FACTORY EVALUATION REPORT: GENERAL MERCHANDISE

TA QF 7.4-1 - General Merchandise Audit Report, Revised 2-July-2021

GENERAL INFORMATION							
Audit Start Date	7-Feb-23	**End Date**	9-Feb-23	**Auditor**	Lori Leach	**UL Report #**	670741
Vendor Name	**Chase Products Company**					**Vendor Client Reference**	N/A
Factory Name	**Chase Products Company**					**Factory Client Reference**	N/A
Factory Address	2727 Gardner Rd., Broadview, IL 60155					**Country**	USA
Product Category	Formulated Products					**Audit type**	Annual
Product Description	Manufacture of Aerosols					**Retailer Classification**	Hardlines
Scope of Audit	The manufacturing and packaging of aerosols						
Factory Representative	Peter Chin			**Position**	Director of Engineering		

SCORE							
SECTION		**Critical**	**Major**	**Minor**	**Satifactory**	**N/A**	**Scoring**
A	QUALITY MANAGEMENT SYSTEM (QMS)	0	0	2	13	0	**92%**
B	FACILITIES	---	0	0	7	0	**100%**
C	SUPPLY MANAGEMENT	---	0	4	6	0	**65%**
D	EQUIPMENT CONTROL AND MAINTENANCE	---	0	0	8	0	**100%**
E	CONTAMINATION CONTROL	0	0	2	14	8	**88%**
F	PRODUCTION SET UP	---	0	0	8	2	**100%**
G	PRODUCT CONFORMITY - Formulated Products	0	0	5	45	0	**93%**
H	ADMINISTRATION AND TRAINING	---	0	0	7	0	**100%**
COMPLIANCE TO REQUIREMENT		**0**	**0**	**13**	**108**	**10**	**93.0%**

OVERALL RATING	**A**	**HIGH PERFORMANCE**

Comments
None

DOCUMENTS EVIDENCED				
No.	**Document Type**	**When Supplied:**		
		Before Audit	**During Audit**	**Not Supplied**
1	Organisation Chart for Site		X	
2	Site Plan / Layout			X
3	Factory Profile			X
4	Quality Policy & Manual (QA & QC Process)		X	
5	Product Risk Assessment & Critical Control Points		X	
6	Production Process Flow or List Of Key Steps		X	

General Merchandise - Factory Technical Audit Checkpoints

Section	Clause	Criteria / Requirements	Checkpoints	Weighting	0	1	2	3	N/A	Severity of finding	Observation or Non-Conformance
QUALITY MANAGEMENT SYSTEM (QMS)	A01	Quality Manual and System	The facility shall establish and maintain comprehensive Quality Procedures, detailing all processes related to Product Quality.	**CRITICAL**				X		Acceptable	The firm has a comprehensive library of Quality Procedures and Quality Manual detailing processes related to product quality.
QUALITY MANAGEMENT SYSTEM (QMS)	A02	Quality Manual and System	The Quality Manual and system shall be reviewed regularly, (at least once per 12 months), The review process shall identify any new, updated or changed processes to new production items or production processes, and also take into account complaints or incidents with this or similar products and should reflect any changes in legislation.	MEDIUM				X		Acceptable	Quality Manual, v 12.5, was reviewed and updated 2/22/2022.
QUALITY MANAGEMENT SYSTEM (QMS)	A03	Quality Manual and System	Output and quality reports shall be regularly analyzed (weekly or monthly) by management and corrective actions shall be determined and actioned when results are adverse to the facility's set targets.	MEDIUM				X		Acceptable	Quality issues are reviewed twice daily during pre production meetings. Any topics that require corrective actions are captured within the firm's nonconformance system.
QUALITY MANAGEMENT SYSTEM (QMS)	A04	Hazard Assessment & Risk Management system, and Critical Control Points (CCPs)	The facility shall have a Hazard Assessment and Risk Management system in place to ensure:- --All hazards to consumer safety, legality and retailer brand policies are identified, documented, implemented and maintained on the products and production processes. --The process should carried out by a suitably qualified person (either internal or external) with the cross-functional team --Any new, update or changes to new production items or production processes shall have a new risk assessment and Risk Management process completed.	**CRITICAL**				X		Acceptable	Hazard Assessment is described within the Quality Manual, version 12.5, eff 2/22/2022 and includes assessment by qualified individual(s) for EPA/regulatory/Legal compliance. Any new, updated or changes to production are managed via the firm's change management process, where the same risk assessment process is commenced.
QUALITY MANAGEMENT SYSTEM (QMS)	A05	Hazard Assessment & Risk Management system, and Critical Control Points (CCPs)	The Critical Control Points (CCPs) shall be Identified, controlled and documented as per the Hazard Assessment and Risk Management system. Those Critical controls should provide evidence of effective implementation and be well maintained.	**CRITICAL**				X		Acceptable	Control points include R&D evaluation of materials used in formulation based upon intended use, Lab testing and 90 day shelf life study to confirm formulation characteristics, Legal and Regulatory review and approval, Artwork approvals, In process and finished product testing and release.
QUALITY MANAGEMENT SYSTEM (QMS)	A06	Hazard Assessment & Risk Management system, and Critical Control Points (CCPs)	The Risk Assessment shall be reviewed regularly, (at least once per 12 months) while the products are still in production. The review process shall identify any changes to the last assessment, shall take into account any complaints or incidents with this or similar products and reflect any changes in legislation.	MEDIUM				X		Acceptable	Risk assessment is included and reviewed within the Quality Manual, rev 12.5, eff 2/22/2022.
QUALITY MANAGEMENT SYSTEM (QMS)	A07	Customer Complaint/ Recall Handling	All Customer Complaints shall be:- -- Recorded with appropriate actions taken -- Corrective Action Plan (CAP) should be taken place and documented. -- Those should be reviewed and approved by factory management team.	MEDIUM				X		Acceptable	SOP 23, rev 2, eff 11/12/2013 Complaint Procedures describes this process. Reference: Complaint ID S-5983061 for scope product, lot code G06015 dated 5/2/2022 and complaint dated 7/2/2020 (non scope product) for product lot CN100N4 that included laboratory investigation via review of retains.
QUALITY MANAGEMENT SYSTEM (QMS)	A08	Customer Complaint/ Recall Handling	The facility shall establish and maintain an effective product recall procedure (between the client, supplier and facility if different business or locations).	HIGH				X		Acceptable	Product recall process is adequately described in the Quality Manual, rev 12.5, eff 2/22/2022.
QUALITY MANAGEMENT SYSTEM (QMS)	A10	Health and Safety Policy	The facility shall develop, maintain and document a Heath and Safety Policy:- -- which shall be approved by Senior Management. -- shall be available for all employees to reach and see. -- shall be in compliance with local legal requirements.	MEDIUM				X		Acceptable	Health and Safety Policy dated 2023 is in place and acceptable.
QUALITY MANAGEMENT SYSTEM (QMS)	A11	Internal Audit	Is there evidence to demonstrate that the facility conducts effective Internal Audits of their Quality Management System and other internal processes on a regular basis? (can be conducted by external party) Does facility act upon the outcomes ? Internal audits should take place at intervals of less than 18 months	MEDIUM	X					Minor	CAR 1: 'The firm does not have an internal audit programme in place to evaluate their Quality Management System.
QUALITY MANAGEMENT SYSTEM (QMS)	A12	Management Commitment	Senior Management shall review the Quality System on a planned, regular basis, taking into account company strategy, quality related feedback from customers and internal quality metrics	MEDIUM				X		Acceptable	Senior Management is noted as reviewing and approving the annual review of the Quality Manual.

