

Audit Report Global Standard Food Safety Issue 9

1. Audit Summary			
Company name	Amalgamated Sugar Company	Site code	1587775
Site name	Amalgamated Sugar Company - Portland		
Scope of audit	Melting of granulated sugar into liquid sucrose and invert sugar and packed into totes and liquid tankers. Transfer of bulk sugar from rail cars to bulk trucks.		
Exclusions from scope	None		
Justification for exclusion	None		
Audit start date	6/27/2023	Audit finish date	6/28/2023
Re-audit due date	9/30/2024	Head office	No

Additional modules included			
Modules	Result	Scope	Exclusions from Scope

2. Audit Results					
Audit result	Certificated	Audit grade	A+	Audit programme	Unannounced – mandatory 1 in 3 years
Previous audit grade	AA		Previous audit date	9/13/2022	
Certificate issue date	7/14/2023		Certificate expiry date	11/11/2024	

SGS United Kingdom Ltd					
Page 1 of 57	CB Report No.	607344	Auditor:	Eric Taft	



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2. Audit Results		
Number of non-conformities	Fundamental	0
	Critical	0
	Major	0
	Minor	6

3. Company Details			
Site address	2600 N.E. Columbia Blvd Portland Oregon 97211		
Country	UNITED STATES	Site telephone number	2083836594
Commercial representative name	Kelly Malone	Email	Kmalone@amalsugar.com
Technical representative name	Lacey Messing	Email	Lmessing@amalsugar.com

4. Company Profile					
Plant size (metres square)	<10K sq.m	No. of employees	1-50	No. of HACCP plans	1-3
Shift pattern	2 shift 5 days per week, 5am-1:30pm and 8a-4:30pm				

SGS United Kingdom Ltd					
Page 2 of 57	CB Report No.	607344	Auditor:	Eric Taft	



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4. Company Profile

Seasonal site	No	
Seasonal opening times (Start/end date)		
Other certificates held	Kosher	
Outsourced processes	No	
Outsourced process description	N/A	
Regions exported to	North America	
Company registration number	14902222162	
Major changes since last BRCGS audit	None	

Company Description

Amalgamated Sugar Company-Portland is part of Amalgamated Sugar Company and is located in a light industrial area of downtown Portland, Oregon. The site was built in 1950. The entire site encompasses 3 acres with two main buildings (office and production). A rail spur leads into the facility for bulk deliveries into the granulated sugar silo and once melted the melted sugar is stored in 6 bulk liquid tanks. The main building (production area) is approximately 500 sq metres and the site employs approximately 9 which includes production workers and front office staff.

Granulated sugar is shipped into the site and melted into liquid. The site also utilizes tanker rinse equipment prior to loading into the liquid tankers. Once melted, the product is delivered to customers using contracted transport. Equipment includes a granulated sugar silo, melting tanks, storage tanks for liquid and invert sugar, and an external hot water rinse station for liquid tankers. The site loads approximately 40 tankers per week depending on orders.

The facility operates 2 shift per day with some employees working a 5am-1:30pm shift while others work an 8am-4:30pm shift. This audit is being conducted as the 1 in 3 mandatory unannounced audit.

5. Product Characteristics

SGS United Kingdom Ltd				
Page 3 of 57	CB Report No.	607344	Auditor:	Eric Taft



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5. Product Characteristics					
Product categories		15 - Dried food and ingredients			
Finished product safety rationale		Low aW on products, mostly enclosed product zones.			
High care	No	High risk	No	Ambient high care	No
Justification for area		Low aW, enclosed product zones			
Allergens handled on site		None			
Product claims made e.g. IP, organic		Kosher			
Product recalls in last 12 months		No			
Products in production at the time of the audit		Melting of liquid sugar from granulated; loadout of granulated sugar.			

6. Audit Duration Details			
Total audit duration	18	Duration of production facility inspection	6
Reasons for deviation from typical or expected audit duration	Very small site, easily observable, closed product zones.		
Combined audits	None		
Next audit type selected	Announced		

SGS United Kingdom Ltd				
Page 4 of 57	CB Report No.	607344	Auditor:	Eric Taft



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Present at audit					
Note: the most senior operations manager on site should be listed first and be present at both opening & closing meetings (ref: clause 1.1.11)					
Name	Job title	Opening meeting	Site inspection	Procedure review	Closing meeting
Larry Lee	Foreman (alternate for Terminal Manager)	X	X	X	X
Lacey Messing (remote via TEAMS)	Food Safety and Quality Professional	X		X	X
Kelly Malone (remote via TEAMS)	Quality Assurance Manager	X		X	X

GFSI Post Farm Gate Audit History			
Date	Scheme/Standard	Announced/Unannounced	Pass/Fail
10/26/2020	BRCGS Food 8	Announced	Pass
9/13/2021	BRCGS Food 8	Announced	Pass
9/13/2022	BRCGS Food 8	Announced	Pass

Document control
Certification Body

SGS United Kingdom Ltd				
Page 5 of 57	CB Report No.	607344	Auditor:	Eric Taft



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Theta building			
UNITED KINGDOM			
CB Report number	607344		
Template Name	F908 Food Safety Audit Report Template		
Standard Issue	9	Template issue date	12/16/2022
Directory allocation		Version	

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Page 6 of 57	CB Report No.	607344	Auditor: Eric Taft



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Non-Conformity Summary Sheet

Critical or Major Non-Conformities Against Fundamental Requirements			
Clause	Detail	Critical or Major	Re-audit date

Critical		
Clause	Detail	Re-audit date

Major						
Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

SGS United Kingdom Ltd					
Page 7 of 57	CB Report No.	607344	Auditor:	Eric Taft	



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Minor						
Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by
4.4.1	Minor 4.4.1 Wall surfaces were not consistently maintained to prevent the accumulation of dirt, minimize condensation and mould growth, and to facilitate cleaning. A section of the wall located behind the sugar melt station, beside the Ro-tap machine, and directly behind pest control internal device #13 was noted to be slightly damaged	Informed the maintenance personnel to fix the wall during the audit. Wall has been repaired.	The Monthly Sanitation Inspection has been updated with a question on walls being clean and intact.	Work was done behind the wall and the wall was not placed back correctly.	7/13/2023	Eric Taft

SGS United Kingdom Ltd					
Page 8 of 57	CB Report No.	607344	Auditor:	Eric Taft	



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Minor						
	resulting in a harbourage area.					
4.8.7	Minor 4.8.7 Food was not consistently stored in accordance with the site's policies. An employee working in the sugar melting process was noted with four beef jerky stick in their pocket.	Employee was spoken to during the BRCGS Audit and removed the enclosed beef jerky from pant pocket right away.	Toolbox Meeting was completed for training. The July 2023 toolbox meeting shows a diagram for food and drink areas and an allergen awareness for employees.	Employee had snack available on hand before break.	7/13/2023	Eric Taft
4.9.3.2	Minor 4.9.3.2 Procedures for handling glass and other brittle materials were not in place for all areas. The list of items used for the checks of the condition of items did not include the number of items inspected in all areas.	Audit was completed on 6.29.23 by Foremen and secondary personnel confirmed amount was correct. The Audit has been updated with the amount of lights.	Perform monthly audits with new form.	Lights have been accounted for in the monthly inspections but no specific amount of lights had been identified per code.	7/13/2023	Eric Taft

SGS United Kingdom Ltd					
Page 9 of 57	CB Report No.	607344	Auditor:	Eric Taft	



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Minor						
4.11.2	Minor NC 4.11.2 Documented cleaning procedures were not consistently followed in all instances in regards to cleaning chemicals and concentrations. The test strips currently used to monitor the PPM of the sanitizer used to clean sample ports was noted to be expired in May 2020. An unexpired set was found in the office and was used to replace this roll.	During the BRCGS Audit the strips were switched out with a new set within date. A toolbox meeting was completed with the employees so they are aware of the expiration date. A new set of strips have been purchased.	The monthly sanitation inspection will verify the strips are within date.	Employees were unaware of the expiration date.	7/13/2023	Eric Taft
5.3.4	Minor 5.3.4 Procedures to ensure the effective management of allergenic materials was not consistently applied. A hand cleaner containing both walnut shell and soy ingredients was noted in the	Contacted Supplier that this specific hand cleaner (allergens) is not allowed on our facility. Removed the hand cleaner ASAP and collected the SDS and Allergen Information.	During the weekly sanitation inspection allergens will be inspected as one of the questions to confirm none are onsite. The July Toolbox Meeting was given to the	Supplier (Cintas) provides us and switches out our hand cleaners in our dispensers.	7/13/2023	Eric Taft

SGS United Kingdom Ltd					
Page 10 of 57	CB Report No.	607344	Auditor:	Eric Taft	



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Minor							
	employee restroom area attached to the production area. It was noted that product was not touched by employees with uncovered hands.			employees for awareness of allergens.			
7.2.4	Minor 7.2.4 Not all bandages were present in the records reviewed of metal detectable plasters. Lot number A09522 was not present in the records reviewed at the site.	Employee's notified not to combine the band-aid together with two different lots. A band-aid verification will be documented and performed on the new lot number. It was verified on July 6, 2023 during the internal audit 4 that the new, un-open band-aid box did not have matching lot numbers on the band-aids and box.		A form was created to inform individuals to provide a band-aid with a new lot number to the front office. This will ensure we are current and that it has been tested and recorded. A log has been completed to show current inventory.	Employee combined the current band-aids into the new box of band-aids. The new band-aids were pulled from the front office.	7/13/2023	Eric Taft

Comments on non-conformities

SGS United Kingdom Ltd					
Page 11 of 57	CB Report No.	607344	Auditor:	Eric Taft	



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SGS United Kingdom Ltd				
Page 12 of 57	CB Report No.	607344	Auditor:	Eric Taft



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Additional Modules / Head Office Non-Conformity Summary Sheet

Critical		
Clause	Detail	Re-audit date

Major						
Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

Minor						
Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

SGS United Kingdom Ltd					
Page 13 of 57	CB Report No.	607344	Auditor:	Eric Taft	



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SGS United Kingdom Ltd				
Page 14 of 57	CB Report No.	607344	Auditor:	Eric Taft



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Audit team

Lead auditor		
Auditor number	First name	Second name
22038	Eric Taft	Taft

Audit team				Attendance (YYYY/MM/DD, 24hr: MM)			Presence	
First name	Second name	Auditor number	Role	Audit Date	Start time	End time	Remote or physical	Professional recognition number
Eric	Taft	22038	Lead Auditor	2023/06/27	08:00	16:00	Physical	N/A
Eric	Taft	22038	Lead Auditor	2023/06/28	07:00	17:00	Physical	N/A

SGS United Kingdom Ltd				
Page 15 of 57	CB Report No.	607344	Auditor:	Eric Taft



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SGS United Kingdom Ltd				
Page 16 of 57	CB Report No.	607344	Auditor:	Eric Taft



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Detailed Audit Report

1. Senior management commitment

The site has a documented policy Commitment to Food Safety and Quality 2022-08-10 stating their intention to produce safe, legal, and authentic products to the specified quality and its commitment to it's customers. This policy is signed by the Warehouse Manager at this location, communicated through postings and trainings, and includes statements indicating the sites commitment to improve food safety and quality culture activities through annually reviewing objectives.

