2022 is reviewed. COA / COC for finished product A certificate of compliance of the finished product is generated. This includes parameters such as functionality of all components, Quality of appearance, Special packaging instructions followed, and palletization. There is an inspection instruction (WI-10-20) which includes the inspections carried out on the finished product Quality Checks: Visual (color, cosmetic defects, gate cosmetics, date clocks), performance (stack, lid fit, handle hole, breakage), dimensional (CMM, manual, weight, acceptance criteria). Specification, Allergen Data, GMO statements for finished product There are no allergens. There is no GMO, and the finished products CCP Controls No CCP's were determined by FS Team after running decision tree. oPRP Controls No ORP's were determined by FS Team after running decision tree. Volume / Fill Weight records Container weights are checked through the quality control laboratory every 3 hours. This is recorded in the QUIZ system. Product Release The product is released when the quality parameters are approved during the process. Allergen for line records There are no allergens on the production line. Finished Product Specification There is a Product data. The Lite Latch Screwtop 3.5 Gallon (which is the product being tracked) product specification is revised. Retained Samples No samples are retained. Despatch Notes There is a document Shipping instructions (WI-13-1-AZ) Revision date 03-25-2021. Transport Records There is a Pre-Load and incoming trailer inspection form. This includes Glad Hand Locks, Obvious Leaks/Damage, Overall Cleanliness, Holes in Trailer Walls, Holes in Trailer Roof, Holes in Trailer Floor, Hooks or Straps in Trailer Walls, Damage to Trailer Doors, No foul Odors, Infestation – Webs, droppings, insects. PM records on line There is a system (ERP) in which preventive maintenance is carried out. Maintenance performed on March 18, 2022 for Line 6 Husky H500 (being tracked) is reviewed. All activities performed are described, such as clean off conveyor and floor beneath to entire machine. Clean tempersonic rods with alcohol. It also describes who carried out the maintenance, the parts and equipment used, planning and any additional documents. This was shown through the work order form PHX-0000024721. Sanitation on line Monthly cleaning of husky machine # 6. This check list includes the following items: Collect materials required for cleaning, put the machine on

lock out/tag out, put on PPE, Remove all fallen pails or lids from beneath machine, blowout all debris in and around the machine, spray the machine down with cleaner, wipe down inside and outside of machine, WD-40 all linear slides, wipedown all the tempersonic rods with alcohol, clean pail catcher or lid slides, clean off underneath conveyor machine, clean up floor underneath machine, take the machine off lock out/tag out, return to processor. Cleaning schedule for production is filled during production. Cleaning consists of the work station being clean (floors, areas). Sanitation external areas There is a documented cleaning schedule for building maintenance (FPS 3.04) that includes a daily frequency of the following areas: Dumping office trash schedule, sweeping/vacuuming/Mopping office area schedule, Cleaning office bathrooms schedule, cleaning machines/around and behind machines and around chiller, cleaning windows/outside around building schedule, cleaning shipping/HR/Mold shop offices schedule, cleaning conveyor belt hoods schedule. Pre-Start Records There is an operator production report in which the characteristics of the processes are included. The operator prior to start-up and during production must ensure that the process conditions are ready to operate. Analytical Testing Quality analyzes are carried out for the products that are in process, such as diameter measurement, thickness measurement, weight measurement. Micro Testing Total count and coliform bacteria analyzes are performed for the finished product and for material in contact with the product (primary packaging). Results from January 24, 2022 are shown. These were made for the following products: large bag, medium bar (primary packaging), 11827 5.0 M2 LID, 11716 6.5 PAIL. Other results of analyzes carried out on September 24, 2021 are shown. These analyzes are carried out by the Eurofins laboratory (a2La Accreditation: 3329.05). Volume / Fill Weight/ count The weight measurement of the finished products is carried out every 3 hours, one piece for each mold cavity, and these are registered in the QUIZ, which is the system for capturing the measurement parameters of the products. Product Release The product is released through compliance with the specifications that are being measured by the quality area. The measurements are carried out continuously and if they are not met, the product is stopped from the last positive measurement. Allergen for line There is an allergen statement that explains "Rigid plastic packaging containers and components use therein, manufactured by M&M industries. Specifically, our products and processes, and those of our raw material suppliers, do not contain or come in contact with any of the following allergens: peanuts, tree nuts, milk, eggs, wheat/gluten, soy, fish, shellfish, sulphites, food colour, latex. Allergens training is provided as a part of GMP's training, proof of March 22, 2022 is shown. The training that is given through an evaluation is validated; the applied exam is shown. The presentation explaining allergen controls is reviewed. Rework Some rework activities are carried out. There is an area where all the product to be reworked is stored. One of the examples is the revision of each one of the pieces to be reworked to be cleaned. Water potability Water is supplied by the City of Phoenix (Water Services Department). There is a 2020 water quality report, which includes unregulated contaminants (manganese germanium, bromide), disinfectant and disinfection by product monitoring (chlorine, chlorine dioxide, chlorite, bromate, total trihalomethanes, haloacetic acids), aesthetic water quality analysis from distribution system & secondary drinking water guidelines, turbidity monitoring after treatment, heavy metals (lead, copper, arsenic, barium chromium, fluoride, nitrate, selenium), alpha emitters, combined radium uranium, microbiological (total coliform bacteria, E coli). Back flow preventer Is conducted by supplier (American Backflow & Prevention). The report of 02-26-2022 is displayed Cleaning chemicals approval Alpet D2 (NSF: 126509) A letter of guarantee that includes reference to 21 CFR 178.1010, 40 CFR 180.940 and 180.950. Compressed air filter change The air used is not in contact with the product. Suction filters are used to transport the resins. The filters are 10 microns. Other gas filter change No other types of gases are used. Waste labeled materials removal Only the product that is printed and did not meet the quality parameters is destroyed, which is sent to the scrap area to be destroyed. Emergency preparedness and response The business risk assessment plan addresses the company response to emergency situations, catastrophic events or unforeseen incidents that have to potential to imperil operations in both short and long term – time frames. This plan is reviewed by senior management at a minimum of one per year in a forma setting. In the event of a business disruption, will communicate to all necessary parties (customer, suppliers, etc.) what the mitigation process will be relative to their supply and scope of the emergency. Procedures and related training have been prepared for relevant staff regarding the types of events, that constitute an incident, how incidents are to be documented and managed based on the risk to the product. Hazard control FS Team Plant manager Production Manager Quality and FS Manager – FS Team coordinator Maintenance manager Processing Supervisor Warehouse manager Product description Rigid plastic packaging comprising of open head pails and covers. Materials used: resin, color, cardboard tray, plastic handle, label and pallet. Intended use Customers involved in the packaging of food products, consumer goods, industrial products and regulated products. Flow diagram The production flow chart (includes all stages) and the assembly flow chart are reviewed. There is a layout for the distribution of areas and flow of materials in production. Hazard analysis A hazard analysis was carried out that contemplates the raw materials and the stages of