General Merchandise - Factory Technical Audit Checkpoints

QUALITY MANAGEMENT SYSTEM (QMS)	A13	Document Controls	A document control system shall be in operation. It shall include processes to control the approval, review, updating, change identification and obsolescence of documents (Any changes to controlled documents shall be authorized by the appropriate responsible person.)	MEDIUM		X				Minor	CAR 2: Lab procedures and test methods were observed with missing document and revision numbers, approval signatures, effective dates and duplicate copies present with conflicting revised by dates. Operational procedures did include all required information, except they were missing approval signatures. Examples include: Test methods for Appearance, Odor, Identity (FTIR), Refractive Index were missing Doc ID #'s, revision numbers, approval signature(s). Duplicate procedures for Checking Perfume were present in the document binder, one having a revised date of 9/23/2021 and the other 9/22/2021. Operational QA procedures observed were said to be routed for review and approval to the area leaders responsible for executing the procedures, but no records are kept of their review/approvals. Reference SOP 2013, rev 4, eff 11/27/2013 SOP for Procedures.
QUALITY MANAGEMENT SYSTEM (QMS)	A14	Traceability System	The facility shall have a system in place to enable all Good in & Goods out records, production data and quality checking reports from raw materials to finished products ex- facility, to be traced to a batch or order number	**CRITICAL**				X		Acceptable	The traceability process is described in the Quality Manual, v. 12.4, eff 2/22/2022.
QUALITY MANAGEMENT SYSTEM (QMS)	A15	Traceability System	All goods whilst in production, assembly or finished goods shall be identifiable and a system in place to trace back to the batch of raw materials used	**CRITICAL**				X		Acceptable	Evidence of traceability confirmed via mock recall exercise dated 10/4/2022, indicating full accountability for raw materials and finished product in product code 449-8960/lot C2803A5.
QUALITY MANAGEMENT SYSTEM (QMS)	A09	Business Continuity	The company shall have procedures in place to identify methods of ensuring business continuity in the case of incidents and/or informing their customers when incidents occur. Such procedures shall include a developed contingency planning for business continuity in the event of major incidents such as: disruption to key services - e.g. water, energy, staff availability; events such as flood, fire, pandemic and/or natural disaster; malicious contamination or sabotage. The procedure(s) shall include as a minimum: identification of key staff constituting the incident management team and their key responsibilities; an up-to-date list of key contacts, and relative agencies providing advice where applicable.	**CRITICAL**				X		Acceptable	Business Continuity Plan is described in Quality Manual, rev 12.5, eff 2/22/2022 and is acceptable.
	A		**TOTAL:**	**15**	**0**	**0**	**2**	**13**	**0**		**92.0%**

Section	Clause	Criteria / Requirements	Checkpoints	Weighting	0	1	2	3	N/A	Severity of finding	Observation or Non-Conformance
FACILITIES	B01	Internal Perimeter / External exposure of goods	The facility grounds, meaning within the facility perimeter and outside the facility buildings, shall be kept tidy and free from unnecessary items that could cause or encourage pest and other contamination issues	MEDIUM				X		Acceptable	Facility grounds were observed as free from unnecessary items that could cause or encourage pest and other contamination issues.
FACILITIES	B02	Internal Perimeter / External exposure of goods	The facility shall ensure that any raw materials, finished goods, packaging and equipment that is stored outside the production building or warehouse, must be stored or transported in a way that ensures there is no risk of contamination or deterioration. Product stored in this way must be inspected before going into production or being shipped.	HIGH				X		Acceptable	Drums of chemicals were observed being stored outside, with drum bonnets to protect tops from the elements.
FACILITIES	B03	Facility Building Maintenance and Reparation	The facility buildings shall be well maintained and in good visual state of repair. The organization shall have a valid commercial license/permit from local jurisdiction as appropriate for the products being manufactured.	HIGH				X		Acceptable	Facility were observed as maintained and good state of repair. Commercial license in place.
FACILITIES	B06	Security: Control of Access To Site	-- All site visitors, contractors and delivery drivers shall be required to sign in upon entry to the premises. -- At all times, appropriate measures to control access on site to high risk and secure areas shall be in place. -- Raw materials and finished goods shall be adequately protected from possible malicious damage.	MEDIUM				X		Acceptable	Sign in, access restriction and protection of materials and finished goods were all observed as acceptable.
FACILITIES	B07	Materials and Finished Goods Storage	The facility shall not store any goods tight against the walls. They shall ensure that any goods stored on the floors shall have enough space around them to allow for pest inspection and QC checks. Any storage shall be in appropriate warehouse/storage areas in order to prevent and minimize contamination and damage.	MEDIUM				X		Acceptable	Goods were stored in a manner to allow for pest inspection and QC checks.

General Merchandise - Factory Technical Audit Checkpoints

FACILITIES	B08	Warehouse Management. Material Storage and Allocation	The facility shall have a policy / procedure to control the oldest materials being used first (FIFO) (Materials must be used within their shelf life, where applicable, a suitable control system should be in place to manage shelf life and special storage / usage instructions of raw materials.)	MEDIUM				X		Acceptable	FIFO of materials and finished product is outlined in the firm's Quality Manual, rev 12.5, eff 2/22/2022 and is acceptable.
FACILITIES	B09	Drains and Waste Water	Controls shall be in place to manage waste water and contamination. Appropriate controls shall be in place where risks have been identified.	HIGH				X		Acceptable	Adequate controls are in place per SOP 57, rev 23, eff 6/13/2012 Hazardous Waste Handling to manage waste water and contamination. Application of this procedure was evidenced by the EHS labeling/instructional posted placards describing the various waste streams and their proper handling and management.
	B		**TOTAL:**	**7**	**---**	**0**	**0**	**7**	**0**		**100.0%**

