

Perseco Quality and Safety Audit for Packaging Items

Company Information	Audit Information
<p>Facility: 2K350 - ZIBO BLUE SAIL PLASTIC & RUBBER PRODUCTS CO. LTD.</p> <p>Address: SOUTH OF QING TIAN ROAD, LINZI DISTRICT ZIBO CITY, SHANDONG CHINA</p> <p>Contact: MS. KAREN ABELL Title: BASIC MEDICAL CONTACT Phone: Fax: Email: KarenA@BasicMedical.com</p>	<p>Audit#-Visit#: 126472 - 102176</p> <p>Audit Type: PKGMCD-Perseco Quality and Safety Audit for Packaging Items</p> <p>Template Version: 1.4</p> <p>Audit Category: REGULAR</p> <p>Auditor: LING(LAURA) LIU</p> <p>Auditor Phone:</p> <p>Audit Start Time: 22-APR-2008 08:30:00 AM</p> <p>Audit End Time: 22-APR-2008 06:00:00 PM</p> <p>Prior Audit Date: 20-APR-07</p> <p>Prior Audit Score: 93.5455%</p>

Facility And Operating Profile

No	Question/Notes
1	<p>Facility and Operations Description:</p> <p>Auditor's Notes: Shandong Blue Sail Plastic & Rubber Co.,Ltd was founded in May.,2003. It was located in Qilu Chemical industrial area in Linzi district of Zibo city in Shandong Province. There were three workshops in the plant. The plant produces PVC gloves which are all exported to other countries. There are appoximately 1,600 employees and the production has three shifts. The staff works 6 days a week.</p>
2	<p>Describe the product warehoused/produced for the client.</p> <p>Disposable vinyl food contact gloves powerdered free</p>
3	<p>The following departments and individuals participated in the audit process:</p> <p>- Mr. Zhang, QA manager. Liu Wei ,Assitant Marketing Manager Yan Dandan , officer in Zibo Intco Co, Ltd</p>
4	<p>Is the facility exempt from the Perseco HACCP addendum (score of 95% or higher on the previous audit)?</p> <p>No</p>
Section Notes:	

Score Summary By Section

Section Name	Section Score
Section A - Administration and Regulatory Compliance	89.00%
Section B - HACCP Management	92.00%
Section C - Facilities and Equipment	88.00%
Section D - Sanitation, Housekeeping and Hygiene	91.00%
Section E - Rodent and Pest Control Management	89.00%
Section F - Receiving and Inventory Control	96.00%
Section G - Process and Product Evaluation	93.00%
Section H - Packaging and Labeling	97.00%
Section I - Storage and Shipping	91.00%
Section J - Analytical Records and Laboratory Support	95.00%
Section K - Product Defense	95.00%
Product Safety, Quality and Product Defense Average Score:	92.36%

Overview

No	Question/Notes
	<p>Notes from the auditor: See Notes</p> <p>Zibo Blue Sail Company was built in 2002 and put into production in 2003. This company grows very rapidly. The third workshop was built and put into mass production in 2007. The company is in the plan of the production line expansion and equipment repair. Thus, some areas of workshop 1 and workshop 2 were in repair and under construction during this visit. Some equipments and utensils as well as construction materials were present outside.</p> <p>The company has been authorized the certification of ISO9001 and ISO13485 by TUV for the scope of the design, development, production and distribution of disposable patient examination and industrial gloves. The company has established a complete quality and safety and defense system. However, the recall plan needs to be improved to ensure the traceability as the deficiency noted at the report.</p> <p>The company has assembled a team and established the HACCP plan. In this HACCP plan, 4 CCPs were identified and monitored by trained staff. The documentation for CCP activities needs to be improved and the activities should be recorded in a correct way. The HACCP plan is suggested reviewed comprehensively by the team and verified for the effectiveness.</p> <p>For food packaging materials production, even though no microbiological testing required in the specification, the finished product exposed area such as drawing and packing room should be separated effectively from other production area to ensure the operation in a better hygienic condition. Additionally, the sanitation and hygienic practice of personnel at this area needs to be improved to avoid cross contamination or adulteration.</p> <p>The plant has written preventive maintenance program in place. The maintenance activities for major equipments and supporting facilities were documented and kept on file. Master maintenance schedule was suggested to be established so as that the regular activity would be easily identified and followed.</p> <p>The traceability exercise was practiced from the raw material to the finished product on site. It took nearly 4 hours. The batch blending sheet B310-080419-020 produced the products through different production line. This batch sheet number was documented on each production sheet from each production line to the finished product packaging. Purchase order number of the packaging sheet corporate with the batch sheet number to achieve the traceability. Due to one batch blending material for quite a few production line uses, the traceability exercise took a relatively long time. The recovery is 100%.</p>
Section Notes:	