The site maintains a clear plan (Food Safety and Quality Culture Improvement WHS-WI-003 for the development and continuing improvement of a food safety and quality culture. Activities based on Training, Behavior changes, Clear and Open communications on product safety through Monthly Toolbox Meetings, feedback, and Performance Measurement on product safety, authenticity, legality and quality related activities. All findings were evaluated annually. The quality and food safety culture plan were last updated on 2023-02-06 (annually at a minimum). Evidence of review was also found in the internal audits.

The following objectives (defined in to maintain and improve the safety, legality and quality have been set:

1. Food Safety Objectives/Quality Metrics of

- a. Successful shipment rate of 99.5% calculated by a ratio of number of shipments and complaints
- b. Successful shipment rate of 99.9% for food safety related issues where culpability is assigned to facility
- c. Reduce total cost of complaints per shipment by 3%.
- d. Complaint response goal of 100%

2. Third Party Audit Certification – Maintain A grade for BRCGS facilities

3. Documentation and Recordkeeping

- a. MSS completion rate of 85%
- b. Preventive maintenance inspections with completion rate of 80%

4. Food safety and Quality Internal Issues

- a. Reduce number of incidents by 3%
- b. Reduce number of unplanned equipment repairs by 3%
- c. Maintain zero catches in designated no-catch zones
- d. Reduce number of HACCP deviations by 3%
- e. Meeting all internal facility inspection criteria
- f. Reduce the number of unplanned Liquid-only shipments by 5% annually

SGS United Kingdom Ltd

Page 17 of 57

CB Report
No.

607344

Auditor: Eric Taft



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All were found to have goals and clear measures of success and each were monitored, and results reported on a quarterly at a minimum basis (last on 2023-04-26). Each target is monitored by the Assistant Warehouse Manager and reported in Management reviews.

Management Review Meeting Notes reviewed from 2022-07-08 indicated that the company goals are currently being met. Management review meetings (monthly and at least quarterly) that include discussion of previous actions, audit results, objective/CAPA, customer complaints, incidents (including recalls), non-conforming product, HACCP, food defence, authenticity, the food safety and quality culture plan, and resource requirements are held annually, and a summary of the review was dated 2022-07-08 and again on 2023-04-26.

Employees are encouraged to bring one-on-one discussion to supervisors and a weekly meeting (Toolbox meeting) takes place between supervisors that allows food safety, legality and integrity to be brought to senior management attention. Employees were aware of the need to report any evidence of unsafe or out-of-specification product or raw materials, to upper management to enable the resolution of issues requiring immediate action.

There is a confidential reporting system in place for employees who have concerns relating to product safety, integrity, quality and legality; this includes a designated phone number to file complaints. The procedure for assessment is to have all suggestions reviewed by Human Resources at corporate where the phone number for confidential reporting is located. This is posted for employees to review and is documented in the company code of business conduct pages 4-5.

Sufficient resources were noted. A budgetary plan, set out by the plant manager, was in place to assist in the development of the food safety systems.

The site is kept informed of new risk to authenticity, scientific and technical developments, industry codes of practice, and regulatory issues in the country where the product will be sold through

Email notifications from NSM (corporate), website information from FDA, BRCGS, and a designated corporate member.

A genuine electronic copy of the Standard is available on site and there is awareness of the change to the standard through subscription to the BRCGS Participate website.

The audit is occurring during the window listed on the prior certificate.

The alternate for the warehouse manager attended the opening and closing meetings. Additional department heads were available for relevant sections of the audit. The quality culture plan was evaluated using input from a member of the senior management team, Food safety, Warehouse Manager, and Assistant Manager.

The previous 5 non-conformance issues were found to be addressed with corrective and preventive actions and did not recur during this audit.

The site is currently registered with the FDA Bio-terrorism act with registration number xxxxxx2162 with a valid expiration date of 2024-12-31. Additional registrations are not required by the State of Oregon.

SGS United Kingdom Ltd

Page 18 of 57

CB Report No.

607344

Auditor:

Eric Taft



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There is an organization chart Organizational chart WHS-DI-001 Rev 2 dated 2022-12-08 that clearly defines responsibilities of management to ensure effective implementation of the product food safety, authenticity, legality, and quality systems. The CEO is listed at the top of the page with the Plant Manager reporting to this position. Deputies are listed in Organizational chart on the 2nd page with backups listed as Foreman as the backup for Warehouse Manager.

Responsibilities include ensuring staff are aware of their responsibilities; job descriptions are detailed and discussed upon hire. Reviewed information for two individuals (Warehouse Manager and Assistant Warehouse Manager.) Documents reviewed included JSA-REC-001 Version 0. Both are signed by the person in this position to ensure they are aware of their job duties.

Included in job descriptions and job duties is the requirement to all employees to report any evidence of unsafe or out-of-specification product, equipment, packaging or raw materials that may be subject to non-conforming.

The site maintains an in-house food safety team. A Food Safety Professional visits the site on a quarterly basis and this individual works for the company.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
1.1.13	The BRCGS logo is not used.

2. The Food Safety Plan – HACCP

The HACCP team consists of 6 members (2 from corporate) and is led by the Food Safety and Quality Professional Manager L.M. who has the following training: FSPCA for PCQI dated 2016-08-26 and HACCP from Food HACCP Plan Development from SAI Global dated 2016-02-18. Additional team members include the Warehouse Manager with AIB HACCP training dated 2016-06-17. The scope covers all the products and processes that are manufactured at this site summarized as follows:

The 1 HACCP plans at this location covers all products produced at this site with no exclusions. The scope covers Production of liquid sugar from granulated sugar packed into totes, bags, and bulk trucks and warehouse storage. Two CCP is listed which is outgoing filter inspections for liquid sugar and invert liquid sugar at this location and metal detection for granulated sugar. The plan covers all activities as witnessed during the audit. No allergens are used at this location.

Pre-requisite programs (PRPs) are included that include items such as:

- 1. Pest Control

SGS United Kingdom Ltd				
Page 19 of 57	CB Report No.	607344	Auditor:	Eric Taft



2.GMP

3.Customer Complaints

4.Recall Program

5.Liquid Tank Wash

Each of these programs are risk evaluated based on the risk zones applicable to the site as defined in site diagrams.

Monitoring for each pre-requisite program listed is included in the HACCP program at this site with requirements for monitoring and documenting any issues.

Product descriptions are included that include Product Ingredients and their origins, packaging requirements, intended use, shelf life, target market, and labelling requirements.

All information needed to conduct a hazard analysis appeared to be in place for this plan and included comprehensive information based on food safety sources to ensure that the hazard analysis was conducted thoroughly.

This lists all items as intended for ingredient in many food products and functions as a sweetener. Any alternative uses have been considered including vulnerable groups of the population.

Flow diagrams are on file dated 2023-02-07 that included receipt of raw materials, packaging, storage and all relevant process steps as well as designation of enclosed and product areas. Steps identified for further analysis including Air treatment including UV and filtration, Liquid Sugar Mixing, and Bulk Sugar Receiving.

The accuracy of the flow diagrams is reviewed on an annual basis (or when changes occur), the last on-site review was completed during the internal audit in February by the Food Safety Professional.

The hazards included in the study included: - microbiological (None identified), physical (glass, metal), chemical (Aflatoxin, allergens), radiological, fraud, and malicious contamination in additional risk assessments. Subsequent and preceding steps in the process chain are also taken into account in this hazard analysis.

The actual hazard analysis had considered the likelihood of occurrence and severity for each identified hazard to determine if it was significant. If the hazard is controlled by a current PRP it is listed in the analysis such as Supply Chain Controls.

A decision tree had been used to assess if the control point is a critical one (CCP); there are 2 actual CCPs identified (one in granulated and one in liquid).

For CCP #1 filtration in liquid, the critical limit is

Porosity of 100 microns or less inspected for each load.

CCP#2 is listed as metal detection, critical limit is

SGS United Kingdom Ltd

Page 20 of 57

CB Report No.

607344

Auditor:

Eric Taft



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1.5Fe, 1.8 Nfe, 2.0SS, and 2.0mm Al.

Validation of this CCP is listed as Regulatory requirements in 555.425 for both, customer specifications and customer complaint evaluation as validation studies are not feasible for the filters. Final filters are an industry-accepted device for controlling metal contaminants.

Monitoring of the CCP in this location is defined in the HACCP plan and occurs every load by qualified technicians.

Records of the monitoring procedures are signed by the operator at the time of the check and are verified by the designated QI at this location. Records reviewed from the product trace date were found to include the date, time and result of measurement. They were also signed by the person performing the monitoring and verified 2 days later by a PCQI. Records of shipments on 2023-02-28.

At all steps where deviation from HACCP procedures are noted, corrective actions have been taken and documented.

Validation procedures of the entire study included: - internal audits, violation of critical limits, review of complaints and review of incidents of product withdrawal or recall. An example of this is included in the internal audit and monitored at least quarterly and reported to the HACCP team.