Section	Clause	Criteria / Requirements	Checkpoints	Weighting	0	1	2	3	N/A	Severity of finding	Observation or Non-Conformance
SUPPLY MANAGEMENT	C01	Supplier / Materials Assessment	The facility shall have a documented supplier and sub-contractor approval procedure for raw materials, semi finished goods and services. (This assessment should be based on inspection & quality history, volume of goods supplied and dependency of the product and service.)	HIGH			X			Minor	CAR 3: The firm is lacking a documented review / approval process/procedure for goods and services providers, such as their 3rd party laboratory used for microbiological testing, pest control and metrology service providers. The current process described in the Quality manual, rev 12.5, eff 2/22/2022, Appendix A includes provisions for approval of raw material suppliers only.
SUPPLY MANAGEMENT	C02	Supplier / Sub-Contractor list	The facility shall maintain a list of suppliers and their current supply status, this should include historical data for a minimum of 12 months after becoming inactive. (This should include raw materials and semi-finished products either in stock or shipped which relates to a client PO or shipping inventory.)	MEDIUM				X		Acceptable	Approved suppliers/vendors and their status is maintained in an electronic database. Review of current suppliers and their status was confirmed via review of this database and includes active and inactive status (suppliers reviewed - Sugarman, Summit Packaging, Sun Chemical, Superior Bands)
SUPPLY MANAGEMENT	C03	Supplier Tracking & Improvement	The facility shall establish and maintain a tracking and improvement follow up process for the return and rejection of goods or services from the suppliers / sub-contractors. Where performance issues are identified an appropriate CAP shall be in effect to ensure continuous improvement	MEDIUM				X		Acceptable	The current process is adequately described in the Quality manual, rev 12.5, eff 2/22/2022, Appendix A Supplier Requirements. Evidence of supplier CAP dated 3/21/2022 for packaging supplier Summit Packaging for defect of flat spots on the side of valves was reviewed and is acceptable.
SUPPLY MANAGEMENT	C04	Incoming Material Assessment	The facility shall establish and maintain clear work instructions and appropriate inspection criteria for effective QC of all incoming material / component / printing artwork.	MEDIUM	X					Minor	CAR 4: The facility does not have instructions with appropriate inspection criteria for effective QC of printing artwork. Artwork is not inspected at incoming receipt via comparison to an approved artwork standard, color, content, etc.
SUPPLY MANAGEMENT	C08	Incoming Material Assessment	The facility shall ensure that appropriate equipment is made available and maintained to allow for the QC of incoming raw materials, such as a light box, on site tests, weights and measures etc.	MEDIUM	X					Minor	CAR 5: There is no equipment made available such as a light box to allow for QC of incoming raw materials such as artwork.
SUPPLY MANAGEMENT	C05	Incoming Material Assessment	The facility shall ensure that the incoming QCs have an signed approval reference specification and samples for incoming inspection. (e.g. color swatch, pantone, shade range, reference sample available and in place and appropriately stored)	MEDIUM	X					Minor	CAR 6: There is no reference specification present for artwork and no samples such as color swatch, pantone, shade range available to aid in inspection of incoming artwork.
SUPPLY MANAGEMENT	C06	Incoming Material Assessment	Where applicable, testing reports shall be made available to the facility from their supplier for the materials received / goods in process. The facility shall establish and maintain a process and criteria to ensure the tests demonstrate compliance to the requirement / specification.	HIGH				X		Acceptable	CofAs are required for every material and were observed as present and reviewed by QA.
SUPPLY MANAGEMENT	C07	Incoming Material Assessment	The facility shall establish and maintain a process to check and record every batch of incoming materials / components. The facility shall ensure that only QC approved materials / components are released to production.	HIGH				X		Acceptable	Quality Manual, v 12.5, 2/22/2022 and SOP 110, rev 5, eff 7/11/2011 Propellant Receiving & Unloading to Underground Storage Tanks both adequately describe requirements for checking/recording every batch of materials/components. QC releases materials once approved.
SUPPLY MANAGEMENT	C09	Material Rejection	The facility shall establish and maintain a procedure to clearly identify and segregate rejected materials / components from acceptable materials. The facility shall ensure that separate storage areas for materials waiting for further actions are available and are used for the storage of the segregated items	MEDIUM				X		Acceptable	Quality Manual, v 12.5, eff 2/22/2022 adequately describes the control plan for maintaining proper segregation of rejected materials. Materials with the proper quarantine tags were observed in appropriate storage location.

General Merchandise - Factory Technical Audit Checkpoints

SUPPLY MANAGEMENT	C10	Material Rejection	The facility shall ensure that there is an effective process for final disposal of rejected material/components.	MEDIUM				X		Acceptable	SOP 57, rev 23, eff 6/13/2012 Hazardous Waste Handling describes the process for proper disposal of rejected materials and components. Components and materials are placed in color coded drums, depending on their risk category, and color coded for proper waste stream disposal.
	C		**TOTAL:**	**10**	**---**	**0**	**4**	**6**	**0**		**65.2%**

Section	Clause	Criteria / Requirements	Checkpoints	Weighting	0	1	2	3	N/A	Severity of finding	Observation or Non-Conformance
EQUIPMENT CONTROL AND MAINTENANCE	D01	Production Equipment requirement	The facility shall ensure that all equipment is capable of producing to the agreed specification. It must be maintained and in a good condition in order to prevent quality issues or risk of foreign body contamination.	MEDIUM				X		Acceptable	Scope product equipment (mix tank and packaging line 2) maintenance records were reviewed from Jan 2023 to present and found to be acceptable. Recs included: Coder can line #2, task ID #619 dated 2/6/2023, Blower for Water Batch Line #2, task ID 618 dated 1/23/2023, Tank Farm Union Pump #6, task ID 504B dated 1/28/2023.
EQUIPMENT CONTROL AND MAINTENANCE	D04	Equipment Calibration	The facility shall ensure that measuring and monitoring equipment critical to product safety, legality and quality, which has been identified by risk assessment, must be checked for accuracy and calibrated to national standards where applicable. Calibration results shall be recorded at pre-determined frequencies, dependent upon risk and volume.	HIGH				X		Acceptable	Scales are calibrated annually and gauges calibrated weekly. Cal cert for scale DS12308 dated 1/6/2023, QC weekly gauge calibration checklist dated 1/16/2023 were reviewed and are acceptable.
EQUIPMENT CONTROL AND MAINTENANCE	D05	Equipment verification	The facility shall ensure that all Critical equipment be verified and checked and recorded, at a minimum in accordance with manufacturers guidelines. Verification checks will depend on Risk, CCP's and Volumes. Checks must be appropriate.	HIGH				X		Acceptable	Scope product equipment (mix tank and packaging line 2) maintenance records were reviewed from Jan 2023 to present and found to be acceptable. Recs included: Coder can line #2, task ID #619 dated 2/6/2023, Blower for Water Batch Line #2, task ID 618 dated 1/23/2023, Tank Farm Union Pump #6, task ID 504B dated 1/28/2023.
EQUIPMENT CONTROL AND MAINTENANCE	D06	Preventative Maintenance	The facility shall establish and maintain a Planned Preventative Maintenance Program (PPM) which is based on risk assessment. The facility shall ensure that the parameters and settings of the production machinery conforms with the defined procedure and requirements.	MEDIUM				X		Acceptable	Per the firm's quality manual, engineering and maintenance meetings are held weekly to review status of PM system. Evidence of PMs being complete was reviewed from Jan 2023 to present and are acceptable.
EQUIPMENT CONTROL AND MAINTENANCE	D02	Engineering Work environment	The facility shall ensure that maintenance work areas shall have good standards and strict housekeeping policies to ensure there is no risk of product contamination.	MEDIUM				X		Acceptable	Standards for maintenance activities are defined within the PM's/work order system, where instructions for cleanup and use of approved chemicals are defined within each task assigned.
EQUIPMENT CONTROL AND MAINTENANCE	D03	Maintenance Tools	The facility shall consider tools as Foreign Bodies. The Facility shall establish and maintain a policy for the maintenance, replacement and, where necessary, investigation process of a tool or part of a tool that's missing. (check out - check in). Records should be kept for compliance. The policy shall also apply to visitors and contractors working onsite.	HIGH				X		Acceptable	Tools are managed via the XP Tools process, with sign in and sign out requirements as evidenced by tools issuance records from 2017 to present.
EQUIPMENT CONTROL AND MAINTENANCE	D07	PPE Procedure & Policy	The facility shall establish and maintain a policy / procedure to clearly define the use of personal protective equipment (PPE). The facility shall ensure sufficient instruction and training for workers. The facility shall maintain records of the training given.	HIGH				X		Acceptable	PPE program and areas of required use are defined in PPE Assessment Summary by Department dated 1/24 and 2/1/2023 and glove use usage requirements matrix dated 7/2022. Records of PPE training were reviewed for May and Jun 2022 and are acceptable.
EQUIPMENT CONTROL AND MAINTENANCE	D08	Use of PPE	The facility shall ensure that appropriate PPE is made available and unrestricted. The facility shall ensure it is used by the appropriate workers and that there are sufficient quantities of the PPE available at the applicable work stations / areas.	HIGH				X		Acceptable	PPE was observed as readily available to all personnel.
	D		**TOTAL:**	**8**	**---**	**0**	**0**	**8**	**0**		**100.0%**

Section	Clause	Criteria / Requirements	Checkpoints	Weighting	0	1	2	3	N/A	Severity of finding	Observation or Non-Conformance
CONTAMINATION CONTROL	E01	Sharp Object and Metal Control	The facility shall establish and maintain a metal / sharp object control procedure:- -- The policy shall cover all the production processes, including sampling, material receiving to packing and sub-contracting. -- all the sharp tools are accounted for and controlled. -- ensure that Issue and Return records are maintained to demonstrate compliance. -- sharps tools are checked upon return for intactness, color coded, tethered to work station etc and any other suitable control mechanism. -- for those stationary work station, sharp tools should tied up at fixed positions.	HIGH				X		Acceptable	SOP 174, rev 3, eff 3/17/2015 Safety Knife Procedure includes provisions for issuance/controls of knives.