Non-Compliance Summary

No	Question/Notes	Answer
Section A /3	<p>Specific Training Goals and Programs for Management and Operating Personnel</p> <p>Documents must be available to demonstrate management's commitment to a planned training program for both management and production personnel. The plan must include training of all new employees and refresher training for all current employees on a regular basis.</p> <p>The new hires didn't receive full training prior to work. The recode showed that one soaking operator was worked in Jan. 4,2008, but she was trained on Jan.10,2008.</p>	Minor*
Section A /4	<p>Recall Plan and Procedures</p> <p>A plant specific Recall Plan must be available. The plan must include all necessary contact information. All documentation related to product traceability must be available. A traceability exercise must be conducted at least twice per year.</p> <p>The plant has a written recall plan in place. Mock recall was conducted annually and traceability exercise was practised twice annually. However, the recall plan didn't out reach to the distribution center and the contact information of the client and the related regulatory wasn't included into the recall plan. In addition, it is suggested that the recovery of the recall product needs to be developed and the time frame needs to be recorded for the recall process.</p>	Minor*
Section B /9	<p>Documentation and Record Keeping (HACCP Principle 7)</p> <p>HACCP procedures must be documented with detailed corrective actions and product dispositions. Final records must be in ink, signed by the appropriate personnel and without missing data or blanks. Records must be securely stored and easily retrievable.</p> <p>The record for documenting CCP2 activities was not signed and the record for CCP4 activities was not available. The plant should document all CCP activities in a correct way if they identified the CCPS.</p>	Minor*

Non-Compliance Summary

No	Question/Notes	Answer
Section C /1	<p>Potable Water, Ice, Backflow Prevention, Steam and Waste Water Management</p> <p>The plant must demonstrate that the water supply is potable and that potability is maintained at all times. Potability must meet local requirements at a minimum. Water lines and hose drops must be fitted with backflow prevention devices that are tested by a trained inspector at least annually. There can be no dead ends on potable water lines. Hose nozzles must not be submerged in water reservoirs or left laying on the floor. An adequate supply of hot and cold water must be readily available for production, sanitation and handwashing. The facility must have a procedure for handling backed up drains.</p> <p>The recycled water pool was used for the leakage testing of the sampling gloves. No cleaning procedure was established and followed for this water storage facility.</p>	Minor*
Section C /4	<p>Employee Support Facilities</p> <p>The cafeteria, locker room and toilet facilities must be adequately sized, physically separated from production areas and maintained in a sanitary condition. Toilet facilities must be well ventilated, doors must be self-closing and can not open directly into the production areas. Signs must be clearly posted in locker rooms, toilet facilities and at entrances to work areas reminding employees to wash and sanitize their hands before starting work and when leaving toilet facilities.</p> <p>Toilet facilities at the entrance of the production area was not well ventilate and the doors were not self-closing type.</p>	Minor*
Section C /5	<p>Handwashing Facilities</p> <p>Hand washing facilities must be provided in locker rooms, toilet facilities and at entrances to work areas. They must be adequate in size, quickly deliver tempered water and maintained with hand soap and single service towels. Hands-free activated faucets must be available in and adjacent to processing areas.</p> <p>Hand washing facilities at the entrance to the production area of factory3 couldn't function properly. And the taps for all hand washing facilities were not hand free type.</p>	Minor*
Section D /9	<p>GMP Self Inspections and Corrective Actions</p> <p>Internal GMP self-inspections must be conducted to verify compliance to policies and to evaluate the effectiveness of the policies. Follow-up audit activities must be conducted to record the effectiveness of corrective actions for deficiencies and repeat items.</p> <p>The GMP inspection for hygienic practice and cleaning condition of the production area were performed weekly. However, no effective corrective actions were taken because one operator wore earring in the packaging area a week ago and this deficiency recurred during this on site visit .</p>	Minor*
Section E /1	<p>Documented and Specific Pest Control Program</p> <p>There must be a pest management program in place that is overseen by a licensed Pest Control Operator (PCO). Site maps for all traps and bait stations, documentation of services, Material Safety Data Sheet (MSDS), the PCO applicators license and letter of insurance must be current and on file.</p> <p>The program was established by the plant itself. However, to make the program proper and effective, the employees engaged as PCO should be trained adequately or obtain appropriate license.</p>	Minor*
Section E /4	<p>Pest Tight Doors and Entrance Closures</p> <p>All doors must be tight closing and no exterior holes/cracks in walls, pipe chase, vent openings, windows, etc., to provide easy access to pests.</p> <p>The doors open to the outside couldn't be closed tightly with gap presence around. The windows in the third workshop were not screened when open.</p>	Minor*
Section G /7	<p>Documentation Showing Product Meets Specifications</p> <p>Records must be maintained to assure that the appropriate product attributes were evaluated and that the results were consistent over time.</p> <p>Perseco required the suppliers of the packaging materials to ensure such packaging materials in compliance with safety requirements. The plant is suggested that the compliance documentation is kept on file and reviewed periodically. The product recovery sheet should be developed to facilitate traceability according to peseco quality assurance requirements.</p>	Minor*