the process, the type of potential hazard, and their analysis contemplating severity of occurrence, probability of occurrence and probability of detection, to determine the risk. Biological (mold, bacteria, or other microbiological organism from the contaminated equipment), physical (dirt/debris) and chemical (lubricants of the machines) hazards were determined. The decision tree was applied to evaluate all identified hazards. The FS team did not determine CCPs or OPRPs after running the decision tree. Updating the information specifying the PRPs and the hazard control plan Last update was conducted on May 26, 2022. The FS team meets to review the main changes. Control of monitoring and measuring There is a list of measurement equipment (form 110) in which the equipment and its calibration dates are documented. This document includes Gage type, unit (s/n), model/capacity, location of equipment, method, cal cert., due date. The calibration certificate of the Coordinate Measuring Machine CRYSTA-APEX AC776 carried out by MITUTOYO (a2La Accreditation: 0750.01) on 2021-06-29 and due date 2022-06-29 is reviewed. Which measures the diameter of the buckets? Verification related to PRPs and the hazard control plan Inspections (Food Safety Walk) are carried out on a monthly basis (at least), the one carried out on March 23, 2022 is reviewed. A presentation is made of these tours that is reviewed by the managers. During these inspections, all the PRPs applicable to the operation are reviewed, and a report is generated with photographs of the main findings. Control of product and process nonconformities There is a procedure for the control of conforming product. This document explains that non-conforming product is one that is out of specification, attribute or cosmetic effect or actual/potential product safety conditions. Non-conforming product is appropriately identified and segregated and disposition only by designated personnel. Pursuing corrective action is specified based on the severity of the non-conformity and these are documented. Implemented corrective actions are directed at preventing recurrence and are verified as being effective.