CONTAMINATION CONTROL	E04	Sharp Object and Metal Control	The facility shall ensure that, in the event of a lost or broken tool, appropriate actions are taken to find the missing item. All log sheet records shall be retained.	MEDIUM				X		Acceptable	Log sheet dated 12/30/2021 thru 8/11/2022 for knives #382 thru 391 reviewed and acceptable.
CONTAMINATION CONTROL	E05	Needle Control - (Where Applicable)	The facility shall establish and maintain a needle control policy as below:- (This will only apply for those factories where needles are used in this, or other production lines) -- there shall have a locked needle storage area and control by an appointed person. -- There should have a validated stock record control. -- Each workers should only have 1 needle on hand and in used. -- all the broken and damage needle shall be replaced by one to one basis.	HIGH					X		Needle control is not applicable to this product.
CONTAMINATION CONTROL	E07	Needle Control - (Where Applicable)	**The facility shall ensure that an appropriate action to find the lost or missing broken needle or part of the needle is undertaken and any relevant log sheet retained.** **The facility shall ensure that all needle pieces are returned and attached to the record sheet. And if the fragment is unable to be found, there shall be an appropriate action / procedure in place to ensure that the production shall not be contaminated.**	**CRITICAL**					X		Needle control is not applicable to this product.
CONTAMINATION CONTROL	E08	Metal Detection - (Where Applicable)	**The facility shall have in place a metal detection checking policy which takes place before the packing process. The policy shall be set to the appropriate detection levels.**	**CRITICAL**					X		Metal detection is not applicable.
CONTAMINATION CONTROL	E09	Metal Detection - (Where Applicable)	The packing area after metal detection shall be restricted, so that only finished product following metal detection can be packed in it. -- Sharp tools shall not be used in the restricted zone unless specifically authorized by the management. -- Only authorized workers can work in this restricted zone. -- all products being sent to pack in the restricted zone should be go via the metal detectors. No products should go into this zone without metal detection.	HIGH					X		Metal detection is not applicable.
CONTAMINATION CONTROL	E10	Metal Detection - (Where Applicable)	The facility shall establish and maintain a procedure to ensure the metal detector is calibrated according to the Risk Policy and / or the clients specification. Calibration records must be retained. (It is recommended that the metal detector is calibrated for each 2 hour period, but may vary depending on volumes.) All products shall be subject to metal detection before packing and daily checking records shall be maintained.	HIGH					X		Metal detection is not applicable.
CONTAMINATION CONTROL	E11	Metal Detection - (Where Applicable)	The facility shall establish and maintain a procedure to ensure that when a metal contaminated product is found, an appropriate action plan is implemented and records kept of the outcome? Contaminated products shall be securely segregated for future checks and analysis.	MEDIUM					X		Metal detection is not applicable.
CONTAMINATION CONTROL	E12	Metal Detection - (Where Applicable)	Workers who use the metal detector shall be adequately trained? Only qualified and appointed personnel shall operate the metal detector. Appropriate records shall be maintained to show this.	MEDIUM					X		Metal detection is not applicable.
CONTAMINATION CONTROL	E13	Glass, Brittle, Hard Plastics and Ceramics Control - (Where Applicable)	The factory shall establish and maintain a procedure to ensure that when glass, brittle, hard plastic or ceramics are used in production, the risk of breakage and contamination is managed	MEDIUM				X		Acceptable	SOP 52, rev 3, eff 8/20/2008 Glass and Brittle Plastic Control Policy adequately describes this process.
CONTAMINATION CONTROL	E14	Glass, Brittle, Hard Plastics and Ceramics Control - (Where Applicable)	The factory shall establish and maintain a procedure to ensure that there is a defined frequency for checking for those glass, brittle, hard plastic and ceramics to prevent potential product contamination	MEDIUM	X					Minor	CAR 7: The procedure for glass and brittle plastics has provisions for employees to report when they observe broken glass/plastics/ceramics but there is no process defined for routinely checking for defined locations where glass, plastics and ceramics have been identified as being present.
CONTAMINATION CONTROL	E15	Drinking Bottles & Cups	The factory shall establish and maintain a procedure to ensure that there is a defined place/station for workers to put their drinking cups / bottles. This shall be away from the production line and machinery, in order to avoid potential product contamination	MEDIUM				X		Acceptable	Chase Rules and Regulations, eff 2/21/2022, describes the attire and food/drink policy. This is reviewed daily with operators and signature of understanding obtained. Evidence Rules and Regulations training for Line #2 dated 2/6/2023.

General Merchandise - Factory Technical Audit Checkpoints

CONTAMINATION CONTROL	E16	Wooden Control - (Where Applicable)	The factory shall establish and maintain a procedure to ensure that if the use of wood cannot be avoided in the facility, then the risk of wood / splinter contamination to the products is managed and minimized.	MEDIUM				X		Acceptable	Quality Manual, rev 12.5, eff 2/22/2022 includes requirements for inbound trailer inspection, including pallet quality. Any damaged pallets are replaced before product can be placed in storage.
CONTAMINATION CONTROL	E17	Wooden Control - (Where Applicable)	The fancily shall check all wooden pallets, containers and tools to prevent breakage, dirt, mildew, and insect pest contamination Records shall be kept of the checks	MEDIUM				X		Acceptable	Quality Manual, rev 12.5, eff 2/22/2022 includes requirements for inbound trailer inspection, including pallet quality. Any damaged pallets are replaced before product can be placed in storage.
CONTAMINATION CONTROL	E18	Pest Control	The facility shall establish and maintain a pest control programme. Documentation shall be maintained to identify what those controls are. The process shall also identify who carries out the tasks, either if managed by trained facility personnel or an external pest contractor.	MEDIUM				X		Acceptable	Anderson pest control binder was reviewed, trap map, insurance, pest applicator license, trip reports were up to date and acceptable.
CONTAMINATION CONTROL	E19	Pest Control	The programme shall analyze the pest control results in order to ensure continuous improvement of the control programme?	MEDIUM				X		Acceptable	Trip reports include actions needed to correct any deficiencies during their visit. Evidence of responding to pest control provider's recommendations was confirmed via trip report dated 1/3/2023 where they recommended that a seal was broken on overhead door and it had been repaired.
CONTAMINATION CONTROL	E20	Foreign Body Controls	The facility shall establish and maintain effective procedures to eliminate foreign body hazards, dependent upon risk of contamination . (e.g.. Screen protectors, closed windows and doors, protective covers to lights in risk areas etc.)	HIGH			X			Minor	CAR 8: Slight risk of contamination of finished product was observed near packaging line 2, used in the filling of scope product canisters. A large hole in the ceiling, with flaking paint/drywall, flaking pipe insulation and dirt accumulating on the depalletize catch screen all above open product stream were observed. Additionally, a plastic pallet used to accumulate used slip sheets is being placed above open product stream.
CONTAMINATION CONTROL	E21	Treatment of fumigated materials	The facility shall establish and maintain effective procedures to control heat treatment or use of gas, which is aligned with customer requirements There must be a valid fumigation certification for every batch of fumigated materials. When the fumigated materials is in use, it must be able to be traced back to the valid fumigation certification	MEDIUM					X		Heat treatment/fumigation does not apply.
CONTAMINATION CONTROL	E22	Chemical Control - (Where Applicable)	The facility shall establish and maintain an effective Chemical Control Programme. The facility must be able to demonstrate awareness of chemical restrictions in the country the goods are being supplied to	MEDIUM				X		Acceptable	Chemical control program is outlined in the firm's Hazard Communication Program, rev 10, eff 10/6/2022. Legal and regulatory affairs reviews any country specific restrictions, where applicable, as part of the product review and approval process.
CONTAMINATION CONTROL	E23	Chemical Control - (Where Applicable)	The facility shall have a separate / controlled area for Chemical Storage	MEDIUM				X		Acceptable	Acceptable controlled areas for chemical storage were observed.
CONTAMINATION CONTROL	E24	Chemical Control - (Where Applicable)	The facility shall have the MSDS available at the workshop and warehouse. PPE equipment shall be provided	MEDIUM				X		Acceptable	SDS were observed as readily accessible in multiple locations throughout the facility.
CONTAMINATION CONTROL	E25	Chemical Control - (Where Applicable)	There shall be secondary containers to prevent leakage of chemicals. The facility shall maintain spill / leakage equipment and procedures	MEDIUM				X		Acceptable	SOP 25, rev 5, eff 8/19/2008 Spill Control was reviewed and is acceptable. Secondary containers were observed in use to prevent leakage.
CONTAMINATION CONTROL	E26	Chemical Control - (Where Applicable)	Workers engaged in the use of chemicals shall receive appropriate training to use those chemicals. Appropriate PPE equipment shall always be used when handling chemicals	MEDIUM				X		Acceptable	Hazard Communication training is provided as evidenced by training records reviewed dated 11/21/2022 and 2/3/2021.
CONTAMINATION CONTROL	E27	Water Contamination	The facility shall ensure that any water that comes into contact with articles or materials, during the production process, is of a suitable quality.	MEDIUM				X		Acceptable	Suburban Labs testing report dated 1/31/2023 was reviewed for DI water used in the process. TPC <1.
	E		**TOTAL:**	**24**	**0**	**0**	**2**	**14**	**8**		**88.2%**