Annual reassessment was conducted on 2023-05-05 at this location. The requirements are to perform this review annually and upon any changes.

Documentation and record keeping appeared to be sufficient to enable the site to verify that the HACCP and food safety controls, including controls managed by prerequisite programmes, are in place and maintained.

Details of non-applicable clauses with justification

Clause/Section Ref	Justification
N/A	N/A

3. Food safety and quality management system

3.1 Food safety and quality manual, 3.2 Document control, 3.3 Record completion and maintenance

The company's food safety and quality management system (FSQMS) is electronically maintained and made available to relevant departments through a shared electronic drive and printed copies in the FSQA folders.

SGS United Kingdom Ltd

Page 21 of 57

CB Report No.

607344

Auditor:

Eric Taft



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Members of the facility staff have access to the relevant portions of the FSQMS as needed through electronic access.

The FSQMS is composed of various levels of documents, procedures and work instructions that are written in English.

3.2

The document control procedure Section 2.0 of the Food Safety and Quality Assurance Manual includes a list of controlled documents as well as the process for identification, version control, authorization, amendments and system to replace the former copy.

The system for the electronic control includes password protection to ensure controlled access to documents along with back ups to a corporate server system to prevent loss. Documents are maintained electronically and backed up using suitable storage systems to ensure they are stored securely and easily accessible

The following documents were cross checked in this audit:

Document 6.3-02.0 Rev 3

Document 6.3-01.1 Rev 1

There were all found to be the correct version.

3.3

The process for management of records is covered in section 2.2 Records: Completion and Retention. This includes a procedure for the alteration of hand written records. All records are stored securely and any electronic records are backed up to prevent loss.

Filled out records included:

CCP monitoring for metal detection dated 2023-05-23.

RH6305 Bulk Railcar inspection 10.9.1-08.

These were all found to be in good order.

Records are retained for a minimum shelf life plus 12 months for all BRCGS requirements. These records are backed up daily at corporate and retrievable for review (as evidenced during trace).

3.4 Internal audits

SGS United Kingdom Ltd

Page 22 of 57

CB Report No.

607344

Auditor:

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There is a schedule for internal audits of the FSMS (Internal audits that includes, HACCP, PRPs, Food Defence, Fraud and the written procedures) that is scheduled throughout the year summarized as follows:

A detailed internal audit procedure section 8.4, was conducted throughout the year with all elements of the BRCGS Standard covered. Reviewed reports for 1st quarter section 5.09 that lists all potential hazards for each process step that covered sections 4-6 on 2022-09-26 and 2 of the BRCGS Global Standard performed 2022-05-31. Additional audits performed on 2023-01-10 and 2022-04-06.

The frequency for these audits is based on risks associated with the activity and/or results from previous audits.

Each of the listed audits has a scope for the program being audited.

There are 2 internal auditors performing internal audits to the BRCGS Standards at this location. Training for internal auditors included:

Training for internal auditor K.M. dated 2011-07-20.

Training for internal auditor L.M dated 2013-01-11 by RR Nuts.

Verification recorded on an electronic CAPA database that included root cause analysis and tracking to completion. Internal audits included generated CAPA numbers that were linked back to a database containing actions taken. Example included Site Action # 460.

A documented program of self-inspections is carried out at this location. This includes Monthly Self Inspections. Records dated 2023-04-19 housekeeping audits reviewed and also local conducted on 2023-04-28.

All areas including inside and outside of the facility including building fabrication and production areas. Hygiene practices were also monitored during this inspection. A summary of results is also presented during the management review meetings reviewed in Section 1 of this Standard.

3.5 Supplier and raw material approval and performance monitoring

3.5.1 Management of suppliers of raw material and packaging

The company has a documented risk assessment of raw materials (including ingredients) also including primary packaging to identify potential risks to product safety, legality and quality and includes risks of: - allergen contamination, foreign-body risk, microbiological contamination, chemical contamination, substitution or fraud and any risks associated with raw materials which are subject to legislative control.

The significance or impact of a raw material to the quality of the final product is also included. This was conducted per Risk/Vulnerability Assessment: Ingredient/Raw Material Rev 4 dated 2023-02-23 for Liquid Tote and 2023-02-22 for Granulated Sugar.

SGS United Kingdom Ltd

Page 23 of 57

CB Report No.

607344

Auditor:

Eric Taft



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The risk assessment forms the basis for the raw material acceptance and testing procedure and for the processes adopted for supplier approval and monitoring.

The risk assessment is updated when: - there is a change in a raw material, the processing of a raw material, or the supplier of a raw material or if a new risk emerges. In addition, an update is conducted following a recall or withdrawal where a specific raw material has been implicated and at least every 3 years. Documents reviewed included finished product from the product trace, packaging material (liquid sugar loaded onto bulk trucks).

The company also has a supplier approval procedure Approved Supplier Program section 5.18 that is also based on risk and requires one or a combination of the following: - Valid GFSI certification, supplier audits that includes records of auditor competence and review of a completed audit report.

The suppliers selected earlier had been approved by: a documented risk assessment is in place for each material and included in the food safety plan. COA are additionally required for each load. Items can only be received from an approved supplier. Each supplier is required to provide documentation and/or testing results based on the documented process of review. Examples provided included Granulated Sugar received from location with SQF certificate # 6213 valid through 2024-01-28 and Hydrochloric acid through customer specific SQF #56449.

List of suppliers maintained in electronically which included raw materials and packaging materials.

This procedure also covers ongoing performance and requires review annually. The approved supplier list is maintained electronically and the current version was reviewed. The suppliers from the product trace and also current production items were reviewed.

All vendors are required to have a traceability program.

Procedures for exceptions to this policy are defined. Additional product testing may be required.

3.5.2 Raw material and packaging acceptance, monitoring and management procedures

The packaging and raw materials received are approved based on the information included on the COA and compared against the specifications and considering the information related to the truck inspection and the condition of the materials.

All materials are inspected for condition with packaging inspected for damage and is tested as required upon receipt.

Raw material acceptance for the Granulated sugar, the ingredient traced in the vertical audit, was examined and found to be complete. Random materials observed and documented during the audit could be matched with the approved supplier list and the supporting documents. The receiving information was reviewed for raw materials included as part of the vertical audit documents generated on 2023-02-09 and current shipments dated 2023-06-27.

3.5.3 Management of suppliers of services

Management of suppliers of services is covered in Approved Supplier program listed above and is based on risk to the safety and quality of the products, legal compliance and risks to security (identified in vulnerability and food defence assessments).

SGS United Kingdom Ltd

Page 24 of 57

CB Report No.

607344

Auditor:

Eric Taft



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The following services were reviewed during this audit:

Pest control

Waste management

Uniforms for production area

Laboratory services

Formal agreements were maintained on file for local suppliers and reviewed during the inspection. Included in the procedure for management of suppliers of services is a requirement to review performance on an on-going basis. Records were reviewed for each of the above service providers to ensure compliance on Register No# 1.0-01.0 Version 1 Approved Supplier Registry 2023.

3.5.4 Management of Outsourced processing

No outsourced processing occurs at this site

3.6 Specifications

Specifications are on file for raw materials/packaging materials and services that ensure compliance with relevant safety and legislative requirements. The specifications include defined limits for relevant attributes of the material which may affect the quality or safety of the final products (e.g. chemical, microbiological or physical standards).

The specifications reviewed in this audit included:

Type O Liquid Sucrose dated 2022-09-21 – 30 day shelf life in accordance with HACCP plan.

Specification Sheet for Readyfill Liquid Container for Liquid Sugar dated 2022-10-10.

Up-to-date specifications also existed for finished products that included customer and/or legal requirements as well as the safe use of the product.

Example provided for Type 0 Liquid Sucrose dated 2022-09-21.

Type 50 Medium Invert Sugar dated 2022-09-21.

Specifications are reviewed every three years or whenever products change. All specifications reviewed during this audit were found to be within the 3 year time frame. Reviews and any changes were specified on the documents.

3.7 Corrective and preventive actions

There is a procedure for handling and correcting failures identified in the food safety and quality management system:

Section 1.4 Corrective Actions and Root Cause Analysis

SGS United Kingdom Ltd

Page **25** of **57**

CB Report
No.

607344

Auditor:

Eric Taft



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If the non-conformity places the safety, legality or quality of product at risk investigation is carried out that includes: - clear documentation, assessment of the consequence, immediate correction, action to address the immediate issue, timescale for corrective action, responsibility and verification. The procedure also includes root cause analysis as part of the tool for implementation of ongoing improvements to prevent recurrence that is supported by non-conformance trends to identify the need for this.

Examples reviewed during this audit included:

Verification recorded on an electronic CAPA database that included root cause analysis and tracking to completion. Internal audits included generated CAPA numbers that were linked back to a database containing actions taken. Example included Site Action # 460.

Section 1.4.2.3 lists actions to prevent recurrence based on root cause analysis.

3.8 Control of non-conforming product

The procedure for control of non-conforming (out-of-specification product) is contained in section 7.2 of the Quality policy under Nonconforming Product and Materials. The process in place includes

reporting, identification (putting items on hold physically), secure storage (tagged), proper management of returned items, notification to brand owners, record keeping requirements, and authorized personnel to disposition products. The responsibility of the program lies with Warehouse/General Managers for determining nonconforming product and ensuring warehouses label and segregate items.

Material stored in bag warehouse. No examples of hold of finished product were observed at this site as disposition typically entails remelting through the process.

3.9 Traceability

The site has a documented traceability procedure Section 4.4 designed to maintain traceability throughout the site's processes. The procedure includes: - how the traceability system operates, and the labelling and records required.

The site tests the traceability system across the range of product groups to ensure traceability can be determined from the supplier of raw material (including primary packaging) to the finished product and vice versa, including quantity check/mass balance that is carried out at least annually; this is done in conjunction with the mock recall test. This test includes a summary of documents referenced, Information about the trace, product types, quantities, raw material log numbers, consignee/customers, and Processing documentation (CCP records, BOL and COA's). Documents are retained for prior tests of the system.

Last tested on 2022-08-24 with product and scenario foreign material in liquid sugar with 100.00% success rate in 1 hour 16 minutes.