Non-Compliance Summary

No	Question/Notes	Answer
Section I /3	<p>Storage Facility and Dock Maintenance</p> <p>Warehouse storage areas must be clean and orderly and have adequate space around the periphery for access, inspection and cleaning. Items must be stored off the floor, floors and walls must be in good condition and emergency doors must be tight fitting. Shipping docks, dock plates and levelers must be clean and kept orderly.</p> <p>The in process product case was placed directly on the floor, not off the floor with pallets beneath.</p>	<p>Minor*</p>

Section 1.A Product Name

No	Question/Notes	Answer
1	Product Name:	Disposable vinyl food contact gloves powder free

Section notes:

Section 2.A HACCP Team Assembly

No	Question/Notes	Answer
1	Has an individual or team been assigned to head-up the HACCP program?	Yes

Section notes: The team leader was Mr. Xu Xinrong. The team included vice general manager, QC department, equipment department, production department, technology department and business department. They all at least had 3 years of working experience in each position.

Section 3.A HACCP Plan Review

No	Question/Notes	Answer
1	Is an up-to-date HACCP plan available?	Yes
2	Does the HACCP plan identify the supplier's product?	Yes
3	Does the HACCP plan describe the product and intended use?	Yes
4	Does the HACCP plan list materials and raw ingredients?	Yes
5	Does the HACCP plan include a process flow diagram with CCPs?	Yes
6	Does the HACCP plan include a product/process hazard analysis?	Yes
7	Does the HACCP plan describe CCPs and critical limits?	Yes
8	Does the HACCP plan describe CCP monitoring and frequency?	Yes
9	Does the HACCP plan detail appropriate corrective actions?	Yes
10	Does the HACCP plan include record keeping requirements and responsibilities?	Yes
11	Does the HACCP plan include a verification plan, frequency and responsibilities?	Yes

Section notes: The HACCP review was excutivted along with the internal quality and safety audit annually. It is suggested that the review be specified and reviewed specifically by the HACCP team for the HACCP issue.

Section 4.A HACCP Plan Revalidation

No	Question/Notes	Answer
1	Has the HACCP plan been revalidated when product/process changes have occurred?	Yes

Section notes:

Section 5.A CCPs

No	Question/Notes	Answer
1	Is a procedure written and implemented at all CCPs?	Yes
2	Is a person responsible at each CCP aware of critical limits, monitoring frequency and corrective actions?	Yes

Section notes:

Section 6.A Corrective Actions

No	Question/Notes	Answer
1	Are deviation records available in a deviation file?	Yes

Section 6.A Corrective Actions

No	Question/Notes	Answer
2	Are deviations clearly identified and described?	Yes
3	Are product holds and dispositions appropriate?	Yes
4	Are actions to prevent recurrence fully described and implemented?	Yes
5	Does a manager routinely review deviation files?	Yes

Section notes:

Section 7.A Quality Assurance

No	Question/Notes	Answer
1	Is the effectiveness of the HACCP plan verified by any physical/chemical/microbiological testing?	Yes
2	Are all records accessible for verification?	Yes

Section notes:

Section 8.A Management Commitment

No	Question/Notes	Answer
1	Does plant manager and staff understand HACCP and support the plant's HACCP system?	Yes
2	Are those directly involved with CCPs trained?	Yes
3	Is the HACCP plan current, complete, accurate and being followed correctly? The record for documenting CCP2 activities was not signed and the record for CCP4 activities was not available. The plant should document all CCP activities in a correct way if they identified the CCPS.	No

Section notes:

Section 9.A NACMCF OR Codex Alimentarius Format

No	Question/Notes	Answer
1	Plan identification	PRESENT AND ACCEPTABLE
2	Product description and intended use	PRESENT AND ACCEPTABLE
3	Raw material/ ingredient list	PRESENT AND ACCEPTABLE
4	Flow diagram of process with CCPs	PRESENT AND ACCEPTABLE
5	Product/process hazard analysis	PRESENT AND ACCEPTABLE
6	CCPs and critical limits	PRESENT AND ACCEPTABLE
7	Monitoring method and frequency for CCPs	PRESENT AND ACCEPTABLE
8	Corrective actions (inc. disposition and responsibilities)	PRESENT AND ACCEPTABLE