Section	Clause	Criteria / Requirements	Checkpoints	Weighting	0	1	2	3	N/A	Severity of finding	Observation or Non-Conformance
PRODUCTION SET UP	F01	Specification	The site shall establish and maintain a procedure for the management and validation of the latest production / client specification.	HIGH				X		Acceptable	Quality Manual rev 12.5 dated 2/22/2022 outlines the process for product set up, reviews and approvals. An example of validation of latest scope product production run, item 429-1799 CVS Disinfectant Fresh Linen dated 1/31/2022 was reviewed and is acceptable.
PRODUCTION SET UP	F02	Work Order Instruction	The site shall maintain records to demonstrate that Work Order Instructions are created from the agreed controlled Final Specification.	MEDIUM				X		Acceptable	Batch records reviewed indicate proper set up instructions are contained within the steps as outlined within the manufacturing and packaging instruction. Reference batch records for item 7-7806-1 dated 12/15/2022, lot 71052.

General Merchandise - Factory Technical Audit Checkpoints

PRODUCTION SET UP	F03	Production & Setup Sample	The site shall ensure that the Customer Approved Production Sample is available, that it is controlled, stored and maintained responsibly.	MEDIUM					X		The firm will manage production samples per customer request. They have indicated that for scope product, customer has not advised that this is required.
PRODUCTION SET UP	F04	Factory Reference Sample	The facility shall establish and maintain a process for the allocation and control of the production reference sample. The reference sample shall be controlled against the final approved customer sample.	MEDIUM					X		The firm will manage production samples per customer request. They have indicated that for scope product, customer has not advised that this is required.
PRODUCTION SET UP	F05	Testing	The facility shall establish and maintain a process to ensure that the test strategy (what to test, where, when and why?) is defined early in the development phase. The facility shall ensure, and be able to demonstrate, how the product meets the customer specification and legal requirements.	MEDIUM				X		Acceptable	Testing requirements are defined within the Quality Manual, rev 12/5, eff 2/22/2022. R&D, Legal and Regulatory provide testing requirements and evaluate legal compliance at the beginning of the product development stages. There is also a 90 day shelf life study completed as part of the process.
PRODUCTION SET UP	F06	Product / Engineering Change	The facility shall establish and maintain a process to manage, in the event of a change of specification or sample, a clear process, including records, for the implementation of the changes, specifications, production sample, work instruction and approved sample.	MEDIUM				X		Acceptable	SOP Management of Change, rev 5, eff May 2009 adequately describes the change management process. The most recent change was reviewed, Change ID 26, dated 7/11/2016, and is acceptable. Capex projects also include a section to determine and document if the change management process is necessary depending on the project scope.
PRODUCTION SET UP	F07	Product / Engineering Change	A process shall be in place to ensure that changes are validated to meet all specifications / requirements	MEDIUM				X		Acceptable	SOP Management of Change, rev 5, eff May 2009 adequately describes the change management process and includes provisions for trials where validation is identified as a requirement within the scope of the change. Note, no such changes related to scope product have taken place.
PRODUCTION SET UP	F08	Production Controls	The facility shall determine that where appropriate, equipment shall be set up and transition procedures established, in order to prevent cross contamination from one product or material to another.	MEDIUM				X		Acceptable	Cleaning requirements and procedures are included for mix tanks within the manufacturing instruction. Example: Batch for item 429-1799 dated 1/31/2022 includes instructions for cleaning prior to batch commencing. Line clearance for packaging is defined in the Quality Manual, rev 12.5, eff 2/22/2022 and requires QA signoff and approval of cleaning.
PRODUCTION SET UP	F09	Machine Parameter	Machine parameters shall be determined according to the customer approved sample and technical process	MEDIUM				X		Acceptable	Production test runs are performed to determine machine parameters as evidenced by product test report ID #TST-022321-03 dated 2/23/2021.
PRODUCTION SET UP	F10	Machine Parameter	Machine operational instructions / parameters shall be prepared and followed in the production processes	MEDIUM				X		Acceptable	Production test runs are performed to determine machine parameters as evidenced by product test report ID #TST-022321-03 dated 2/23/2021. Once machine settings are determined for a certain line/process they do not change unless the change management process is utilized.
	F		**TOTAL:**	**10**	**---**	**0**	**0**	**8**	**2**		**100.0%**