A vertical traceability test was conducted during the audit on Liquid Sucrose, lot # AP2304004A with a production date of 2022-02-09 with a 99 percent traceability. This included all finished goods and packaging materials used within 52 minutes.

SGS United Kingdom Ltd

Page 26 of 57

CB Report No.

607344

Auditor:

Eric Taft



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1307.78 CWT (hundred weights) produced on this day and the shipping records showed that 4 orders shipped on P.O numbers that week. 100% traceability was achieved in 52 minutes.

The following ingredients were traced: - granulated sugar and packaging material liquid tankers to the lot codes and receiving data (as well as supplier approval status and specifications, etc.)

A mass balance was conducted on the granulated sugar. 1307.78 were received and 1315.11 shipped. It was used for this product run on 2022-02-09 with 99% mass balance achieved.

This exercise was also used to check the records for the controls including control points at each stage of the process, packing and shipping as well as sanitation, maintenance and operator trainings around the selected packing date. This exercise (trace) part took 35 minutes.

Where product is reworked and/or any reworking operation for granulated sugar, traceability of the materials is maintained through AS400. A resource number is assigned to the items to ensure traceability. Returned items to sister locations are then melted and passed back through the systems.

3.10 Complaint-handling

Complaints are recorded and investigated according to Customer Complaint Management section 1.6.

Actions appropriate to the seriousness and frequency of the problems identified are carried out promptly and effectively by appropriately trained staff (final decision by Plant Manager/QA).

Complaint data is analysed for significant trend and if there is an increase or a serious complaint, root cause analysis is used to implement ongoing improvements to product safety, legality and quality, and to avoid recurrence through root cause analysis of the issue. This analysis is be made available to relevant staff and reviewed on a quarterly basis.

Trending reports were available on an electronic system, reviewed monthly by the facility. Trend information was reviewed for this location and no complaints were on file for this location.

Complaint information for 2022 to current was available for review. No information from customer complaints for this location is on file from recent issues as only melted sugar is sent from this location and customer complaint information is limited.

3.11 Management of incidents, product withdrawal and product recall

The procedure(s) for managing incidents and potential emergency situations that impact food safety, legality or quality is contained in a formal crisis management program Emergency Plan for Product Doc # 3.8-01 Rev 12 for employee, facility, or product issues.

Contingency plans are included to maintain product safety, authenticity, quality and legality. Incidents listed included:

Mail handling issues

disruption to key services such as water, energy, transport, refrigeration processes

SGS United Kingdom Ltd

Page 27 of 57

CB Report No.

607344

Auditor:

Eric Taft



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staff availability and communications

events such as fire, flood or natural disaster

malicious contamination or sabotage including digital cyber-security

Where products which have been shipped/released by an incident, consideration is given for the need to withdraw or recall products.

The procedure for managing withdrawal and recall is listed in Section 3.2 Recall Program & Testing. This procedure includes:

- identification of key personnel constituting the recall management team, with clearly identified responsibilities
- guidelines for deciding whether a product needs to be recalled or withdrawn and the records to be maintained
- an up-to-date list of key contacts (including out-of-hours contact details) or reference to the location of such a list (e.g. recall management team, emergency services, suppliers, customers, certification body, regulatory authority)
- a communication plan including the provision of information to customers, consumers and regulatory authorities in a timely manner
- details of external agencies providing advice and support as necessary (e.g. specialist laboratories, regulatory authority and legal expertise)
- a plan to handle the logistics of product traceability, recovery or disposal of affected product, and stock reconciliation
- a plan to record timings of key activities
- a plan to conduct root cause analysis and to implement ongoing improvements, to avoid recurrence.

Last tested on 2022-08-24 with product and scenario foreign material in liquid sugar with 100.00% success rate in 1 hour 16 minutes.

The recall part of the procedure included the requirement to notify the CB within 3-days; there had been 0 recalls in the last 12 months. The company is also required to provide sufficient information to enable the certification body to assess any effects to the current certificate within 21 calendar days. This could include corrective actions taken, root cause analysis and a preventive action plan to prevent recurrence.

Details of non-applicable clauses with justification

SGS United Kingdom Ltd

Page **28** of **57**

CB Report No.

607344

Auditor:

Eric Taft



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Clause/Section Ref	Justification
3.5.1.5	No brokers are used.
3.5.4.1 – 3.5.4.6	No outsourced processing is used.
3.6.3	No customer-branded products are manufactured.

4. Site standards
4.1 External standards
<p>The site is suitably sized, located, constructed and maintained to reduce the risk of contamination and facilitate the production of safe and legal finished products.</p> <p>Local activities include industrial areas with manufacturers of non-food items that presented no contamination risk to the item produced at this location. The facility was established in 1951 with several developments over the next few years and the inspection included the production location, warehouse storage, and outside areas.</p> <p>External travel routes are surfaced in gravel in front and grassed areas in back of the production location in adjacent lots. Residential streets extend next to two sides of the building far separated from the site. A rail spur crosses the location with a double gate for security. All areas are in a state of repair that does not present a risk to the products manufactured and/or stored.</p> <p>Building fabric is maintained to reduce the risk of contamination, ingress of water and pests.</p> <p>Policies were in place to record visitors and/or contractors. All were made aware of the requirements when entering the site.</p> <p>Only authorised personnel have access to production and storage areas. Any person entering the area are the responsibility of a nominated site contact.</p> <p>Staff are trained in site security procedures, last on 2023-05-25 based on records reviewed. External storage tanks and pipes were noted to be locked, secured, and monitored with CCTV footage.</p>
4.2 Site security and food defence
<p>The company conducted a documented risk assessment (internal and external threat assessment) last conducted on 2023-02-07 by L.M. who was training FSPCA Food Defense Awareness on 2019-04-12. This individual has site specific knowledge of this location and principles of food defence. The risk assessment considered all the potential risks to products from any deliberate attempt to inflict contamination or damage.</p>

SGS United Kingdom Ltd				
Page 29 of 57	CB Report No.	607344	Auditor:	Eric Taft



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The output of this was documented in a threat assessment plan (Food Defense Protocol 9.1-01 Rev 3) that is reviewed annually or whenever a new risk emerges or following an incident where product security of food defense is implicated. As this facility only exports to North America, no legal requirements in the country of sale or intended use were required. Key pads and/or keys are required for all areas. These are also included in the annual review.

Mitigation strategies are in place for any areas identified at a significant risk level and are controlled, monitored, and reviewed at least annually along with the plan. This includes not only raw materials but also packaging.

Staff are trained in food defence procedures, last on 2023-05-25 based on records reviewed. Security measures in place included CCTV camera monitoring, alarm monitoring, locked doors, staff training, and fence enclosures.

4.3 Layout, product flow and segregation

The factory layout, flow of processes and movement of personnel is sufficient to prevent the risk of product contamination and to comply with relevant legislation.

The site has assessed the production risk zones as required in the Standard and have not identified any areas of high risk, high care, or ambient high care.

There are site maps, dated 2023-05-30 that show:

Production risk zones, access points for personnel, access points for raw materials (including packaging), semi-finished products and open products, routes of movement for personnel, routes of movement for raw materials (including packaging), routes for the removal of waste, routes for the movement of rework, location of any staff facilities, including changing rooms, toilets, and smoking areas (none on site), production process flows, and any areas requiring time segregation to complete different activities.

This was provided to the auditor in electronic copy to review.

Contractors and visitors, including drivers, are made aware of all procedures for access to premises and the requirements of the areas they are visiting and contractors who work in product processing or storage areas are controlled by a nominated person – a sign-in was made available to the auditor upon reception at the site for every day of the audit.

The movement of personnel and also process flow did not appear to add risk to the safety or contamination of product.

There was sufficient working space and storage capacity to enable all operations to be carried out properly under safe hygienic conditions. Space was limited in some areas of the facility; however, the site properly managed all areas.

SGS United Kingdom Ltd

Page 30 of 57

CB Report No.

607344

Auditor:

Eric Taft



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4.4 Building fabric, raw material handling, preparation, processing, packing and storage areas

The fabrication of the site, buildings and facilities is suitable for the intended purpose.

The walls were made from concrete and paint to resist stains designed hygienically in most cases.

Minor 4.4.1 Wall surfaces were not consistently maintained to prevent the accumulation of dirt, minimize condensation and mould growth, and to facilitate cleaning. A section of the wall located behind the sugar melt station, beside the Ro-tap machine, and directly behind pest control internal device #13 was noted to be slightly damaged resulting in a harbourage area.

The floors were made from concrete and maintained in suitable condition.

Drainage consisted of adequate drainage from all areas. Circle and/or trench drains were available in production areas.

Ceilings were made from wood crossbars in warehouse area and metal in production areas and did not present any contamination risk.

Doors (internal and external) were maintained in good order, external doors were suitably proofed to prevent pest ingress. Any that needed to be open during production were fitted with proper seals and cushions around the door to ensure they were adequately pest proofed.

The standard of lighting was adequate in all areas that included storage, process, packing areas to allow inspection of product and monitor results of cleaning.

Adequate ventilation and extraction were also provided in key areas.

4.5 Utilities – water, ice, air and other gases

Utilities used within the production and storage areas are monitored to effectively control the risk of product contamination.

A municipal water supply is used for the following: - hand washing, cleaning, personal use, sugar melting, .

The municipal water is potable at point of use and poses no risk of contamination according to applicable legislation. Evidence to support this included: City water report April 2023. Water was also analysed according to risk to ensure water stored and handled on site is managed properly.

Samples are tested annually by the facility, last on 2023-06-08 . Results were on file for chemical analysis as well as micro results to include Arsenic, Cadmium, Lead, Mercury, TPC, coliform Count, and E.Coli Count.

There was a schematic diagram that shows the water distribution system on site, including sources of water and drainage from different areas as appropriate. The diagram had been used as a basis for the sampling points and the management of water quality.

SGS United Kingdom Ltd

Page 31 of 57

CB Report No.

607344

Auditor:

Eric Taft



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Air and other gasses used for food contact are monitored; filters are in place. Compressed air is used in direct contact with products. This is UV treated and tested for moisture by the facility on a weekly basis. For liquid sugar, air is used to purge lines and pushed out for filling.