Clause	Requirement	Grade (Yes / No)	Conform (Minor / Major / Critical)	if No – detail	NC#
9	Performance evaluation				
9.1	Monitoring, measurement, analysis and evaluation	Yes			
9.1.1	General	Yes			
9.1.2	Analysis and evaluation	Yes			
9.2	Internal audit	Yes			
9.2.1	The organization shall conduct internal audits at planned intervals to provide information on whether the FSMS conforms to: a) - b)	Yes			
9.2.2	The organization shall a) - g)	Yes			
9.3	Management review	Yes			
9.3.1	General	Yes			
9.3.2	Management review input	Yes			
9.3.3	Management review output	Yes			

Summary: Monitoring, measurement, analysis and evaluation Inspections are carried out in accordance with inspection plans. Each inspection is compared to specifications. Any out of specification condition is processed in accordance with non-conforming material control. Individuals performing inspections are

properly trained and this training is documented and retained on file. Subcontractors are used for analyses critical to product performance and to meet legal requirements. Internal audit FSMS is audited at planned intervals encompassing a three-year auditing cycle. There is an internal audit procedure (PM-18). Audits are performed by trained/certified auditor and are independent from the activity being audited to ensure impartiality. All results of audits (including those indicating conformity as well as non-conformity) are to be documented on an internal audit report, with the supervisor or manager of the department being audit acknowledging via signature each non-conformity recorded. The 2022 audit plan is shown. Last internal audit was carried out on May 20, 2022. Only 2 observations were documented. The summary of the audited requirements and the results obtained in each of the audio tests carried out, as well as the status of each of them (closed or open), are reviewed. Currently there are 4 internal auditors. Management review Management reviews are conducted quarterly. The last management review was held on April 30, 2022. The information reviewed during this last management review was: Financial results, status of corrective actions, follow-up of previous review topics, 2022 goals, new projects, results of internal audits, external inspections and the results obtained, training events.

Clause	Requirement	Grade (Yes / No)	Conform (Minor / Major / Critical)	If No – detail	NC#
10	Improvement				
10.1	Nonconformity and corrective action	Yes			
10.1.1	When a nonconformity occurs, the organization shall: a) - e)	Yes			
10.1.2	The organization shall retain documented information as evidence of: a) - b)	Yes			
10.2	Continual improvement	Yes			
10.3	Update of the food management system	Yes			

Summary: Nonconformity and corrective action There is a Corrective action procedure (PM-23). During 2021, 20 corrective actions were generated. All corrective actions have been closed. In 2022, 9 corrective actions have been generated. A corrective action is shown with folio 22-01-AZ-CRM that was generated on January 24, 2022, for received in two pallets of 1.25 NG pails that were extremely dirty. These shipped against order # ORD05978. Root cause analysis was: Trays came off in transit. Shipped via XPO logistics. Notified XPO of issue. Trays are too large on 1.25 pails. They hang over 6+ inches when pails are sacked down. Trays buckle once wrapped. Pallets shipped LTL by XPO which was arranged by customer. The corrective action was “Possibly go back to a smaller tray on 1.25 and 0.6 pails so trays do not buckle when wrapped so badly. Looking into getting better banding tightener/sealer. Continual improvement A presentation is generated in which each quarter is evaluated. The quality presentation is reviewed where changes such as a new drop tester are explained, and a training that was had regarding the way in which tools for housekeeping, communication and a vending machine for personal protective equipment are generated. It was possible to confirm the 3 tools during the tour. HACCP online training was also proposed (and is currently being carried out). Likewise, trainings are being carried out in English and Spanish for personnel who do not speak English and work at the plant. Update of the food management system Last update of information regarding HACCP plan and PRP’s was conducted on May 26, 2022. The FS team meets to review the main changes.

ISO/TS 22002-4:2013 - FOOD PACKAGING MANUFACTURING

Clause	Requirement	Grade (Yes / No / N/A)	Conform (Minor / Major / Critical)	If No – detail, N/A – provide justification	NC#
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4.1	Establishments				
4.1.1	General requirements	Yes			
4.1.2	Environment	Yes			
4.1.3	Location of establishments	Yes			
<p>Summary: The facilities are sheltered in an industrial area that does not imply any problem of contamination in the surroundings of the company. During the tour, it was possible to see that the building in which the operational activities are carried out is made of material suitable for operations and durable. All the access doors were closed as well as the boarding and receipt curtains. The surroundings were in a clean and orderly condition. The roads around the plant are paved and in clean condition. An exterior route was made (from the parking lot to the resin discharge area). The facilities are located in an industrial area, no source of contamination was detected.</p>					

Clause	Requirement	Grade (Yes / No / N/A)	Conform (Minor / Major / Critical)	If No – detail, N/A – provide justification	NC#
4.2	Layout and workspace				
4.2.1	General requirements	Yes			
4.2.2	Internal design, layout and traffic patterns	Yes			
4.2.3	Internal structures and fittings	Yes			
4.2.4	Equipment	Yes			
4.2.5	Temporary/mobile structures	Yes			
4.2.6	Storage	No	Minor	Based on the requirement 4.2.6 Storage of ISO / TS 22002-4 which establishes that "All raw materials, intermediate products, chemicals and food packaging shall be stored in a manner to minimize the potential for contamination and with sufficient distance from the walls to allow inspection", a PP 25 Melt raw material was found open at the top (exposed to the environment).	