Section	Clause	Criteria / Requirements	Checkpoints	Weighting	0	1	2	3	N/A	Severity of finding	Observation or Non-Conformance
PRODUCT CONFORMITY - Formulated Products	G01	Pre-Production Meeting and Preparation	The facility shall hold pre-production meetings where objectives are set. Appropriate meeting records shall be kept.	MEDIUM				X		Acceptable	Records of twice daily shift meetings were reviewed from Oct 2022 to present and are acceptable.
PRODUCT CONFORMITY - Formulated Products	G02	Pre-Production Meeting and Preparation	The facility shall ensure that Pre-Production meetings involve the appropriate representatives from all the related production departments	MEDIUM				X		Acceptable	Records of twice daily shift meetings were reviewed from Oct 2022 to present and are acceptable. Such meetings are attended by appropriate QA/QC, Engineering and Production staff.
PRODUCT CONFORMITY - Formulated Products	G03	Pre-Production Meeting and Preparation	The meeting shall highlight CCPs for the production and QC/QA	MEDIUM				X		Acceptable	Records of twice daily shift meetings were reviewed from Oct 2022 to present and are acceptable.
PRODUCT CONFORMITY - Formulated Products	G04	Pre-Production Meeting and Preparation	The facility shall ensure that operational instructions are prepared and posted in appropriate areas for those critical production processes	MEDIUM				X		Acceptable	Operational instructions were observed as being available in multiple locations.
PRODUCT CONFORMITY - Formulated Products	G05	Control Sample / Approved Sample	The facility shall control each of the production samples. The samples shall be approved and signed with comments by the facility quality assurance department	MEDIUM				X		Acceptable	Samples of bulk solution and finished packaged product are reviewed and approved by QA.
PRODUCT CONFORMITY - Formulated Products	G06	First Output or Pilot Run	The facility shall have an appropriate first output/pilot run inspection arrangement. The inspector shall have the necessary authority to stop or change the production to address quality issues.	HIGH				X		Acceptable	Quality Manual rev 12.5 dated 2/22/2022 states that all employees are empowered to stop/change production to address quality issues.
PRODUCT CONFORMITY - Formulated Products	G07	First Output or Pilot Run	The facility shall make available for review any inspection reports or samples for the first output/pilot run	HIGH				X		Acceptable	Production test run report ID #TST-022321-03 dated 2/23/2021 was reviewed and is acceptable.

General Merchandise - Factory Technical Audit Checkpoints

PRODUCT CONFORMITY - Formulated Products	G08	Quality Control	The facility shall establish and maintain an effective in-line quality control and inspection process. The frequency of the process shall be effective for the respective volumes and risks. Records and samples from the in-line QC process shall be retained	MEDIUM				X		Acceptable	In-line QC inspection is defined within batch records and the Quality Manual, rev 12.5, eff 2/2022. Batch records reviewed indicated these were followed and retained. Reference batch records for item 7-7806-1 dated 12/15/2022, lot 71052.
PRODUCT CONFORMITY - Formulated Products	G09	Finished and Packing	The facility shall establish and maintain a packing approval process for the 1st output packing, to include, but not limited to barcodes and labelling etc.	HIGH				X		Acceptable	First output packaging approval for scope product dated 11/19/2020 was reviewed and barcoding and labeling is checked within packaging records.
PRODUCT CONFORMITY - Formulated Products	G10	Finished and Packing	The facility shall ensure that there is an AQL inspection (or other equivalent inspection system) for the finished goods before shipment. Where issues are identified, the facility shall develop and implement necessary corrective actions. Records of said corrective actions and results shall be maintained.	HIGH				X		Acceptable	Finished product is not released until QA has provided approval that all in process batching and finished product packaging inspections are complete and pass.. This is outlined in the Quality Manual, rev 12.5, eff 2/22/2022. If any issues are identified, they would be managed via the firm's nonconformance process.
PRODUCT CONFORMITY - Formulated Products	G11	Finished and Packing	The facility shall ensure that the utilized Sampling plan is appropriate to the lot size and respective product risk	MEDIUM				X		Acceptable	Finished product is not released until QA has provided approval that all in process batching and finished product packaging inspections are complete and pass.. This is outlined in the Quality Manual, rev 12.5, eff 2/22/2022. If any issues are identified, they would be managed via the firm's nonconformance process.
PRODUCT CONFORMITY - Formulated Products	G12	Testing (external and internal)	The facility shall maintain evidence to demonstrate that all products are subjected to analysis or testing to confirm product safety, legality and quality. Any relevant 3rd party testing reports shall be retained and provided for the auditors review upon request.	MEDIUM				X		Acceptable	All products are subjected to in process analysis for bulk solution and during packaging. This includes water bath testing for DOT compliance, DI water micro testing and in - house analysis.
PRODUCT CONFORMITY - Formulated Products	G13	Testing (external and internal)	Production samples shall be selected and tested at CCPs during production and samples retained for reference.	MEDIUM				X		Acceptable	Production retains are kept as evidenced by retain lot of scope product 492t2 produced 10/19/2022 and retain of bulk solution dated 12/15/2022 lot 2co57. All product is tested per Quality Manual rev 12.5, eff 2/22/2022
PRODUCT CONFORMITY - Formulated Products	G14	Reject / Reworked Product Handling	The facility shall establish and maintain a process to ensure effective handling of defective items. Defectives in production shall be segregated, labelled, recorded and analyzed. Reworked product to be resubmitted to the production line shall be subject to testing and inspection. Evidence shall be retained to demonstrate that results are analyzed and any highlighted corrective actions are followed, with measurable and timely improvements	MEDIUM				X		Acceptable	Quality Manual rev, 12.5, eff 2/22/2022 includes provisions for defective items. These are handled via the firm's nonconformance system. There have been no nonconformances for scope product; however, a list of all nonconformances was provided from 2022 to present and found to be acceptable.
PRODUCT CONFORMITY - Formulated Products	G15	Waste Handling	Liquid and solid waste/refuse receptacles shall be adequately labeled for identification.	MEDIUM				X		Acceptable	SOP 57, rev 23, eff 6/13/2012 Hazardous Waste Handling describes the process for proper disposal of rejected materials and components. Components and materials are placed in color coded drums, depending on their risk category, and color coded for proper waste stream disposal.
PRODUCT CONFORMITY - Formulated Products	G16	Waste Handling	Liquid and solid waste/refuse receptacles shall be properly handled and disposed.	MEDIUM				X		Acceptable	SOP 57, rev 23, eff 6/13/2012 Hazardous Waste Handling describes the process for proper disposal of rejected materials and components. Components and materials are placed in color coded drums, depending on their risk category, and color coded for proper waste stream disposal.
PRODUCT CONFORMITY - Formulated Products	G17	Production Change Over	Pre-operational or change over inspection records shall show: sanitation effectiveness and line conditions prior to start up; and note when these conditions are deficient.	HIGH				X		Acceptable	Sanitation effectiveness and line conditions are documented in batch records.
PRODUCT CONFORMITY - Formulated Products	G18	Environmental Controls	Within production and storage areas, the facility shall establish and maintain control of temperature, humidity, and light conditions.	MEDIUM				X		Acceptable	Some materials used at the site only require protection from freezing, and no other controls are required. The firm stores such materials in HVAC controlled storage areas that are maintained at ambient temps.
PRODUCT CONFORMITY - Formulated Products	G19	Environmental Controls	The physical conditions of production and storage areas shall be maintained in accordance with the requirements of the products under assessment.	MEDIUM				X		Acceptable	Some materials used at the site only require protection from freezing, and no other controls are required. The firm stores such materials in HVAC controlled storage areas that are maintained at ambient temps.
PRODUCT CONFORMITY - Formulated Products	G20	Job Details and Qualification	Current CVs/Resumes shall be available for supervisory/management personnel demonstrating qualification for assigned roles.	MEDIUM				X		Acceptable	Current resumes for laboratory technician and accountant were reviewed and acceptable. Other managers responsible for Q related activities are tenured (over 20 years).