4.6 Equipment

All the food-processing equipment is suitable for the intended purpose and is used to minimise the risk of contamination of product; it was constructed of appropriate materials, designed and located to allow for effective cleaning and maintenance.

The purchasing of equipment is performed according to a documented purchase specification detailing the site's requirements for purchase depending on its intended use and requires authorisation from a multi-disciplinary team (maintenance log and capital approval). Suppliers of equipment provide detailed diagrams and contracts to ensure that equipment meets these requirements. Any new equipment will be subject to the Change Management procedure in section 1.2. No examples are on file for this site as new equipment installation has been limited in the past 50 years.

The design and construction of equipment, based on risk, appeared to be maintained to prevent product contamination. No issues were noted during the inspection.

All items were made of stainless steel or were industry standard equipment.

Records of a risk-based commissioning procedure for equipment were reviewed including post-installation cleaning.

Movement of static equipment, if needed, is addressed in the commissioning procedure.

Storage of infrequently used equipment or equipment removed from service did not appear to have any negative effect on food safety.

Mobile equipment (forklifts and other lifts) did not appear to have an impact on the risk to the product. Equipment appeared clean and sanitary during the inspection.

Battery-changing areas were removed from production areas to ensure no risk to products handled. The site has two propane lifts and two battery lifts (scissor lift and forklift).

No examples were on file at this location; however, a Capital expenditure Authorization form dated 2022-09-07 was reviewed for Liquid Sugar Blend Tank #7 to replace with a stainless tank at a different location for a sister facility. This required approval from Project Manager, Director of Warehouse and Logistics, Corporate Engineering, VP of operations, CFO, and President. Additional approvals were noted for quality, safety, and environmental to ensure material is food safe.

4.7 Maintenance

There is a maintenance programme in operation for plant and equipment to prevent contamination and reduce the potential for breakdowns. The planned maintenance program is addressed through Section 5.6 Facility and Equipment Maintenance, it includes a schedule of work and a condition monitoring system (inspection of equipment where there is a risk of product contamination) that includes all plant and

SGS United Kingdom Ltd

Page 32 of 57

CB Report No.

607344

Auditor:

Eric Taft



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processing equipment. The maintenance requirements are defined when commissioning new equipment or based on history. The system also covers unplanned or breakdown maintenance using a work order system. PM are included in the June and May Maintenance logs for 2023. The following planned schedules were reviewed during this audit:

pH water adjustment dated 2023-06-01.

Greasing all the bearings and sweco in the silo dated 2023-05-09.

Document 11.1-REC-001 Rev 1 Preventive Maintenance Schedule listing monthly, quarterly/semi annually, and annual activities.

While maintenance policy is in place, it should be noted that repairs at this site are performed by contractors as no maintenance personnel are present.

There was a temporary repair policy covered in Temporary Repair Procedure section 5.6.2.5 listing procedure and materials to be used, no issues were observed linked to this during this audit.

There was a documented hygiene clearance procedure for line clearance. Maintenance, operations, and QA must sign off on the form prior to work being completed. All areas subject to maintenance are cleaned by facility-designated personnel and documented on the MSS for the week.

Materials used (non-equipment chemicals, lubricating oils) are required to be 'food approved' and of a known allergen status according to the label and the SDS. Examples reviewed during this audit included:

PVC-21 Pipe Cement

4.8 Staff facilities

Changing facilities for factory personnel included: - locations for the storage of employee personal items along with rules for the correct storage.

Visitors and contractors are required to perform donning of hair nets/beard guards and washing hands prior to entrance.

Sufficient size storage locations (locker rooms) were provided to accommodate personal items.

Segregation of outdoor clothing was achieved by racking systems for the storage of uniforms and hangers for uniforms for the mixing area with no outdoor clothing allowed.

Handwashing stations were located at the entrance to production and within restrooms in the office; and included:

-advisory signs to prompt handwashing

-water at adequate temperature

SGS United Kingdom Ltd

Page 33 of 57

CB Report No.

607344

Auditor:

Eric Taft



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-hands free taps

-soap (liquid/foam)

-drying with single use paper towels.

Toilet areas appeared to be adequately segregated and did not open directly into production or packing areas. No issues were noted with the hand-washing facilities inside toilet areas.

Smoking (including the use of electronic cigarettes) is allowed in outside areas only. Adequate arrangements for dealing with smokers' waste was provided.

Areas for the proper storage of food brought into the site is provided inside the employee break area.

Minor 4.8.7 Food was not consistently stored in accordance with the site's policies. An employee working in the sugar melting process was noted with four beef jerky stick in their pocket.

4.9 Chemical and physical product contamination control: raw material handling, preparation, processing, packing and storage areas

4.9.1 Chemical control

Processes are in place to manage the use, storage and handling of non-food chemicals to prevent chemical contamination listed in Chemical control section 5.17 Chemical Control and Approval; these included:

an approved list of chemicals for purchase, availability of material safety data sheets and specifications, confirmation of suitability for use in a food-processing environment, avoidance of strongly scented products, labelling and/or identification of containers of chemicals at all times, a designated storage area with restricted access to authorized personnel, use by trained individuals only, procedures to manage any spills, and procedures for the safe, legal disposal or return of obsolete or out-of-date chemicals and empty chemical containers contained in Spills and Disposal of chemical or cleaner bottles 10.9-06.

Chemicals reviewed in this audit included:

Kroil Penetrant

WD-40

The risk of taint or contamination during building work was covered in capital procedures where strongly scented material have to be used to prevent the risk of taint contamination of products.

4.9.2 Metal control

There is a documented Physical Contaminant Control section 5.9 for the controlled use and storage of sharp metal implements including knives, cutting blades on equipment, needles and scissors. This section of the FSQM also notes policies for glass and wood discussed in later sections.

The policy also prohibits the use of snap-off blades and any disposable blades in production.

SGS United Kingdom Ltd

Page 34 of 57

CB Report No.

607344

Auditor:

Eric Taft



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The policy also prohibits the use of staples, paper clips or push pins in areas where there is open product such as in make-up and production areas.

No issues of concern were noted during this audit.

4.9.3 Glass, brittle plastic, ceramics and similar materials

Policy statements indicate that all glass and other brittle materials will be excluded or protected in open product areas.

Procedures for handling glass and other brittle materials are contained in Physical Contaminant Control section 5.9. This includes:

A detailed list indicating the location and type of each instance of material was in place (Inventory list audited 2023-05-24).

Minor 4.9.3.2 Procedures for handling glass and other brittle materials were not in place for all areas. The list of items used for the checks of the condition of items did not include the number of items inspected in all areas.

This includes procedures for cleaning and replacing line items to minimize the potential for product contamination. A local work instruction is in place titled Glass and Brittle Breakage and Cleanup 10.8.1-01 Rev 3

Documented procedures are in place to address the following areas:

Training

Quarantining of product

Cleaning

Inspection

Changing of workwear and inspection of footwear when needed

Responsible personnel

Record keeping

Disposition of products affected.

Where glass windows pose a risk to product, these are protected against breakage and monitored.

All strip lights were noted to be shatterproof. In the event that a non-shatterproof bulb must be used, alternative management procedures are in place.

4.9.4 Products packed into glass or other brittle containers

No glass or other brittle containers are used at this location.

SGS United Kingdom Ltd

Page 35 of 57

CB Report No.

607344

Auditor:

Eric Taft



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4.9.5 Wood

The use and condition of wood is covered in Physical Contaminant Control section 5.9 to ensure that all wood is inspected prior to use. No wood utensils were noted in open product areas and no issues of concern were noted during this audit. Any wood used for food contact purposes is fit for food use in regards to condition and any treatments and/or paint/taints used.

4.9.6 Other physical contaminants

Procedures are in place to prevent physical contamination of product to include debugging and deboxing procedures in Section 5.9 Physical Contaminant Control. Procedures ensure that all packaging materials are only opened with company issued tools that are monitored.

Pens and other handheld portable equipment (mobile phones, tablets and similar) are controlled to minimize the risk of physical contamination. Employees are only authorized to use company approved pens in product areas. This risk is evaluated along with the HACCP plan for physical contamination.

Based on risk, other types of foreign-body contamination not listed in section 4.9 of this standard is addressed in the HACCP program at this location.

4.10 Foreign-body detection and removal equipment

4.10.1 Selection and operation of foreign-body detection and removal equipment

A risk assessment had been conducted in conjunction with the HACCP / Food Safety Plan study to determine if equipment was needed to detect/remove foreign matter in the process. This assessment identified the need for:

Filters

Metal Detection

Magnets

The equipment identified was documented (location and sensitivity) in the facility Food Safety Plan; in the FSQM section 5.9; and in equipment specific SOPs for the identified control devices.

The frequency of the testing/checking of the foreign-body detection and/or removal equipment is defined in various documents including those mentioned above. These take into consideration the site's ability to identify, hold and prevent the release of any affected materials, should the equipment fail.

These documents also detailed corrective action to be taken. Records reviewed in this audit included: oil metal detector monitoring, filter inspection; magnet inspection and cleaning from several dates. These records are used to document checks performed and any findings noted. Trends are reviewed during management meetings (held as noted in Section 1) to determine if corrective action/preventive action is necessary.

4.10.2 Filters and sieves

SGS United Kingdom Ltd

Page 36 of 57

CB Report No.

607344

Auditor:

Eric Taft



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The liquid used for foreign matter detection had the following mesh/gage size: 100 micron or less for liquid filters .002 micron utilized in two locations. This is listed as the CCP at this location.

Liquid Filters are checked to ensure there are no holes or other damage per CCP Monitoring: Liquid Filter Document 6.3-02 Rev 4. This lists a monitoring frequency of after each load. Any deficiency must be reported to senior management and recorded on 6.3-02 HACCP Deviation: Liquid Filter Rev 3. No deviations were on file within the past year.

4.10.3 Metal detectors and X-ray equipment

Risk assessment had been used to determine the need for metal detection equipment located prior to loading.