Section 9.A NACMCF OR Codex Alimentarius Format

No	Question/Notes	Answer
9	Record keeping requirements and responsibilities	PRESENT AND ACCEPTABLE
10	Verification plan, frequency and responsibilities The responsibilities for the team member should be specified and the review should be executed by the specified team according to the plan.	NEEDS IMPROVEMENT
11	Based on our review of records, methods, and procedures, it is our opinion that this is an effectively implemented HACCP plan that complies with all McDonald's guidelines.	Yes
Section notes:		

Section A Administration and Regulatory Compliance

No	Question/Notes	Answer
1	Product Quality, Safety and Product Defense Organization and Responsibilities There must be a plant management organization chart that shows the reporting structure of the plant operating departments. The chart must clearly show the reporting relationship of the Quality Manager.	Acceptable
2	Product Quality, Safety and Product Defense Policies and Procedures There must be policies and procedures that address relevant product safety, quality and security requirements for the receiving, handling, manufacturing and shipping of product. The expectations should be defined through product and process specifications, testing procedures, sampling programs and accept/reject criteria.	Acceptable
3	Specific Training Goals and Programs for Management and Operating Personnel Documents must be available to demonstrate management's commitment to a planned training program for both management and production personnel. The plan must include training of all new employees and refresher training for all current employees on a regular basis. The new hires didn't receive full training prior to work. The recode showed that one soaking operator was worked in Jan. 4, 2008, but she was trained on Jan. 10, 2008.	Minor*
4	Recall Plan and Procedures A plant specific Recall Plan must be available. The plan must include all necessary contact information. All documentation related to product traceability must be available. A traceability exercise must be conducted at least twice per year. The plant has a written recall plan in place. Mock recall was conducted annually and traceability exercise was practised twice annually. However, the recall plan didn't out reach to the distribution center and the contact information of the client and the related regulatory wasn't included into the recall plan. In addition, it is suggested that the recovery of the recall product needs to be developed and the time frame needs to be recorded for the recall process.	Minor*
5	Regulatory Compliance The facility must maintain a file of regulatory actions, visits, reports or other notifications received from any regulatory agency. Written responses with appropriate corrective actions must be documented. A log of samples submitted for pathogen, antibiotic or environmental testing must be maintained.	Acceptable
6	Document and Records Management A document control policy must be in place that covers all aspects of creating, storing and disposing of documents.	Acceptable
7	Change Management There must be a policy in place to manage and communicates changes in specifications, policies and procedures in order to maintain continuity and the control of systems.	Acceptable
8	Documentation to Track Effectiveness of Policies Management reviews must take place to evaluate the level of conformance to operational policies.	Acceptable
9	Management Awareness and Commitment to Product Quality, Safety and Product Defense Management must be committed to product safety and quality. There active support should be shown through training programs, auditing for compliance to policies and provision of corrective actions.	Acceptable

Section A Administration and Regulatory Compliance

No	Question/Notes	Answer
10	Crisis and Natural Disaster Management A crisis management plan must be in place that defines emergency procedures, outlines the crisis team members and provides key contacts with 24/7 access.	Acceptable
11	Customer/Consumer Complaints (Policies, Follow Up and Response) There must be a customer complaint program in place that addresses responsibilities, response time and corrective actions based on the investigation of a complaint.	Acceptable
Section notes:		

Section B HACCP Management

No	Question/Notes	Answer
1	Prerequisite Programs Prerequisite programs must be well developed, documented and monitored.	Acceptable
2	Preliminary HACCP Tasks A HACCP team must be assembled with team member responsibilities clearly identified. Process flow diagrams outlining each step in the process must be constructed by the HACCP Team and they must perform an on site review to verify its accuracy.	Acceptable
3	Hazard Analysis (HACCP Principle 1) The HACCP team must prepare a list of all chemical, physical and biological hazards that may occur and conduct a hazard analysis to identify the hazards that are critical and controllable.	Acceptable
4	Critical Control Points (HACCP Principle 2) Documentation for determining a step or process as a CCP or not, must be clearly explained. Meetings must be conducted on a regular basis by the HACCP team to review any changes in the process that might affect the CCP determination.	Acceptable
5	Critical Limits (HACCP Principle 3) Control measures identifying operating and critical limits must be established and for each CCP. All critical limits must be measurable. Process capabilities must be documented to establish that CCP limits are compatible with the plant process and that limits are attainable.	Acceptable
6	CCP Monitoring (HACCP Principle 4) CCP monitoring procedures must be conducted at a frequency sufficient enough to detect any loss of control. The data must be evaluated by those empowered to implement corrective actions and must be documented on HACCP records.	Acceptable
7	Corrective Actions (HACCP Principle 5) Corrective actions must be developed for each CCP including instructions with the necessary actions to take to secure product and bring the CCP under control in the event a critical limit is exceeded.	Acceptable
8	Verification and Validation (HACCP Principle 6) Documentation must be available confirming the HACCP plan is scientifically and technically sound. The documentation should also confirm that all hazards have been identified and CCPs are effective and valid. Validation of the plan must be performed and documented on an annual basis.	Acceptable
9	Documentation and Record Keeping (HACCP Principle 7) HACCP procedures must be documented with detailed corrective actions and product dispositions. Final records must be in ink, signed by the appropriate personnel and without missing data or blanks. Records must be securely stored and easily retrievable. The record for documenting CCP2 activities was not signed and the record for CCP4 activities was not available. The plant should document all CCP activities in a correct way if they identified the CCPS.	Minor*
Section notes:		