General Merchandise - Factory Technical Audit Checkpoints

PRODUCT CONFORMITY - Formulated Products	G21	Failure Investigations	Where Non-Conforming Material/Defect investigations are conducted Quality shall be actively involved. Follow up actions shall be based upon sound rationale with root cause analysis, and be documented with records maintained.	HIGH				X		Acceptable	Nonconformance log from 2022 to present was reviewed and is acceptable. Product nonconformance report #22-070 dated 3/1/2022, #22-094 dated 12/28/2022 were reviewed and are acceptable.
PRODUCT CONFORMITY - Formulated Products	G22	Internal Audits	Follow up audits shall be conducted on findings and non-conformances to verify effectiveness of Corrective Actions taken. If repeat items are found they shall be escalated to Management to effect a timely Corrective Action.	MEDIUM	X					Minor	CAR 9: The current nonconformance management process does not include an effectiveness verification of CAPAs. This is under development.
PRODUCT CONFORMITY - Formulated Products	G23	Corrective Actions/Corrective Action Plans	Internal Audit Findings or Non-Conformances shall be recorded and acted upon in Corrective Action/Preventive Action format addressing root causes.	HIGH			X			Minor	CAR 10: The firm does not have an internal audit programme to assess their Quality Management System and therefore there are no nonconformances issued for internal audit findings.
PRODUCT CONFORMITY - Formulated Products	G24	Corrective Actions/Corrective Action Plans	CAPAs shall be: ACTIVELY managed (evidenced by discussion in regular Quality/Production/Management meetings) and established within a reasonable time frame.	HIGH				X		Acceptable	CAPA tracking log from 2022 to present was reviewed and indicated that they were being properly managed to ensure closure in a timely manner.
PRODUCT CONFORMITY - Formulated Products	G25	Corrective Actions/Corrective Action Plans	Quality shall be involved with CAPAs for oversight, approval, and effectiveness verification.	HIGH				X		Acceptable	QA lab leader owns/oversees the nonconformance/CAPA management process.
PRODUCT CONFORMITY - Formulated Products	G26	Incoming Material Assessment	Procedures shall be established and maintained requiring both inbound and outbound shipping vehicles to be inspected for: cleanliness; pest activity; state of good repair; foreign materials; odor; or potential sources of contamination.	MEDIUM				X		Acceptable	SOP 140, rev 1, eff 12/02/2010 Trailer Inspection - Incoming includes provisions for inbound trailer inspections; SOP 141, rev 2, eff 6/1/2011 Trailer Inspections - Outgoing includes provisions for inspection of outbound/finished goods trailers.
PRODUCT CONFORMITY - Formulated Products	G27	Incoming Material Assessment	Shipping/receiving documents shall show: inspections are conducted; objectional conditions are recorded and addressed appropriately.	MEDIUM				X		Acceptable	Evidence - PO PP-012423 dated 1/24/2023 for material p/n 5-8890 Value Lemon Mod fragrance includes inbound trailer inspection stamp as acceptable. BOL 19108615 dated 12/30/2022 included an approval stamp for outbound trailer inspection.
PRODUCT CONFORMITY - Formulated Products	G28	Material Storage	The facility shall secure all materials within their control (raw materials, work in progress, finished products, Etc.) in a manner to prevent intentional (malicious/economically motivated) and unintentional contamination.	HIGH				X		Acceptable	Materials were observed as securely stored.
PRODUCT CONFORMITY - Formulated Products	G29	Material Requalification	The facility shall have a formal program for the requalification of raw materials held for extended periods of time or past manufacturers expiration date, ensuring requalified materials meet required specifications.	HIGH				X		Acceptable	The Quality Manual, rev 12.5, eff 12/22/2022 includes provisions for out of date materials to be re-certified by the supplier with a new CofA sent, otherwise they are not used.
PRODUCT CONFORMITY - Formulated Products	G30	Complaint Handling	The facility shall have a documented program for the handling of customer and consumer complaints. The program shall address: responsible personnel; investigations; corrective actions; unique identification of each complaint; product identification; production dates; cause and origin of complaint; and timeliness of actions.	HIGH				X		Acceptable	SOP 23, rev 2, eff 11/12/2013 Complaint Procedures describes this process. Reference: Complaint ID S-5983061 for scope product, lot code G06015 dated 5/2/2022 and complaint dated 7/2/2020 (non scope product) for product lot CN100N4 that included laboratory investigation via review of retains.
PRODUCT CONFORMITY - Formulated Products	G31	Incident Management System	The facility shall establish and maintain a documented program requiring Certification Body notification without undue delay In the event of: a Recall or Market Withdrawal due to safety or quality issues; or any action taken against products by a governing body (e.g. US Consumer Product Safety Commission; US Environmental Protection Agency).	HIGH				X		Acceptable	Quality Manual, rev 12.5, eff 2/22/2022 describes the notification requirements and includes customers and regulatory bodies.
PRODUCT CONFORMITY - Formulated Products	G32	Returned Products	A documented program shall be established and maintained for the administration of returned finished products.	HIGH				X		Acceptable	Return goods process is outlined in the Quality Manual, rev 12.5, eff 2/22/2022. There have been no returns of scope product.
PRODUCT CONFORMITY - Formulated Products	G33	Returned Products	Records for returned products shall show: reason for return; determination of scrap, rework, restock, or other disposition; dates of decisions; and individuals with authority.	HIGH				X		Acceptable	Return goods process is outlined in the Quality Manual, rev 12.5, eff 2/22/2022. There have been no returns of scope product.
PRODUCT CONFORMITY - Formulated Products	G34	Finished Goods Release	The facility shall establish and maintain adequate controls preventing the unauthorized release or shipment of finished products.	HIGH				X		Acceptable	Finished product is not released until QA has provided approval. This is outlined in the Quality Manual, rev 12.5, eff 2/22/2022.
PRODUCT CONFORMITY - Formulated Products	G35	Laboratory Chemicals	The facility shall establish and maintain a documented procedure for the: receipt; handling; storage; preparation; use; and disposal of all chemicals, standards, reagents, and solutions used in the laboratory.	HIGH			X			Minor	CAR 11: The facility does not have a documented procedure for the receipt, handling, storage, preparation, and use of standards, reagents and solutions used in the lab. There is a procedure for lab waste disposal included in the hazardous waste management process.