The metal detectors incorporate automatic rejection devices which divert suspect product to a bin with access to the QA performing the check only.

The procedure for testing the detector is Metal Detectors 29.06 and Food Safety plan; it includes responsibilities, test frequency, and test piece size. Sizes are listed as follows for each line.

1.5 Fe, 1.8NFe, 2.0SS, 2.0Al

Tests of the 1 metal detector was observed during the audit and were performed to the site's SOP and results were correctly recorded. Interviews with the QC technician J.N. indicated understanding of the procedure in the event of a failed test or metal findings. Metal detector test records were reviewed for 2022-02-09 and during the site inspection conducted on 2023-06-27. Checks are recorded on Metal Detector Bulk Loading Document 6.3-01.1.

4.10.4 Magnets

Four magnets are in use in the plant on bulk flour lines and one on the use bin. Locations are noted on the food safety plan flow diagram. Magnet procedure 10.3.1-01 details checking procedure. Annual testing is performed by the site. Records of the inspection and strength testing of magnets used for food safety purposes is maintained with date of last testing performed 2023-03-24.

4.10.5 Optical sorting equipment

No optical sorting equipment is used at this location.

4.10.6 Container cleanliness – glass jars, cans and other rigid containers

There are no rigid containers used at this facility.

4.10.7 Other foreign-body detection and removal equipment

No other foreign body detection and remove equipment is used.

4.11 Housekeeping and hygiene

SGS United Kingdom Ltd

Page 37 of 57

CB Report No.

607344

Auditor:

Eric Taft



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Housekeeping and cleaning systems are in place to ensure appropriate standards of hygiene are maintained and the risk of product contamination is minimised.

All areas of the facility were maintained in a clean and hygienic condition per section 5.4 Cleaning, Sanitation and Waste. Cleaning observed including dusting the tops of pallets in storage and general warehouse cleaning.

Minor NC 4.11.2 Documented cleaning procedures were not consistently followed in all instances in regards to cleaning chemicals and concentrations. The test strips currently used to monitor the PPM of the sanitizer used to clean sample ports was noted to be expired in May 2020. An unexpired set was found in the office and was used to replace this roll.

Documented cleaning procedures are in place and maintained for the building, plant and all equipment. Cleaning procedures for the processing equipment section 5.7 Cleaning, Sanitation and Waste Management found to include:

- responsibility for cleaning
- item/area to be cleaned
- frequency of cleaning
- method of cleaning, including dismantling equipment for cleaning purposes where required
- cleaning chemicals and concentrations
- cleaning materials to be used
- cleaning records (including records for completion and sign-off) and responsibility for verification. The frequency and methods are based on risk of the areas being cleaned.

Cleaning procedures reviewed included:

SOP for Tanks CIP and System (Kettle) Sanitizing Procedure Doc 10.6-02 Rev 0

Limits of acceptable and unacceptable cleaning performance have been defined for food contact surfaces and processing equipment as visual inspection only. Cleaning records included a review of Master Cleaning records from Warehouse and Liquid room for January 2023. Procedures define the corrective actions to be taken when monitored results are outside the acceptable limits.

No validation is required of the cleaning procedures at this location.

Cleaning staff are trained on each SOP (this includes an evaluation and sign off by the trainer) according to the JSA-REC-001 Station / Job Training.

The cleanliness of equipment is checked by the team leader and supervisor prior to releasing back to production. These checks included ensuring the equipment met standards. This was not witnessed during the audit however associated records were reviewed for the month of June 2023.

Cleaning equipment was:

SGS United Kingdom Ltd

Page 38 of 57

CB Report No.

607344

Auditor:

Eric Taft



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- hygienically designed and fit for purpose
- suitably identified for intended use (e.g. colour-coded or labelled)
- cleaned and stored in a hygienic manner to prevent contamination.

4.11.7 Cleaning in place (CIP)

There is no CIP system at this location. The facility utilizes a hot water flush system to clean tanks; however, this does not meet the requirements of CIP as defined in the BRCGS Standard.

4.11.8 Environmental monitoring

An environmental monitoring program is not maintained based on risk. A risk assessment dated 2023-02-24 Rev 4 is performed based on the aW of finished product (.32), classification of finished product and its pathogen growth potential, customer recommendations, heat treatment options, and FDA guidance.

4.12 Waste and waste disposal

Waste disposal is managed in accordance with legal requirements and to prevent accumulation, risk of contamination and the attraction of pests.

Waste containers observed during this audit (internal and external) were being managed to minimize risk and handled to ensure waste removal from open product areas does not compromise product safety. Dedicated routes and isolated waste areas are used to control any issues.

4.13 Management of surplus food and products for animal feed

Processes are in place to ensure the safety and legality of by-products of the primary processing activity of the site. Surplus items are disposed of per customer requirements. Samples are provided for in-house products to employees and no donation of customer items is made.

By-products and downgraded/surplus products are not intended for animal feed at this location and are sent to waste.

4.14 Pest management

The site has an effective preventive pest management programme in place to minimise the risk of infestation that also complies with applicable legislation. Measures have been taken to control any pest activity identified through regular inspections to prevent it present a risk to products, raw materials or packaging. The procedure 5.4 Integrated Pest Management lists the requirements for pest control.

SGS United Kingdom Ltd

Page 39 of 57

CB Report No.

607344

Auditor:

Eric Taft



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A contracted service provider with a current business license, performs all pest monitoring services at this location. A current scope of service indicated that services are performed for rodent issues (internal and external), pheromone monitors and fly lights at this location. Service is performed on a weekly basis.

The site utilizes a contractor for all services.

Training materials on file for the PCO performing services at this location.

PCO license expires 2023-12-31 and an insurance expiration 2024-01-01.

An approved list of chemicals to be applied at this location and no pesticides are stored at this location.

EPA registered baits are used at this location. Example reviewed were

Selontra Rodent Bait EPA# 7969-382

24/7 contact information is available for the pest control provider.

Service reports maintained at this location were reviewed and the following areas were noted:

An up-to-date map dated 2022-11-29 of the full site is in place

Pest activity is noted on service reports and trend files are available.

Details sufficient to show proper treatment is available. Records from January 2022 through current service in February 2023 were reviewed during the audit. Specific records inspected included

2023-06-20

2023-05-03

Service reports were maintained as an electronic copy and were available for review.

All insect killing and monitoring devices were operational and sited appropriately at this location.

Bird escalation procedures were in place upon the event of an issue. All areas were noted to be sealed to prevent the inclusion of birds.

Records of pest management inspections and recommendations are maintained. These records list the dates of notification and corrective actions to address the issue.

An in-depth survey was performed 2023-01-13 at this location and included review of the existing pest management measures taken and an in-depth inspection of the facility for pest activity.

Trend data is maintained by the contracted service provider and analyzed on a quarterly basis. These trend reports are also reviewed during the annual review of the pest management system. Trend reports reviewed for insect activity in July 2022 to current.

Pest sighting log is utilized by employees and is included in the dispatch office.

4.15 Storage facilities

SGS United Kingdom Ltd

Page 40 of 57

CB Report No.

607344

Auditor:

Eric Taft



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The facilities used for the storage of raw materials, packaging, in-process products and finished products were found to be suitable for purpose.

The site had documented procedures for storage and stock rotation contained in Storage and Handling Food Products Program contained in Section 6.4 and in several sections including 5.11.

Procedures to maintain product safety and quality during storage included:

- segregation of products where necessary to avoid cross-contamination (physical, microbiological or allergens) or taint uptake

- storing materials off the floor and away from walls (18" perimeter maintained)

- specific handling or stacking requirements to prevent product damage

The site facilitates correct stock rotation of raw materials, intermediate products and finished products in storage and ensures that materials are used in the correct order in relation to their manufacturing date and within the prescribed shelf life using FIFO procedures per Section 6.4 under First-in-First-Out (FIFO) Inventory Management.

4.16 Dispatch and transport

Procedures are in place to ensure that the management of dispatch and of the vehicles and containers used for transporting products from the site do not present a risk to the safety, security or quality of the products. These included and are detailed section 5.15 for liquid tankers. This included:

- the use of covered bays for vehicle loading or unloading

- securing loads on pallets to prevent movement during transit

- inspection of loads prior to dispatch.

Section 5.15 lists procedures for all vehicles or containers used for the transport of raw materials and the dispatch of products are inspected for:

- in a clean condition
- free from strong odours which may cause taint to products
- in a suitable condition to prevent damage to products during transit

Records for the dispatch of product for the item trace exercise were reviewed for compliance.

SGS United Kingdom Ltd

Page 41 of 57

CB Report No.

607344

Auditor:

Eric Taft



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In addition, maintenance systems and documented cleaning procedures are in place for loading/unloading.

Procedures were also in place for:

- mixed load restrictions
- requirements for the security of products during transit, particularly when vehicles are parked and unattended
- clear instructions in the case of vehicle breakdown or accident

Contract reviewed for trucking company used by the facility. All elements of sanitary transportation and procedures covered in section 4.16.1 through 4.16.5 of the BRCGS Standard are addressed.

During the audit, loading procedures for trucks were observed. Paperwork from 2023-02-09 was reviewed with shipping to ensure all procedures listed in this section were followed including truck inspection, seals, wash tickets, and security procedures.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
4.3.6	No temporary structures were observed.
4.4.5	No suspended ceilings or roof voids were present.
4.4.6	No elevated walkways, access steps or mezzanine floors are adjacent or pass over production lines.
4.4.7	No windows and roof glazing designed to be opened for ventilation were observed.
4.4.11	No plastic strip curtains are present.
4.7.6	There were no engineering workshops.
4.8.8	No catering facilities (including vending machines) are provided.

SGS United Kingdom Ltd

Page 42 of 57

CB Report No.