Section C Facilities and Equipment

No	Question/Notes	Answer
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Section C Facilities and Equipment

No	Question/Notes	Answer
1	<p>Potable Water, Ice, Backflow Prevention, Steam and Waste Water Management The plant must demonstrate that the water supply is potable and that potability is maintained at all times. Potability must meet local requirements at a minimum. Water lines and hose drops must be fitted with backflow prevention devices that are tested by a trained inspector at least annually. There can be no dead ends on potable water lines. Hose nozzles must not be submerged in water reservoirs or left laying on the floor. An adequate supply of hot and cold water must be readily available for production, sanitation and handwashing. The facility must have a procedure for handling backed up drains. The recycled water pool was used for the leakage testing of the sampling gloves. No cleaning procedure was established and followed for this water storage facility.</p>	Minor*
2	<p>Facility Construction and Design The construction of the facility must be such that it facilitates the production of wholesome product and that it meets the customer and regulatory product safety and quality requirements. Materials must be easily cleanable, floors well drained and drains must have traps and covers. The plant must be designed in a manner appropriate to prevent the contamination of product. A glass and brittle plastic program must be in place.</p>	Acceptable
3	<p>Facility Condition (Walls, Ceilings, Floors, etc.) Walls, ceilings and floors must be well maintained, orderly, clean and sealed. No evidence of water leakage, rust or flaking paint. No string, rope, wire or tape used as supports or temporary repairs. Overhead structures must be clean and free of buildup.</p>	Acceptable
4	<p>Employee Support Facilities The cafeteria, locker room and toilet facilities must be adequately sized, physically separated from production areas and maintained in a sanitary condition. Toilet facilities must be well ventilated, doors must be self-closing and can not open directly into the production areas. Signs must be clearly posted in locker rooms, toilet facilities and at entrances to work areas reminding employees to wash and sanitize their hands before starting work and when leaving toilet facilities. Toilet facilities at the entrance of the production area was not well ventilate and the doors were not self-closing type.</p>	Minor*
5	<p>Handwashing Facilities Hand washing facilities must be provided in locker rooms, toilet facilities and at entrances to work areas. They must be adequate in size, quickly deliver tempered water and maintained with hand soap and single service towels. Hands-free activated faucets must be available in and adjacent to processing areas. Hand washing facilities at the entrance to the production area of factory3 couldn't function properly. And the taps for all hand washing facilities were not hand free type.</p>	Minor*
6	<p>Equipment Layout, Design and Conditions Equipment must be designed, installed and maintained in a manner that provides a safe, wholesome and quality product with easy access for cleaning and sanitizing. Product contact surfaces must be constructed with materials that are smooth, impervious, non-toxic, non-absorbent and corrosion resistant with appropriate covers and no metal-to-metal contact between moving parts.</p>	Acceptable
7	<p>Facility Lighting and Protection Adequate illumination must be provided and lighting must be protected from breakage and possible contamination. Light fixtures must be maintained clean, free of cracks, dust or other materials that could cause contamination.</p>	Acceptable
8	<p>Maintenance Standard (Support of GMPs, Housekeeping, Lubricants) There must be a documented preventative maintenance program that covers the equipment and facilities. Permanent repairs must be made promptly.</p>	Acceptable

Section notes:

Section D Sanitation, Housekeeping and Hygiene

No	Question/Notes	Answer
1	<p>Master Sanitation List and Monitoring There must be a documented cleaning procedure for operational areas, equipment, warehouse, storage, maintenance, employee support areas and other plant areas. There must be scheduled tasks for all cleaning procedures that are monitored and documented.</p>	Acceptable