Summary: The facilities were adequately observed in terms of their physical condition. Racks have been installed to store the raw materials and materials used for the process. New equipment has been installed and an area has been planned to install additional equipment. The maintenance area is totally isolated from the rest of the areas and is physically separated with walls and controlled access through an access door. The production area is located in a separate area from the rest of the areas. There is a finished product storage area and another area for material storage. The flows of personnel, materials, and products are observed in a logical order that does not put at risk the food safety of the finished products, or of the materials. The workspaces are clearly identified by areas (raw materials warehouse, maintenance workshop, production, finished product warehouse and shipments). The walls and floors were found in adequate cleaning conditions, they are washable and cleanable. No puddles or stagnant water were found inside the plant. The ceilings are covered with insulating material, which was found to be adequate, clean and that it did not represent a source of contamination for the products. The doors were found closed. The equipment is accessible for maintenance and cleaning. There are no temporary structures. There is a warehouse for materials (raw materials). Chemicals are stored in a separate area (next to the laboratory) to avoid risk of cross contamination. mNC1- Based on the requirement 4.2.6 Storage of ISO / TS 22002-4 which establishes that "All raw materials, intermediate products, chemicals and food packaging shall be stored in a manner to minimize the potential for contamination and with sufficient distance from the walls to allow inspection", a PP 25 Melt raw material was found open at the top (exposed to the environment).

Clause	Requirement	Grade (Yes / No / N/A)	Conform (Minor / Major / Critical)	If No – detail, N/A – provide justification	NC#
4.3	Utilities				
4.3.1	General requirements	Yes			
4.3.2	Water supply	Yes			
4.3.3	Air quality and ventilation	Yes			
4.3.4	Compressed air and other gases	Yes			
4.3.5	Lighting	Yes			

Summary: Water potability: Water is supplied by the City of Phoenix (Water Services Department). There is a 2020 water quality report, which includes unregulated contaminants (manganese germanium, bromide), disinfectant and disinfection by product monitoring (chlorine, chlorine dioxide, chlorite, bromate, total trihalomethanes, haloacetic acids), aesthetic water quality analysis from distribution system & secondary drinking water guidelines, turbidity monitoring after treatment, heavy metals (lead, copper, arsenic, barium chromium, fluoride, nitrate, selenium), alpha emitters, combined radium uranium, microbiological (total coliform bacteria, E coli). Backflow preventer: Is conducted by supplier (American Backflow & Prevention). The report of 02-26-2022 is displayed Compressed air filter change: The air used is not in contact with the product. Suction filters are used to transport the resins. The filters are 10 microns. Other gas filter change: No other types of gases are used.

Clause	Requirement	Grade (Yes / No / N/A)	Conform (Minor / Major / Critical)	If No – detail, N/A – provide justification	NC#
4.4	Waste disposal				
4.4.1	General requirements	Yes			

4.4.2	Waste handling	Yes			
4.4.3	Drains and drainage	Yes			

Summary: Waste labeled materials removal: Only the product that is printed and did not meet the quality parameters is destroyed, which is sent to the scrap area to be destroyed. There are containers to deposit the garbage generated from the processes. These are located outside the plant and are closed and made of resistant materials. Likewise, there is an area where the pallets that will be sent as garbage and that cannot be used again are protected. There is a SOP waste or raw material determination guidance. Some of the controls that this procedure describes are that unusable material must be properly disposed of and cannot be stored. Suitable and sufficient waste containers with lids are provided to contain refuse. Containers are emptied regularly. Wastewater and oil are appropriately stored in designated containers and in designated locations outside the facility. Waste products that can be re-used are recycled as acceptable regrind and are stored in designated containers. Waste product that cannot be re-used (e.g., extruder purging and contaminated product) are stored in designated containers, identified and sold to external companies for recycling and destruction. Certificates of destruction are provided on a monthly basis by the third-party enterprise.

Clause	Requirement	Grade (Yes / No / N/A)	Conform (Minor / Major / Critical)	If No – detail, N/A – provide justification	NC#
4.5	Equipment suitability, cleaning and maintenance				
4.5.1	General requirements	Yes			
4.5.2	Hygienic design	Yes			
4.5.3	Food packaging contact surfaces	Yes			
4.5.4	Maintenance	Yes			

Summary: There is a procedure (WI-08-1-AZ) Periodic injection molding machine maintenance. There is a system (ERP) in which preventive maintenance is carried out. Maintenance performed on March 18, 2022 for Line 6 Husky H500 (being tracked) is reviewed. All activities performed are described, such as clean off conveyor and floor beneath to entire machine. Clean tempersonic rods with alcohol. It also describes who carried out the maintenance, the parts and equipment used, planning and any additional documents. This was shown through the work order form PHX-0000024721.