General Merchandise - Factory Technical Audit Checkpoints

PRODUCT CONFORMITY - Formulated Products	G36	Laboratory Chemicals	The facility shall adequately document the preparation, and use, of standards, reagents, and solutions in laboratory notebooks.	HIGH			X			Minor	CAR 12: There is no documentation in lab notebooks retained as to the preparation and use of standards, reagents and solutions.
PRODUCT CONFORMITY - Formulated Products	G37	Laboratory Chemicals	Standard, reagent, and solution containers shall be labeled to indicate: date received; date opened; and expiration date.	HIGH			X			Minor	CAR 13: Standard, reagent and solution containers are labeled only with the date of receipt and do not include date opened or expiration date.
PRODUCT CONFORMITY - Formulated Products	G38	Quality Release	Quality shall conduct a documented and appropriate review of production and laboratory/testing records prior to release of finished products.	HIGH				X		Acceptable	QC/QA complete bulk solution testing once the batch is mixed. They release the bulk solution once lab testing is complete. The release form is forwarded to the mixing department as an approval to send the solution on to be packaged. Packing QC checks are completed throughout the packing process. QA attaches a release tag to the final pallets of finished product as indication that the batch is approved for release. Evidence batch approval for finished product code 429-1799, dated 2/1/2022.
PRODUCT CONFORMITY - Formulated Products	G39	Record Retention	The facility shall establish and maintain a program for the retention of production and laboratory documents and records. Documents and records shall be retained for the use life of the product.	HIGH				X		Acceptable	Quality Manual, rev 12.5, eff 2/22/2022 describes the record retention requirements as production records need to be kept for 5 years unless customer requires a longer retention period.
PRODUCT CONFORMITY - Formulated Products	G40	Batch Production Records	Batch production records shall contain the following: Required quantities of materials needed (BOM); Instructions with adequate details for critical steps in manufacturing process (blend times, sequence of raw materials use, collection of samples, etc.).	HIGH				X		Acceptable	Batch records for scope product batch 7-7806, lot 3A069 dated 1/11/2023 and lot 71-52 dated 15/15/2022 were reviewed and are acceptable.
PRODUCT CONFORMITY - Formulated Products	G41	Batch Production Records	Batch production records shall record the following: Actual quantities and lot codes of materials used; Documentation of critical step execution with verification by second individual (recording date/time/ duration of blending, recording date/time/sequence of raw material use); Personnel involved in production; Equipment used in production; Production batch lot code.	HIGH				X		Acceptable	Batch records for scope product batch 7-7806, lot 3A069 dated 1/11/2023 and lot 71-52 dated 15/15/2022 were reviewed and are acceptable.
PRODUCT CONFORMITY - Formulated Products	G42	Production Equipment Cleanliness	The facility shall establish written procedures and maintain a documented program to ensure cleanliness of production equipment.	HIGH				X		Acceptable	Cleaning instructions are included in both the Preventive Maintenance work orders and within batch records. Batch records for scope product batch 7-7806, lot 3A069 dated 1/11/2023 and lot 71-52 dated 15/15/2022 were reviewed and are acceptable.
PRODUCT CONFORMITY - Formulated Products	G43	Production Equipment Cleanliness	Production equipment cleanliness and operational capacity/status shall correlate with cleaning records.	HIGH				X		Acceptable	Cleaning records observed on line 2 production and packaging lines during tour confirmed cleaning steps defined in batching and packing records were completed prior to commencement.
PRODUCT CONFORMITY - Formulated Products	G44	Retain Samples	Retain samples shall be examined or tested during a complaint investigation, as necessary.	MEDIUM				X		Acceptable	Retain samples are utilized for complaint investigations as evidenced by complaint for lot CN1004 dated 7/2/2022.
PRODUCT CONFORMITY - Formulated Products	G45	Rework	The facility shall establish and maintain a documented Rework program. Rework shall be traceable to finished products, and shall be used "same into same". Rework shall be clearly identified, stored, and documented demonstrating full accountability. Reworked products shall be reviewed and released by authorized personnel.	CRITICAL				X		Acceptable	Rework is managed via the non-conforming product report, where QA reviews any non-conformance, provides instruction for rework activities, with final inspection sampling and release requirements. There has been no rework of scope product, however an example of another product rework report for incident #23-003 dated 1/24/2023 was reviewed and is acceptable.
PRODUCT CONFORMITY - Formulated Products	G46	Measurement Equipment Verification	On a daily basis, the facility shall verify the precision and accuracy of measuring and monitoring equipment critical to product safety, legality, and quality.	HIGH				X		Acceptable	Scales used for packaging weight checks are checked daily prior to use. Scale metrology service provider also calibrates on site every month. Evidence: Calibration certs for scale s/n 1228410533 and 3703005 dated 4/21/2022 to present.
PRODUCT CONFORMITY - Formulated Products	G47	Laboratory Testing	The facility's laboratory shall utilize analytical methods based upon appropriate methodology (e.g. USP, CSMA, ASTM, AOCA, Etc.).	CRITICAL				X		Acceptable	Test methods for Appearance, Odor, Identity (FTIR), Refractive Index were reviewed and are acceptable.
PRODUCT CONFORMITY - Formulated Products	G48	Laboratory Analysis	Release testing, including laboratory analysis, shall provide evidence that all finished products meet required release criteria, including microbiological testing (when applicable).	CRITICAL				X		Acceptable	Release testing for batch records for scope product batch 7-7806, lot 3A069 dated 1/11/2023 and lot 71-52 dated 15/15/2022 were reviewed and are acceptable.
PRODUCT CONFORMITY - Formulated Products	G49	Chemical Control	Restricted, potentially toxic, or hazardous chemicals shall be inventoried upon receipt with use logs maintained.	HIGH				X		Acceptable	Restricted, potentially toxic or hazardous chemicals area inventoried upon receipt and are logs maintained.

General Merchandise - Factory Technical Audit Checkpoints

PRODUCT CONFORMITY - Formulated Products	G50	Chemical Control	Restricted, potentially toxic, or hazardous chemicals shall be subject to regular cycle counts, with inventory discrepancies investigated and explained.	HIGH				X		Acceptable	Restricted, potential toxic or hazardous chemicals are subject to regular (daily) cycle counts with inventory discrepancies investigated and explained. For example a cycle count dated 12/20/2022 of material SDA indicated a discrepancy. QA completed an investigation that concluded the measurement probe was defective and a replacement was ordered.
	G		**TOTAL:**	**50**	**0**	**0**	**5**	**45**	**0**		**92.5%**

Section	Clause	Criteria / Requirements	Checkpoints	Weighting	0	1	2	3	N/A	Severity of finding	Observation or Non-Conformance
ADMINISTRATION AND TRAINING	H01	Organization & Structure	An organization chart shall be in place and show the management structure.	MEDIUM				X		Acceptable	Org chart dated 2/7/2023 reviewed and acceptable.
ADMINISTRATION AND TRAINING	H02	Deputizing Cover	Personnel who are crucial to the implementation of the QMS and responsibility for the production of safe and legal products (i.e. manage CCP) must have a documented deputy cover.	MEDIUM				X		Acceptable	QMS responsibilities are defined within the Quality Manual, rev 12.5, eff 2/22/2022, job descriptions and procedures. The firm has highly tenured QA, Regulatory, Legal personnel, with over 20 years experience.
ADMINISTRATION AND TRAINING	H03	Job Details and Organization	There shall be clear definition of functions, roles and responsibilities for core members. (i.e. Designer, Technicians, Engineers, Pattern Maker...etc.) Written job descriptions should be available for the core roles.	MEDIUM				X		Acceptable	Responsibilities are defined within the Quality Manual, rev 12.5, eff 2/22/2022, job descriptions and procedures. Job descriptions for Quality Control Inspector, Maintenance Mechanic, Maintenance Supervisor reviewed and are acceptable.
ADMINISTRATION AND TRAINING	H04	Training - Worker Qualification	Workers must have appropriate qualifications and training to perform their assigned tasks (e.g. Chemical Handling, heavy machinery use, Assembly workers, QA/QC, Ironing, CAD/CAM...etc.) Sufficient supervisory support shall be provided where needed. Relevant training records shall be maintained.	HIGH				X		Acceptable	Training records for Quality Control Inspector, Gasser Line Operator and Maintenance Supervisor were reviewed and are acceptable.
ADMINISTRATION AND TRAINING	H05	Performance Review	The continual competency of employees shall be reviewed at defined intervals and re-training provided where necessary.	MEDIUM				X		Acceptable	Competency of training topic understanding is assessed via testing and performance reviews.
ADMINISTRATION AND TRAINING	H06	Hygiene	The facility shall establish and maintain a policy regarding personnel hygiene requirements. Relevant training shall be provided as necessary (Such as: food policy, wearing of Jewelry & rings,...etc.) ** note wedding bands are typically allowed. Any other such exclusions shall be documented in the policy.	MEDIUM				X		Acceptable	Chase Rules and Regulations, eff 2/21/2022, describes the attire and food/drink policy. This is reviewed daily with operators and signature of understanding obtained. Evidence Rules and Regulations training for Line #2 dated 2/6/2023.
ADMINISTRATION AND TRAINING	H07	Inspectors	Inspectors shall be independent to the production team. They shall have the necessary authority to stop goods being shipped.	HIGH				X		Acceptable	QC Inspectors are independent of production; however per the Quality Manual rev 12.5, eff 2/22/2022 all Chase employees have authority to intervene when quality issues are detected.
	H		TOTAL:	**7**	**---**	**0**	**0**	**7**	**0**		**100.0%**