Section D Sanitation, Housekeeping and Hygiene

No	Question/Notes	Answer
2	<p>Standard Sanitation Operating Procedures and Monitoring There must be documented Standard Sanitation Operation Procedures detailing the cleaning methods and frequency of cleaning for all equipment and facility structures. All cleaning and sanitizing must be documented and monitored. Records must be kept of all deficiencies found and the corrective action that is taken to bring the equipment into a sanitary condition and prevent a reoccurrence.</p>	Acceptable
3	<p>Cleaning Chemical Control There must be procedures that specify the proper dilution of chemicals and/or sanitizers. All chemical containers must be properly labeled and used for their intended purpose only. Chemicals must be securely stored during periods of non-use.</p>	N/A
4	<p>Monitoring and Corrective Action A routine documented inspection program must be in place to assess sanitation practices and conditions prior to daily operation. Deficiencies must be noted and corrective actions taken.</p>	Acceptable
5	<p>Verification of Cleaning Effectiveness The effectiveness of the sanitation program must be monitored visually prior to production and supplemented with an objective measurement at a frequency that demonstrates effectiveness.</p>	Acceptable
6	<p>Operational Housekeeping and Monitoring All areas of the plant must be kept clean, orderly and free from accumulation of litter. Garbage, trash and waste materials must be accumulated in identified containers and disposed of properly. Floor drains must be kept clean, odor free and covered. No tool storage or materials on top of equipment, electrical boxes or window ledges.</p>	Acceptable
7	<p>Personal Hygiene and Good Manufacturing Practices There must be a dress code that is enforced for everyone entering the facility. Employees must wear clean clothing and shoes appropriate for the working conditions. Hair restraints must be worn in all processing and warehouse areas. Employees working in production areas must not wear fake fingernails, fingernail polish, jewelry, rings, or watches, etc. Employees cannot work in processing areas if they have a communicable illness, or open sores. Employees must wash their hands before starting work and any time necessary to avoid product contamination. If gloves are worn, they must be intact, with no holes, and kept clean. There must be a means to avoid contamination of outer clothing when using the toilet facilities. Eating, drinking or using tobacco products must not be permitted except in designated areas.</p>	Acceptable
8	<p>Sanitation and Corrective Action Employees working with products that could become food contact surfaces must take additional precautions to protect product from microbiological cross contamination. Personnel handling products that could become food contact surfaces must wear sanitary gloves.</p>	Acceptable
9	<p>GMP Self Inspections and Corrective Actions Internal GMP self-inspections must be conducted to verify compliance to policies and to evaluate the effectiveness of the policies. Follow-up audit activities must be conducted to record the effectiveness of corrective actions for deficiencies and repeat items. The GMP inspection for hygienic practice and cleaning condition of the production area were performed weekly. However, no effective corrective actions were taken because one operator wore earring in the packaging area a week ago and this deficiency recurred during this on site visit .</p>	Minor*
Section notes:		

Section E Rodent and Pest Control Management

No	Question/Notes	Answer
1	<p>Documented and Specific Pest Control Program There must be a pest management program in place that is overseen by a licensed Pest Control Operator (PCO). Site maps for all traps and bait stations, documentation of services, Material Safety Data Sheet (MSDS), the PCO applicators license and letter of insurance must be current and on file. The program was established by the plant itself. However, to make the program proper and effective, the employees engaged as PCO should be trained adequately or obtain appropriate license.</p>	Minor*
2	<p>Outside Premises Management (Grounds, Waste Disposal Areas) The buildings exterior and grounds must be well maintained and free from pest harborages. Adequate trash and waste disposal facilities must be available and the premises must be free from standing water that could attract pests.</p>	Acceptable

Section E Rodent and Pest Control Management

No	Question/Notes	Answer
3	Inside Premises Management Interior conditions must be orderly, clean throughout and allow for easy access and evaluation along walls. Control measures must be used at distances from product surfaces to avoid any potential for contamination. Trapping devices must be in proper working condition and no bait stations can be used inside the plant or warehouse.	Acceptable
4	Pest Tight Doors and Entrance Closures All doors must be tight closing and no exterior holes/cracks in walls, pipe chase, vent openings, windows, etc., to provide easy access to pests. The doors open to the outside couldn't be closed tightly with gap presence around. The windows in the third workshop were not screened when open.	Minor*
5	Secure Storage and Documentation of Pest Related Chemicals If pest related chemicals are stored on site, they must be stored in a secured location with limited access. An up to date inventory log of chemicals must be maintained. Containers must be destroyed once empty. Safety precautions for storage of pest related chemicals must be available.	Acceptable
6	Activity Reports Detailed with Corrective Actions Activity reports must be available with specific details about all pest activity observed. Recommended corrective actions should be included on the reports as well as details about the chemicals used in response to the observed activity. Activity reports must be signed by the PCO and by a designated plant representative. All deficiencies require documented corrective action.	Acceptable
Section notes:		