Clause	Requirement	Grade (Yes / No / N/A)	Conform (Minor / Major / Critical)	If No – detail, N/A – provide justification	NC#
4.6	Management of purchased materials and services				
4.6.1	General requirements	Yes			
4.6.2	Selection and management of suppliers	Yes			
4.6.3	Incoming raw materials	Yes			

Summary: 1st Ingredient: Resin 08452N-6 Melt. Approved supplier: DOW Chemical Company There is an approved vendor list where the vendor was listed on 2017-10-19. Receiving Records trailer inspection

and amount received: It was received on March 1, 2022. COA / COC Certified of analysis – Polyethylene 08452N High Density Order number 113489508 – 188900.00 lbs Date shipped 2022-02-18 Shipment 40448135 Manufacturing date 2022-02-13 Melt index and density. 1st packaging material: Cardboard tray Approved supplier: Cactus container – There is an approved vendor list where the vendor was listed on 2016-06-01. Receiving Records trailer inspection and amount received: The receiving order tally report records for March 4, 2022 are displayed. COA / COC Currently no COA is received for this type of material, the material reception area checks that the materials come in clean and correct operating conditions.

Clause	Requirement	Grade (Yes / No / N/A)	Conform (Minor / Major / Critical)	If No – detail, N/A – provide justification	NC#
4.7	Measures for prevention of contamination				
4.7.1	General requirements	Yes			
4.7.2	Microbiological contamination	Yes			
4.7.3	Physical contamination	Yes			
4.7.4	Chemical contamination	Yes			
4.7.5	Chemical migration	Yes			
4.7.6	Food allergen management	Yes			

Summary: Total count and coliform bacteria analyzes are performed for the finished product and for material in contact with the product (primary packaging). Results from January 24, 2022 are shown. These were made for the following products: large bag, medium bar (primary packaging), 11827 5.0 M2 LID, 11716 6.5 PAIL. Other results of analyzes carried out on September 24, 2021 are shown. These analyzes are carried out by the Eurofins laboratory (a2La Accreditation: 3329.05). There is an allergen statement that explains “Rigid plastic packaging containers and components use therein, manufactured by M&M industries. Specifically, our products and processes, and those of our raw material suppliers, do not contain or come in contact with any of the following allergens: peanuts, tree nuts, milk, eggs, wheat/gluten, soy, fish, shellfish, sulphites, food color, latex. Allergens training is provided as a part of GMP’s training, proof of March 22, 2022 is shown. The training that is given through an evaluation is validated; the applied exam is shown. The presentation explaining allergen controls is reviewed.

Clause	Requirement	Grade (Yes / No / N/A)	Conform (Minor / Major / Critical)	If No – detail, N/A – provide justification	NC#
4.8	Cleaning				
4.8.1	General requirements	Yes			
4.8.2	Cleaning programmes	Yes			
4.8.3	Cleaning agents and tools	Yes			
4.8.4	Monitoring cleaning programme effectiveness	Yes			

Summary: Monthly cleaning of husky machine # 6. This check list includes the following items: Collect materials required for cleaning, put the machine on lock out/tag out, put on PPE, Remove all fallen pails or lids from beneath machine, blowout all debris in and around the machine, spray the machine down with cleaner, wipe down inside and outside of machine, WD-40 all linear slides, wipe down all the tempersonic rods with alcohol, clean pail catcher or lid slides, clean off underneath conveyor machine, clean up floor underneath machine, take the machine off lock out/tag out, return to processor. Cleaning schedule for production is filled during production. Cleaning consists of the work station being clean (floors, areas). There is a documented cleaning schedule for building maintenance (FPS 3.04) that includes a daily frequency of the following areas: Dumping office trash schedule, sweeping/vacuuming/Mopping office area schedule, cleaning office bathrooms schedule, cleaning machines/around and behind machines and around chiller, cleaning windows/outside around building schedule, cleaning shipping/HR/Mold shop offices schedule, cleaning conveyor belt hoods schedule.

Clause	Requirement	Grade (Yes / No / N/A)	Conform (Minor / Major / Critical)	If No – detail, N/A – provide justification	NC#
4.9	Pest control				
4.9.1	General requirements	Yes			
4.9.2	Control programmes	Yes			
4.9.3	Preventing access	Yes			
4.9.4	Harbourage and infestations	Yes			
4.9.5	Monitoring and detection	Yes			
4.9.6	Eradication	Yes			

Summary: There is an external company Truly nolen. It has a 4020-license issued by the Arizona Department of Agriculture and the due date is May 31, 2022. The technician who attends Gerard's services. Edward Jackson with license number 140695 expiring May 31, 2022. The report of 10/03/2022 with number 45021732 is reviewed. A report describing the number of external traps 39, internal 100 and insect light trap 5 is reviewed. A video inspection summary is provided where the percentage of activity of the traps and lamps is determined. There was no activity in the traps. No pesticide application. During the tour, the rodent traps were observed, which were well placed and made of suitable and robust materials for use both inside and outside the facilities. No activity was observed. The doors were closed and no clearings were observed that implied a risk of pest entry.