607344

Auditor:

Eric Taft



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4.10.3.5	No X-ray systems are used.
4.10.5.1	No optical sorting is used.
4.10.6.1 – 4.10.6.2	No glass jars, cans and other rigid containers are used.
4.10.7.1	No other foreign-body detection and removal equipment is used.
4.11.7.1 – 4.11.7.4	No CIP systems as defined by this Standard are used.
4.11.8.2 – 4.11.8.3	No environmental monitoring program is performed based on risk.
4.12.4	No unsafe products or substandard trademarked materials are transferred to a third party for destruction or disposal.
4.13.1 – 4.13.2	No customer-branded products are made.
4.13.3	No materials intended for animal feed are produced.
4.14.3	A contractor is used for all services.
4.15.3	No temperature control is required.
4.15.4	No controlled atmosphere storage is required.
4.15.5	No storage outside is necessary.
4.16.3	No temperature control is required.

5. Product control

5.1 Product design/development

The procedure section 1.2 details how new products or processes and any changes to product, packaging or manufacturing processes are managed to ensure that safe and legal products are produced. It also

SGS United Kingdom Ltd				
Page 43 of 57	CB Report No.	607344	Auditor:	Eric Taft



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includes guidelines on any restrictions to the scope of new product developments to control the introduction of hazards that are unacceptable to the site or customers (e.g. the introduction of allergens, glass packaging or microbiological risks).

All new products and changes to product formulation, packaging or methods of processing are formally approved by the HACCP team leader or authorised HACCP committee member; Capital expenditure Authorization form dated 2023-02-16 was reviewed for Replace Water Main. This required approval from Project Manager, Director of Warehouse and Logistics, Corporate Engineering, VP of operations, CFO, and President. Additional approvals were noted for quality, safety, and environmental to ensure material is food safe.

If trials are required to validate that product formulation and manufacturing processes to produce a safe product of the required quality, these are also documented according to the procedure in section 5.7

No shelf-life trails are performed at this location. Shelf-life is determined through industry practice and a September 2016 shelf life study published by the National Sugar Marketing for the 30 day shelf life listed for liquid sucrose, 90 for invert sugar, and 5 years for granulated.

5.2 Product labelling

The process for product labelling is covered in section 4.1 that details how legal requirements are met as well as information to enable the safe handling, display, storage and preparation of the product within the food supply chain or by the customer.

Labelling information is reviewed by the plant loading technician whenever changes occur to: the product recipe, raw materials, the supplier of raw materials, the country of origin of raw materials, applicable legislation. Most item are shipped in liquid containers with no labels and the example below is for a granulated shipment to one customer performed approximately 2x per year.

Examples reviewed included labels created (dated 2023-06-08) per section 4.1 Product Lot Numbers which includes the following:

PFYYJJJ

P = Partner Letter Designator

F = Facility Location

YY = Last two digits of year

JJJ = Julian Date

Example provided AP23002

SGS United Kingdom Ltd

Page 44 of 57

CB Report No.

607344

Auditor:

Eric Taft



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5.3 Management of allergens

The site has a system for the management of allergenic materials that minimises the risk of allergen contamination of products and meets legal requirements for labelling in the country of sale.

The site conducted a risk assessment of raw materials to establish the presence and likelihood of contamination by allergens.

No allergens are present at this site.

A documented hazard analysis indicated the risk/severity of each item along with control measure. This is contained along with the HACCP risk assessment reviewed in section 2 of this Standard.

There is a list of all allergen containing items is maintained inside the hazard analysis for each material handled at this site that covers raw materials, processing aids, intermediate and finished products and the allergens present.

The site conducted a process allergen risk assessment on with the HACCP plan reviewed during this audit that included:

- consideration of the physical state of the allergenic material (i.e. powder, liquid, particulate)
- identification of potential points of cross-contamination (cross-contact) through the process flow
- assessment of the risk of allergen cross-contamination (cross-contact) at each process step
- identification of suitable controls to reduce or eliminate the risk of cross-contamination (cross-contact).

Procedures in section 5.16 are in place for the allergenic materials to prevent cross-contamination (cross-contact) of products not containing the allergen. These may include (as applicable to the site):

Segregated areas (physical or time segregation)

Protective clothing requirements

Dedicated tools, utensils, and equipment

Production scheduling

Air movement

Waste handling and spillage controls

GMP procedures for employees

Use of rework

SGS United Kingdom Ltd

Page 45 of 57

CB Report No.

607344

Auditor:

Eric Taft



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Minor 5.3.4 Procedures to ensure the effective management of allergenic materials was not consistently applied. A hand cleaner containing both walnut shell and soy ingredients was noted in the employee restroom area attached to the production area. It was noted that product was not touched by employees with uncovered hands.

A gluten-free certificate is in place; however, no claim is made for the sugar produced at this site. Validation of this claim is performed via annual gluten-gliadin testing to outside labs. Report dated 2023-01-27 from Eurofins is on file for sugar testing.

5.4 Product authenticity, claims and chain of custody

A process for assessing information related to adulteration or substitution is maintained at this site. Personnel engaged in vulnerability assessments are properly trained to understand potential food fraud risks which includes knowledge of raw materials used by the site and the principles of vulnerability assessment. The person performing the assessment, J.A. has been employed by the facility since 2011 and is PCQI trained on 2016-01-21, HACCP training dated 2013-04-18, Food Safety and HACCP 2015-05-14, and FSPCA Intentional Adulteration Conducting Vulnerability Assessments using Key Activity Sites dated 2019-12-26.

This information is based on information received from trade associations (mailing lists and maintained and covered under job descriptions) and discussed in Section 9.2 Food Fraud

Government sources (FDA for U.S and CFIA for Canadian sources

Private resource centres (Food Chain ID) for ingredient status.

A documented vulnerability assessment is performed for all raw materials at this site. Vulnerability Assessments and risk analysis reviewed dated 2023-02-22. This is incorporated into a list of all ingredients (sugar only at this site). This assessment takes into account:

Historical evidence

Economic factors in the country of origin

Access

Testing ability

Nature of the raw material

This plan is reviewed at least annually, last on 2023-02-22, and upon any changing economic circumstances and market intelligence which may alter the potential risks.

The following claims are made:

Orthodox Union certificate for Kosher performed on 2022-12-06 and valid through 2023-12-31 OUV4-4E19D86 for invert sugar. Additional certificates available for liquid and granulated.

Process flows are in place to ensure all claims are met.

SGS United Kingdom Ltd

Page 46 of 57

CB Report No.

607344

Auditor:

Eric Taft



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All claims are fully validated and substantiated. Appropriate controls are established per identified risk zone to ensure the integrity of the product claims.

5.5 Product packaging

Product packaging is appropriate for the intended use and was being stored under conditions to prevent contamination and minimize deterioration as specified in Product Packaging section 4.3.

5.6 Product inspection, on-site product testing and laboratory analysis

Inspection and analyses that are critical to confirm product safety, legality, integrity and quality are performed by trained employees in-house or at an approved laboratory that uses appropriate procedures, facilities and standards.

There are scheduled testing programs found in various documents which included Product Sampling, 7.5-02: Liquid Products (frequency)

The testing programs include:

- chemical test frequency and specified limits
- physical testing; frequency and specified limits

The frequencies of testing are based on risk. All batches of finished product are analysed for physical and chemical parameters including color, pH, turbidity, and brix specified in S200. Any results out of spec. would require the lot placed on hold and product issue further analysed using Non-Conforming Product procedures.

Test and inspection results are recorded and reviewed regularly by the Warehouse Assistant Manager to identify trends for internal and/or external laboratories. Appropriate actions are implemented to address any unsatisfactory results or trends. All testing is reviewed by QA including the uncertainty of measurement associated with any laboratory test results is also considered.

Shelf-life is determined through a shelf-life study reviewed in section 5.1 of this Standard.

Testing laboratories on-site for physical and chemical tests only are located designed and operated to eliminate potential risks to product safety.

5.7 Product release

All items must meet specifications prior to release per Section 7.3 Product Hold and Release. All items are on positive quality hold until appropriate monitoring and analyses occur per HACCP monitoring and recipe. Items can only be approved for shipment by the Warehouse manager or designee.

5.8 Pet food and animal feed

SGS United Kingdom Ltd

Page 47 of 57

CB Report No.

607344

Auditor:

Eric Taft



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No pet food is made at this location.
5.9 Animal primary conversion
No animal conversion is performed at this site.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
5.2.3	Label information is not the responsibility of the customer
5.2.4	No cooking instructions are provided.
5.3.5	No rework containing allergens is used.
5.3.6	No warnings are needed as no allergens are used.
5.3.8	No allergens are used.
5.4.4	No items are identified as being at a particular risk of adulteration.
5.4.5	No claims of this type are made
5.5.2	The site does not use product liners and bags.
5.6.4	No pathogen monitoring is performed.
5.6.5	No internal testing labs are present at the site.
5.8.1 – 5.8.4	No pet food or animal feed is produced.
5.9.1 – 5.9.4	No animal primary conversion is performed.

SGS United Kingdom Ltd				
Page 48 of 57	CB Report No.	607344	Auditor:	Eric Taft



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6. Process control

6.1 Control of operations

The site has prerequisite programs to ensure the production of consistently safe and legal product with the desired quality characteristics, in full compliance with the HACCP food safety plan. This is contained in:

Interviews indicate employees are familiar with corrective action procedures and the general operations.

Only trained and experienced workers can perform equipment adjustments or can perform QC tasks.

Documents available included process specifications and work instructions/procedures for the key processes that included

recipes – including identification of any allergens

mixing instructions (speed, time)

equipment process settings

cooking and cooling times/temperatures

labelling instructions (for the one customer item)

coding and shelf-life marking

storage requirements (if applicable)

any additional controls such as CCP identified in the HACCP plan.

Process specifications reviewed agreed with the finished product specification(s). These are reviewed prior to any changes which may affect the food safety, legality and quality of the product.

Work instructions (including wash time/temperature of trailer cleaning Document 10.9.1-04 Rev 0) are available to ensure any temperature, time, pressure, and other chemical properties are properly implemented.

Where process parameters or product quality is controlled by in-line monitoring devices, these are linked to a suitable failure alert system that is tested by the site to ensure any deviation is noted. A circle recording chart is used to continuously monitor the hot water flush used on tankers and is reviewed on each wash.

No validation is required.

There had been 0 cases of equipment failure or deviation from the process specification in the last 12 months. In the case of equipment failure, material is subject to the non-conforming product procedure.