Section F Receiving and Inventory Control

No	Question/Notes	Answer
1	Incoming Vehicle Review and Documentation There must be a written inspection program that describes acceptable and/or unacceptable conditions for all inbound carriers. All inbound carriers must be inspected for product safety, quality and security related concerns at the time of receiving.	Acceptable
2	Specific Receiving Policies with Inspection and Acceptance Plans All materials and supplies must be purchased from approved vendors. Current specifications for purchased supplies must be available. Incoming materials must be inspected for damage, contamination and other unacceptable conditions as described by the receiving policy. Records must be maintained along with supplier codes for lot traceability.	Acceptable
3	Release Criteria for Materials. All materials must be maintained in a secure fashion and released for use against a defined approval program. An inventory management system must be in place to assure proper rotation.	Acceptable
4	Storage and Handling Policies and Practices There must be established procedures to assure that materials and supplies do not become a source of contamination. Receiving areas and storage locations must be maintained in a clean and sanitary manner. All materials and supplies must be held under conditions necessary to maintain product integrity.	Acceptable
5	Bulk Receiving Systems Sanitation and Monitoring Bulk material handling and storage equipment must be maintained in a sanitary and secure manner. The cleaning procedures and frequencies must be documented.	Acceptable
6	Restricted and/or Sensitive Material Control, Including Chemical Compounds All restricted or sensitive materials, potentially toxic chemicals and allergenic materials must be maintained under strict control and stored separately to minimize the potential for accidental product contamination.	Acceptable
Section notes:		

Section G Process and Product Evaluation

No	Question/Notes	Answer
1	Process Control and Documentation Procedures There must be established process control procedures to assure products meet all product safety requirements. In-process materials and products must be adequately protected and properly labeled with date and lot number.	Acceptable

Section G Process and Product Evaluation

No	Question/Notes	Answer
2	Specification and Formulation Control and Accuracy Records must be available that demonstrate compliance to product formulations and finished product specifications. Test protocols and frequencies must be followed as identified in the specification. Production records must be maintained for twelve months beyond product shelf life.	Acceptable
3	Routine Calibration of Operational Equipment and Measuring Devices (such as thermometers, scales, flow meters, counters, metal detectors, etc.) Key process control devices must be calibrated by an outside contractor at least annually. All devices must also be monitored internally at a frequency adequate to verify accuracy during day to day usage. Corrective actions must be documented when measuring devices are found to be out of calibration.	Acceptable
4	Foreign Material Control All finished product must be scanned through an instrument calibrated to identify and separate contaminated product. There must be a written procedure describing the maintenance, set-up and verification tests of detector systems with documentation to show the procedures are being followed. The cause for any rejection must be recorded on a calibration/test log.	Acceptable
5	Application of Statistical Control Statistical control must be used to determine the capability of the process equipment and the setting of critical limits for critical control points.	Acceptable
6	Allergen and Sensitive Materials Controls In facilities where allergens or sensitive materials are present, there must be detailed procedures to prevent the contamination of other products. Products containing allergens must be labeled as required by regulations.	N/A
7	Documentation Showing Product Meets Specifications Records must be maintained to assure that the appropriate product attributes were evaluated and that the results were consistent over time. Perseco required the suppliers of the packaging materials to ensure such packaging materials in compliance with safety requirements. The plant is suggested that the compliance documentation is kept on file and reviewed periodically. The product recovery sheet should be developed to facilitate traceability according to perseco quality assurance requirements.	Minor*
8	Rework and Carryover Products There must be a documented procedure for managing rework and carry over products. Rework must be traceable to its original production and to finished product. Production dates and original lot numbers must be carried forward in production documents. Rework and carry-over must be kept to a minimum and used promptly at the first opportunity. There must be a routine and documented "clean break" in the rework/carryover cycle.	Acceptable
9	Analytical Records Management Established systems must be used to properly store and retrieve analytical information, documents, reports, records, etc.	Acceptable
Section notes:		

Section H Packaging and Labeling

No	Question/Notes	Answer
1	Label Accuracy and Regulatory Compliance There must be procedures in place to assure products are labeled properly and that the labels meet regulatory requirements.	Acceptable
2	Documented Net Weight or Count Compliance Policy and Performance Plants must have a documented policy for net weight, liquid contents or product count to verify compliance to label requirements and/or specifications.	Acceptable
3	Clear Manufacturing Codes on Individual and Cased Product All product must have a code date that is of such size, color and contrast to afford easy legibility at a reasonable distance. Each individual sell unit must have a production or lot code. Packages within the sell unit must have a lot code. The individual package code dates and the case codes dates must be the same.	Acceptable
4	Package Integrity and Function for Distribution All packaging must be designed and assembled to provide protection for the product from environmental and shipping conditions. Verification of proper sealing and closure of the packaging must be conducted.	Acceptable