Clause	Requirement	Grade (Yes / No / N/A)	Conform (Minor / Major / Critical)	If No – detail, N/A – provide justification	NC#
4.10	Personnel hygiene and facilities				
4.10.1	General requirements	Yes			
4.10.2	Personnel hygiene, changing facilities and toilets	Yes			
4.10.3	Staff canteens and designated eating and smoking areas	Yes			

4.10.4	Work wear and protective clothing	Yes			
4.10.5	Illness and injuries	Yes			
4.10.6	Personal cleanliness	Yes			
4.10.7	Personal behaviour	Yes			

Summary: Staff facilities are provided. Restrooms and lockers are outside the production area. During the tour, the facilities for the staff could be observed. There are policies and guidelines for personal hygiene. The policies are posted in different parts of the plants. There is an assigned area so that the staff can consume their food. Food is brought by the same staff. There are guidelines related to the clothing that staff must wear. Hairnets are used in the production areas. A letter is shown where you have the personnel practices policies – Food product safety requirements. Any employee with a cut or open wound must consult with their supervisor so that a determination can be made on whether it is safe to remain for their shift. Guidelines for personnel GMP's are documented.

Clause	Requirement	Grade (Yes / No / N/A)	Conform (Minor / Major / Critical)	If No – detail, N/A – provide justification	NC#
4.11	Rework				
4.11.1	General requirements	Yes			
4.11.2	Storage, identification and traceability	Yes			
4.11.3	Rework usage	Yes			

Summary: Some rework activities are carried out. There is an area where all the product to be reworked is stored. One of the examples is the revision of each one of the pieces to be reworked to be cleaned. The handling of the product for reprocessing is carried out according to the procedure for the control of non-conforming product. In the case of the product being traced, no reprocessing was carried out. The product that cannot be processed is sent for destruction.

Clause	Requirement	Grade (Yes / No / N/A)	Conform (Minor / Major / Critical)	If No – detail, N/A – provide justification	NC#
4.12	Withdrawal procedures				
4.12	Withdrawal procedures	Yes			

Summary: There is a documented work instruction for product withdrawals and recalls (WI-42-1). The procedure includes the origin of the recall / withdrawal (product withdrawal determination), withdrawal plan and event and mock withdrawal. Mock recalls are held once a year. Last mock recall was carried out on was carried out on January 5, 2022 for the product 500630 5.0 M4 WH C/W PAIL, and date of manufacture July 23, 2021. The time that the exercise took was 45 minutes. 100% of the product involved was identified.

Clause	Requirement	Grade (Yes / No / N/A)	Conform (Minor / Major / Critical)	If No – detail, N/A – provide justification	NC#
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4.13	Storage and transport			
4.13.1	General requirements	Yes		
4.13.2	Warehousing requirements	Yes		
4.13.3	Vehicles, conveyances and containers	Yes		
<p>Summary: Out bound finished product trailer inspection and amount shipped: There is a packing slip of the shipped product. This one shipped on May 26, 2022. When the product is shipped, a photograph is taken of the conditions in which it was shipped, the photograph of the product shipped on May 26, 2022 is reviewed.</p>				

Clause	Requirement	Grade (Yes / No / N/A)	Conform (Minor / Major / Critical)	If No – detail, N/A – provide justification	NC#
4.14	Food packaging information and customer communication				
4.14	Food packaging information and customer communication	Yes			
<p>Summary: Specifications of finished products are available. Finished Product Specification: There is a Product data. The Lite Latch Screwtop 3.5 Gallon (which is the product being tracked) product specification is revised. The organization has a letter of customer complaint program when all the complaints received are documented an entered into at the CRM system by customer service at the time of the complaint being received, and is notify to Director of Quality who will log the complaint and then forward it to the department head responsible for determining the root cause.</p>					