6.2 Labelling and pack control

SGS United Kingdom Ltd

Page **49** of **57**

CB Report
No.

607344

Auditor: Eric Taft



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There appeared to be adequate management control of product labelling activities to ensure that products are correctly labelled and coded.

Labels are not required for tanker loads; product identification is via COA and BOL and confirmed by the operator. Review shipping documentation records generated 2023-02-09, 2023-02-10, and date of inspection dated 2023-06-27 and found them complaint.

6.3 Quantity, weight, volume and number control

The plant operates to a quantity control system which conforms to customer requirements. Weight checks are recorded on operator forms and verified during the product trace. Finished product weights are taken per Section 6.6 Package Weights and Scale Licensing.

A calibration is performed by an outside vendor the scales used on the truck scales. Records of these calibrations were provided for review last on 2022-04-27

Product not governed by legislative requirements appeared to conform with any customer requirements for weight control. The site has maintained checks of these weights for liquid tankers and is printed on the COA.

6.4 Calibration and control of measuring and monitoring devices

The site has processes in place to make sure that measuring equipment is sufficiently accurate and reliable to provide confidence in measurement results.

There was a procedure Equipment calibration Section 5.5 that identified the following measuring equipment used to monitor critical control points and product safety, legality and quality that needed to be calibrated:

Thermometers

Scales

The procedure included:

- a documented list of equipment and its location
- an identification code and calibration due date
- prevention from adjustment by unauthorized staff
- protection from damage, deterioration or misuse.

The procedure also referenced the need for reference measuring equipment also be calibrated and traceable to a recognized national or international standard and records maintained. The uncertainty of

SGS United Kingdom Ltd

Page 50 of 57

CB Report No.

607344

Auditor:

Eric Taft



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calibration was considered when equipment is used to assess critical limits. External calibration of metal detector by outside vendor. Calibration records on file for the following test piece serial numbers:

Circle Recording chart for Tank wash (calibration record dated 2023-06-27) performed weekly and recorded on RH8.12.16 form.

Weekly verification of thermometers using a NIST certified device with current date.

The results of the records for the equipment identified in this audit were all found to be in good order.

The procedure in the Calibration Program also detailed actions to be taken when the prescribed measuring devices are found not to be operating within specified limits and action taken to ensure at-risk product is not offered for sale.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
6.1.4	No settings critical to the safety and legality of the product are identified.
6.1.7	No products or materials outside the scope of the audit are made.
6.2.4	No online verification equipment is used.

7. Personnel

7.1 Training: raw material handling, preparation, processing, packing and storage areas

The company has systems in place to ensure that all personnel who perform work that affects product safety, legality and quality are competent to carry out that activity, through training, work experience or qualification through a documented Section 5.2 Employee Food Safety and Quality Training.

All relevant personnel receive training on the company's internal policies at orientation and again on an annual basis.

Staff have received training during their induction or orientation and annually, covering basic sickness reporting, with health and safety, personal hygiene rules, allergens, quality requirements, basic HACCP, cleaning, machine operation, quality inspections, and sampling, as appropriate.

Orientation training records were reviewed during the visit for operators on the production floor. Records reviewed in this audit were all found to be in good order.

SGS United Kingdom Ltd				
Page 51 of 57	CB Report No.	607344	Auditor:	Eric Taft



The records for the following personnel were reviewed:

Allergen training for all personnel (including engineers, agency-supplied staff, temporary staff and contractors) was performed on 2023-06-07.

Labelling and Packing processes which are designed to ensure the correct labelling and packing of products was performed last on 2023-06-07. This was performed with all relevant personnel.

Warehouseman #1 J.N. responsible for checking the CCP of metal detection at this location was chosen to review training records. Interviews with this employee also confirmed understanding of the procedures. Training records for these individuals were all found to be in good order. Witnessed forms dated 2023-06-07 for CCP training.

The training program reviewed annually includes provisions for identifying refresher training needs and implementation of training courses accordingly. Employees are cross-trained on multiple jobs as this is a small facility.

The training program covered:

- identifying the necessary competencies for specific roles
- providing training or other action to ensure staff have the necessary competencies
- reviewing the effectiveness of training
- delivery of training in the appropriate language of trainees.

All training is delivered in English as needed and is understood by trainees.

Records of training reviewed for J.N Warehouseman were reviewed and found to contain

- the name of the trainee and confirmation of attendance
- the date and the duration of the training
- the title or course contents, as appropriate
- the training provider
- for internal courses, a reference to the material, work instruction or procedure that is used in the training.

The process for reviewing competency of staff included: initial training with a test, refresher training, direct observation, coaching, mentoring or on-the-job experience.

Training is performed annually and GMP items are included in shift meetings on a weekly basis.

7.2 Personal hygiene: raw material handling, preparation, processing, packing and storage areas

GMP Procedures in section 5.1 Good Manufacturing Practices and Prerequisite Programs and section 5.3 Personnel Practices details instructions on

SGS United Kingdom Ltd

Page 52 of 57

CB Report No.

607344

Auditor:

Eric Taft



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- watches and similar wearable devices are not to be worn
- jewellery is not to be worn, with the exception of a plain wedding ring, wedding wristband or medical alert jewellery
- rings and studs in exposed parts of the body, such as ears, noses and eyebrows, are not be worn
- fingernails will be kept short, clean and unvarnished. Any nail art and false fingernails are not permitted
- Excessive perfume and aftershave is not to be worn.

Requirements are checked by Warehouse Manager or Foreman daily.

Hand washing stations are provided at the entrance to the production area and hand washing is required when entering all production areas.

Metal detectable plasters are used by the company.

Plasters are checked on an as supplied basis as they are from an outside vendor and stocked by the location. Bandages were stored in the QA lab only.

Minor 7.2.4 Not all bandages were present in the records reviewed of metal detectable plasters. Lot number A09522 was not present in the records reviewed at the site.

The GMP policy includes written instructions to control the use and storage of personal medicines.

7.3 Medical screening

Personnel GMP's GMP Procedures contains procedures for the notification of any disease or infection.

Visitors and contractors review a medical /health questionnaire, which is checked by an appropriate manager, or confirm that they are not suffering from any symptoms, which may put product safety at risk before entering the raw material preparation, processing, packing, and storage areas.

Defined actions are provided to any staff (including temporary employees), contractors and visitors for actions to be taken where they may be suffering from or been in contact with an infectious disease.

7.4 Protective clothing: employees or visitors to production areas

GMP rules are documented and followed by all associates (including temp personnel, contractors, and visitors) regarding the wearing of protective clothing in specified work areas.

GMP rules details the wearing of protective clothing in specified work areas (e.g. production areas) and also the policies relating to the wearing of protective clothing away from the production environment (e.g. removal before entering rest rooms and use of canteen and smoking areas).

Protective clothing includes:

SGS United Kingdom Ltd

Page 53 of 57

CB Report No.

607344

Auditor:

Eric Taft



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- is of suitable design to prevent contamination of the product
- fully contains all scalp hair to prevent product contamination
- includes snoods for beards and moustaches, where required, to prevent product contamination. No violation was observed during this audit.

The laundering of protective clothing is carried out by an outside firm (Cintas) with a current outside lab accreditation on cleaning methods. Reviewed lab certificate from Hohenstein.

If protective clothing is required to be washed by the employee, it is only for protective clothing not used for product safety purposes and is only worn in enclosed or low-risk areas of the facility only.

Changes of protective clothing appeared to be conducted at an appropriate frequency to reduce risk.

Gloves were being used in the facility in production and mixing areas; they were blue Nitrile; no issues of concern were noted during this audit.

Where items are not suitable for laundering, these are cleaned and disinfected at a frequency based on risk and defined in program 5.3.2.9.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
7.4.6	All items are suitable for laundering or are disposable.

SGS United Kingdom Ltd

Page 54 of 57

CB Report No.

607344

Auditor:

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8. Production risk zones – high risk, high care and ambient high care production risk zones
8.1 Layout product flow and segregation in high-risk, high-care and ambient high-care zones
Not applicable
8.2 Building fabric in high-risk and high-care zones
Not applicable
8.3 Equipment and maintenance in high-risk and high-care zones
Not applicable
8.4 Staff facilities for high-risk and high-care zones
Not applicable
8.5 Housekeeping and hygiene in the high-risk high-care zones
Not applicable
8.6 Waste/Waste disposal in high risk, high care zones
Not applicable
8.7 Protective clothing in the high-risk high-care zones
Not applicable

Details of non-applicable clauses with justification

SGS United Kingdom Ltd				
Page 55 of 57	CB Report No.	607344	Auditor:	Eric Taft



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Clause/Section Ref	Justification

9. Requirements for traded products
9.1 The food safety plan - HACCP
Not applicable
9.2 Approval and performance monitoring of manufacturers/packers of traded food products
Not applicable
9.3 Specifications
Not applicable
9.4 Product inspection and laboratory testing
Not applicable
9.5 Product legality
Not applicable
9.6 Traceability
Not applicable

Module 11: Meat Supply Chain Assurance
11.1 Traceability
11.2 Approval of meat supply chain

SGS United Kingdom Ltd				
Page 56 of 57	CB Report No.	607344	Auditor:	Eric Taft



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11.3 Raw material receipt and inspection

11.4 Management of cross-contamination between species

11.5 Product testing

11.6 Training

Module 13: Meeting FSMA Requirements for Food – July 2022

Preventive Controls for Human Food: 21 CFR Part 117 (Clauses 13.1.1 – 13.1.33)

Preventive Controls for Animal Food: 21 CFR Part 507 (Clause 13.2.1)

Food Defence: 21 Part 121 (Clauses 13.3.1 – 13.3.11)

Sanitary Transportation: 21 CFR Part 1 Subpart 0 (Clauses 13.4.1 – 13.4.9)

Produce Safety: 21 Part 112 (Clauses 13.5.1 – 13.5.18)

14.1 Additional Specifier Requirements

14.1 Traceability

14.2 Environmental Monitoring

14.3 Product inspection and laboratory testing

14.4 Protective clothing: Employees or visitors to production areas

SGS United Kingdom Ltd

Page 57 of 57

CB Report No.

607344

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