Section H Packaging and Labeling

No	Question/Notes	Answer
5	Label Security and Obsolete Label Controls There must be a written plan in place to prevent the use of unauthorized or incorrect labels.	Acceptable
6	Tamper Evident Packaging Tamper evident packaging must be used and a documented monitoring program must be in place.	N/A

Section notes:

Section I Storage and Shipping

No	Question/Notes	Answer
1	Warehouse and Finished Product Management Warehouse conditions must be maintained in a manner to assure product integrity. Finished product and packaging materials must be held separated and away from chemicals. Product not "cleared" for shipment must be clearly identified and stored in a location where it is not likely to be shipped in error.	Acceptable
2	Retained and Returned Products There must be documented procedures requiring identification, secured segregation, documentation, evaluation, disposition and reconciliation of non-conforming retained and returned products that is placed on hold. Returned products must be placed on hold immediately, designated areas must be established for retained and returned products and an inventory log must be maintained showing current product on hold and the disposition of all released product with proper authorization.	Acceptable
3	Storage Facility and Dock Maintenance Warehouse storage areas must be clean and orderly and have adequate space around the periphery for access, inspection and cleaning. Items must be stored off the floor, floors and walls must be in good condition and emergency doors must be tight fitting. Shipping docks, dock plates and levelers must be clean and kept orderly. The in process product case was placed directly on the floor, not off the floor with pallets beneath.	Minor*
4	Transport Condition There must be written procedures for acceptable carrier conditions available to shipping personnel. Outbound trailers must be inspected and results must be documented. No product can be loaded into unacceptable carriers. When non-dedicated carriers are used, trailer logs must be assessed to determine if unacceptable materials had been present.	Acceptable
5	Release Authorization to Ship Product Release authorization must be required before any product is shipped.	Acceptable
6	Product Traceability Procedures must be established to effectively trace specific lots of materials and finished products through the shipping and distribution channels. Traceability exercises must be conducted at least twice per year to the first level of distribution. Management assessments of each traceability exercise must be conducted. The most recent traceability exercise must demonstrated a 99.5% to 105% level of accountability within 4 hours.	Acceptable

Section notes:

Section J Analytical Records and Laboratory Support

No	Question/Notes	Answer
1	Laboratory Facility and Staffing Laboratories must be adequately equipped and staffed to provide the essential technical support. Lab staff qualifications must be documented, toxic supplies must be securely stored and properly labeled and the laboratory must be clean, orderly and well lit.	Acceptable
2	Laboratory Procedures and Documentation Laboratory procedures must be documented, authorized and dated. Testing procedures must be based on recognized and approved procedures and documentation of all testing must be available.	Acceptable
3	Laboratory Equipment Calibration Calibration records must be maintained for all laboratory balances and test equipment for calibrations performed by a certifying company as well as all internal calibration check.	Acceptable
4	Analytical Accuracy Verification Documented evidence must be available that demonstrates laboratory test results are accurate and reliable.	Acceptable

Section J Analytical Records and Laboratory Support

No	Question/Notes	Answer
Section notes:		

Section K Product Defense

No	Question/Notes	Answer
1	<p>Management</p> <p>A risk assessment must be conducted by an established Product Defense team to evaluate all vulnerabilities and risks that exist in the facilities process. A documented Product Defense program must be in place. Unusual occurrences must be documented and assessed by management.</p>	Acceptable
2	<p>Human Element</p> <p>All individuals entering the facility must show proof of identification. A screening program must be in place for all employees. Temporary employees must be fully supervised at all times. Contractors and visitors must be required to show identification and sign in and out. Visitors must be accompanied while in the facility. A current roster of employees and work assignments must be maintained and employees must be prohibited from bringing personal items into processing areas. There must be a program in place to train Product Defense rules at the facility with documentation for each individual.</p>	Acceptable
3	<p>Facility</p> <p>Procedures must be in place to address access to and from the plant grounds and facility. A schematic of the facility and outside grounds must be available that identifies all entrances into the building, accesses to the roof and sensitive areas. Access to sensitive areas and utilities must be restricted. There must be a documented process for issuing, tracking and retrieving keys, identification badges and passes for the buildings and for secure areas.</p>	Acceptable
4	<p>Operations</p> <p>The facility must be evaluated for vulnerability to sabotage with documented procedures developed to address areas of concern. Non-employee drivers and delivery personnel must have a designated waiting areas. Trucks and/or trailers must be inspected before unloading. There must be a procedure for the receipt of damaged product. Vehicles must be kept secured when not in use and after loading is completed. Seal numbers must be recorded.</p>	Acceptable
Section notes:		