Clause	Requirement	Grade (Yes / No / N/A)	Conform (Minor / Major / Critical)	If No – detail, N/A – provide justification	NC#
4.15	Food defense and bioterrorism				
4.15	Food defense and bioterrorism	Yes			
<p>Summary: Food Defense Threat Assessment and Mitigation (Form FPS-07) was updated on 2021-06-27. The threat analysis is performed by location / activity / Process. The threat analysis considered potential food security threat, potential effects of threat, severity, potential cause / mechanism of threat, occurrence, Current process controls, detection probability, final risk, control measure, responsibility and target completion date. Some of the threats contemplated are: Food contamination or spoilage due to leaching of chemicals ingredients in color use to manufacture pails, finished load is tampered with while being delivered to customer, unauthorized visitor access, potential to adulterate finished goods, raw materials. The threat analysis methodology considered severity (which rates the severity of the potential effect of the failure), occurrence (which rates the likelihood that the failure will occur), detection (which rates the likelihood that the problem will be detected before it reaches the end-user / customer).</p>					

FSSC 22000 - ADDITIONAL REQUIREMENTS

Clause	Requirement	Grade (Yes / No / N/A)	Conform (Minor / Major / Critical)	If No – detail, N/A – provide justification	NC#
2.5.1	Management of Services and Purchased Materials				

2.5.1	Management of Services and Purchased Materials	Yes			
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Summary: The organization has external laboratories that carry out accredited microbiological calibration and monitoring activities. There are specifications for raw materials and supplies to buy. The laboratories to perform microbiological calibrations and evaluations are accredited. There is a format for evaluating suppliers (Form 207). A purchasing procedure (PM-11) has been documented. There are designated 3 tiers of suppliers 1) Primary, those suppliers who represent most of the purchases, critical to product quality, level A, suppliers of resins, additives, etc. 2) Distributors of commodity items or one-time buys, level B, whose impact is limited is evaluated on delivery only, due to product availability and, 3) non-impact suppliers, Level C, general office and/or service providers unrelated to product or service, are not evaluated. No emergency purchases are made from suppliers that have not been approved. This is done through the corporate who approves the suppliers and they must be on the list of approved suppliers to be able to make purchases.

Clause	Requirement	Grade (Yes / No / N/A)	Conform (Minor / Major / Critical)	If No – detail, N/A – provide justification	NC#
2.5.2	Product labelling				
2.5.2	Product labelling	Yes			

Summary: Label declaration: A label is generated for the finished product that is placed on the product pallet which contains the following information: Product description, Item #, Machine number, Resin used, Mold used, Inspection carried out by, Production date and time, Facility, Customer item, Quantity, License of product. Label verification: There is an operational supervisor who is the one who checks that the information on the label is correct for its use.

Clause	Requirement	Grade (Yes / No / N/A)	Conform (Minor / Major / Critical)	If No – detail, N/A – provide justification	NC#
2.5.3	Food defense				
2.5.3.1	Threat assessment	Yes			
2.5.3.2	Plan	Yes			

Summary: Food Defense Threat Assessment and Mitigation (Form FPS-07) was updated on 2021-06-27. The threat analysis is performed by location / activity / Process. The threat analysis considered potential food security threat, potential effects of threat, severity, potential cause / mechanism of threat, occurrence, Current process controls, detection probability, final risk, control measure, responsibility and target completion date. Some of the threats contemplated are: Food contamination or spoilage due to leaching of chemicals ingredients in color use to manufacture pails, finished load is tampered with while being delivered to customer, unauthorized visitor access, potential to adulterate finished goods, raw materials. The threat analysis methodology considered severity (which rates the severity of the potential effect of the failure), occurrence (which rates the likelihood that the failure will occur), detection (which rates the likelihood that the problem will be detected before it reaches the end-user / customer). The GMP's presentation is shown, which includes elements of Food defense which were taught to the staff. This takes place once a year. The revised threat analysis is updated once a year. The controls proposed were reviewed to avoid threats, such as control of the chemical products warehouse, control

Clause	Requirement	Grade (Yes / No / N/A)	Conform (Minor / Major / Critical)	If No – detail, N/A – provide justification	NC#
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2.5.4	Food Fraud mitigation			
2.5.4.1	Vulnerability assessment	Yes		
2.5.4.2	Plan	Yes		

Summary: Food Fraud Vulnerability Assessment (Form FPS-08). This vulnerability analysis was updated on 2021-06-27. The analysis contemplates type of food fraud, location / activity / process, potential food security threat, potential effect (s) of threat, severity, potential cause of threat, occurrence, current process controls, detection, risk, control measure and responsibility and target competition date. Type of food fraud included were substitution, stolen goods, dilution mislabeling, counterfeiting. Some vulnerability identified were reliable sourcing, preferably North America for ease of traceability, absence of heavy metals and allergens, Absence of heavy metals and allergens, finished load is tampered with while being delivered to customer, mixing internal regrind (non-virgin material) at higher levels than what customer is paying for, points of origin missing from product engraving or labeling. Of the plastic pkg originating from China or South America is not identified as such. The vulnerability analysis methodology considered severity (which rates the severity of the potential effect of the failure), occurrence (which rates the likelihood that the failure will occur), detection (which rates the likelihood that the problem will be detected before it reaches the end -user / customer). The vulnerability analysis is updated annually.

Clause	Requirement	Grade (Yes / No / N/A)	Conform (Minor / Major / Critical)	If No – detail, N/A – provide justification	NC#
2.5.5	Logo use				
2.5.5	Logo use	Yes			

Summary: The FSSC 22000 logo is not currently in use. It is used internally in training presentations (power point) and communication banners. It was checked that the correct logo is being used (shape and colors).

Clause	Requirement	Grade (Yes / No / N/A)	Conform (Minor / Major / Critical)	If No – detail, N/A – provide justification	NC#
2.5.6	Management of allergens (Only for categories C, E, FI, G, I & K)				
2.5.6	Management of allergens (Only for categories C, E, FI, G, I & K)	Yes			

Summary: There is an allergen statement that explains “Rigid plastic packaging containers and components use therein, manufactured by M&M industries. Specifically, our products and processes, and those of our raw material suppliers, do not contain or come in contact with any of the following allergens: peanuts, tree nuts, milk, eggs, wheat/gluten, soy, fish, shellfish, sulphites, food color, latex. Allergens training is provided as a part of GMP’s training, proof of March 22, 2022 is shown. The training that is given through an evaluation is validated; the applied exam is shown. The presentation explaining allergen controls is reviewed.

Clause	Requirement	Grade (Yes / No / N/A)	Conform (Minor / Major / Critical)	If No – detail, N/A – provide justification	NC#
2.5.7	Environmental monitoring (Only for categories C, I & K)				

2.5.7	Environmental monitoring (Only for categories C, I & K)	Yes			
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Summary: Total count and coliform bacteria analyze are performed for the finished product and for material in contact with the product (primary packaging). Results from January 24, 2022 are shown. These were made for the following products: large bag, medium bar (primary packaging), 11827 5.0 M2 LID, 11716 6.5 PAIL. Other results of analyzes carried out on September 24, 2021 are shown. These analyzes are carried out by the Eurofins laboratory (a2La Accreditation: 3329.05).

Clause	Requirement	Grade (Yes / No / N/A)	Conform (Minor / Major / Critical)	If No – detail, N/A – provide justification	NC#
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2.5.10	Storage and Warehousing (All Food Chain Categories)				
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2.5.10	Storage and Warehousing (All Food Chain Categories)	Yes			
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Summary: FIFO's are followed with the stored product and that it will be shipped through the same system (ERP) since the same system indicates which is the next product to be shipped. There is no possibility that the FIFOs for the product will not be followed. Products are labeled in such a way that they are identified with date and batch, and newly produced products are placed on the back, so that when using raw materials, the oldest ones are used first. There is a product preservation procedure (PM-15), Shipping instructions (WI-13-1-AZ). Chemical products are stored separately (outside the laboratory area), which is protected (under lock and key).

Clause	Requirement	Grade (Yes / No / N/A)	Conform (Minor / Major / Critical)	If No – detail, N/A – provide justification	NC#
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2.5.11	Hazard Control and Measures for preventing cross-contamination (Food Chain Categories C & I)				
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2.5.11	Hazard Control and Measures for preventing cross-contamination (Food Chain Categories C & I)	Yes			
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Summary: No special characteristics are incorporated into the products, they are packaged in the products made by the plant. For this reason the requirement is not applicable.

Clause	Requirement	Grade (Yes / No / N/A)	Conform (Minor / Major / Critical)	If No – detail, N/A – provide justification	NC#
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2.5.12	PRP Verification (Food Chain Categories C, D, G, I & K)				
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2.5.12	PRP Verification (Food Chain Categories C, D, G, I & K)	Yes			
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Summary: Inspections (Food Safety Walk) are carried out on a monthly basis (at least), the one carried out on March 23, 2022 is reviewed. A presentation is made of these tours that is reviewed by the managers. During these inspections, all the PRPs applicable to the operation are reviewed, and a report is generated with photographs of the main findings.

Clause	Requirement	Grade (Yes / No / N/A)	Conform (Minor / Major / Critical)	If No – detail, N/A – provide justification	NC#
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2.5.13	Product Development (Food Chain Categories C, D, E, F, I & K)				
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2.5.13	Product Development (Food Chain Categories C, D, E, F, I & K)	Yes			
<p>Summary: <i>Not Applicable for onsite operations. The plant does not have design and development activities. All developments are carried out by another office of the company outside the scope of the FSMS.</i></p>					