Audit Report

Global Standard for Food Safety Issue 8: August 2018

1. Audit Summary			
Company name	Tate & Lyle Ingredients Americas LLC	Site Code	1818906
Site name	Tate & Lyle Ingredients Americas LLC-Duluth		
Scope of audit	The hydrolysis and isomerization of maleic anhydride to make malic acid and fumaric acid, drying the material and packing into bags, drums and super sacks		
Exclusions from scope	none		
Justification for exclusion	NA		
Audit Finish Date	2019-05-01		
Re-audit due date	2020-05-06		

Additional modules included			
Modules	Result	Scope	Exclusions from scope
Choose a module	Choose an item		
Choose a module	Choose an item		

Head Office	No

2. Audit Results					
Audit result	Certificated	Audit grade	AA	Audit type	Announced
Previous audit grade	AA	Previous audit date	2018-04-17		
Certificate issue date	2019-05-16	Certificate expiry date	2020-06-17		

Number of non-conformities	Fundamental	0
	Critical	0
	Major	0
	Minor	0

3. Company Details

Address	110 Spring Street, Duluth, MN 55808		
Country	United States	Site Telephone Number	12186280126
Commercial representative Name	Richard Benner	Email	Richard.benner@tateandlyle.com
Technical representative Name	Katherine Stephenson	Email	Katherine.Stephenson@tateandlyle.com

4. Company Profile

Plant size (metres square)	<10K sq.m	No. of employees	1-50	No. of HACCP plans	1-3

Shift Pattern	24 hours/7days a week.5 employees on production floor per shift, 20 employees for office, lab, maintenance. boiler room, and warehouseShifts:07:00–19:00, 19:00 – 07:00 Friday – Tuesday07:00-15:00, 15:00-23:00, 23:00-07:00 Wednesday - Thursday
Subcontracted processes	No
Other certificates held	Kosher, Halal
Regions exported to	North America South America Asia Europe Africa
Company registration number	FDA #6561
Major changes since last BRC audit	No major changes.

4. Company Profile

The Duluth plant is one of the Tate and Lyle food grade plants. The building was built in 1977 and contains 2230 square meters of area. The plant employs 41 people on a 24- hours a day/7 days a week schedule. The plant is located on the shore of St. Louis River on the south side of Duluth, MN. Maleic anhydride is received in rail cars and converted into dry malic acid and fumaric acid. Products are shipped in Kraft paper/poly bags, poly lined fiber barrels and poly super sacks. Finished goods are loaded onto a trailer and held on-site until the product is tested and released. The product is then shipped to an off-site warehouse for subsequent shipment to customers throughout the world.

5. Product Characteristics

Product categories	15 - Dried food and ingredients				
Finished product safety rationale	pH of 2.2, moistures of less than 0.5%				
High care	No	High risk	No	Ambient high care	No
Justification for area	The processing areas are enclosed. All products are shelf stable at ambient temperatures; there is no “kill step”. Packaging area is low risk as per BRC decision tree.				
Allergens handled on site	none				
Product claims made e.g. IP, organic	Kosher , Halal				
Product recalls in last 12 Months	No				
Products in production at the time of the audit	malic acid in 50 pound bags				

6. Audit Duration Details

On-site duration	12 man hours	Duration of production facility inspection	4 man hours
Reasons for deviation from typical or expected audit duration	The plant is very small, the process is completely enclosed and automated. There was a head office audit performed for corporate controlled functions.		
Next audit type selected	Announced		

Audit Duration per day

Audit Days	Audit Dates	Audit Start Time	Audit Finish Time
1 (start date)	2019-04-30	08:00	16:30
2	2019-05-01	08:00	12:00

	Auditor (s) number	Name	Role
Auditor Number	123235	Colette Thiel	Lead Auditor
Second Auditor Number	N/A		Please select

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
Rich Benner/Plant Manager	x	x	x	x
Steve Abramson/Production Superintendent	x			x
Katherine Stephanson/Quality Assurance Manager	x		x	x
Manley Olson/Maintenance Manager	x	x		x
Patrick Duyck/Engineer	x			x
Rick Sheldon/Shift Supervisor	x			

Non-Conformity Summary Sheet

Critical or Major Non Conformities Against Fundamental Requirements				
No.	**Requirement ref.**	**Details of non-conformity**	**Critical or Major?**	**Anticipated re-audit date**

Critical			
No.	**Requirement ref.**	**Details of non-conformity**	**Anticipated re-audit date**

Major							
No.	**Requirement ref.**	**Details of non-conformity**	**Correction**	**Proposed preventive action plan (based on root cause analysis)**	**Evidence provided document, photograph, visit/other**	**Date reviewed**	**Reviewed by**

Minor							
No.	**Requirement ref.**	**Details of non-conformity**	**Correction**	**Proposed preventive action plan (based on root cause analysis)**	**Evidence provided document, photograph, visit/other**	**Date reviewed**	**Reviewed by**
1							

Comments on non-conformities

Major							
No.	**Requirement ref.**	**Details of non-conformity**	**Corrective action taken**	**Root cause analysis and proposed action plan**	**Evidence provided document, photograph, visit/other**	**Date reviewed**	**Reviewed by**

Additional Modules / Head Office Non-Conformity Summary Sheet

Critical			
No.	**Requirement ref.**	**Details of non-conformity**	**Anticipated re-audit date**

Minor							
No.	**Requirement ref.**	**Details of non-conformity**	**Corrective action taken**	**Root cause analysis and proposed action plan**	**Evidence provided document, photograph, visit/other**	**Date reviewed**	**Reviewed by**

Detailed Audit Report

1. Senior management commitment

1.1 Senior management commitment and continual improvement

There is a Global Quality Mission Statement signed by the Plant Manager and Chief Executive (2018-09-25) that is posted in the conference room, quality laboratory/control room and break rooms and is in the food safety manual. The plant is involved in a “First Pass Quality” system, the goal is 99.4%. The plant’s current performance level is 99.5%. Reduce tramp metal by 5% (goal started in April, better than last year so far).
The customer complaint target is 0.70 complaints per 100 shipments; the plant’s current performance is level is at 0.94 complaints per 100 shipments.
There is a posting board that lists the KPIs and monthly reports and daily shift meetings.
The food safety and quality culture of this site has been evaluated with a survey and there is an improvement plan. A portion of the Management Review meeting is dedicated to the food safety and quality culture. There is a new “stop work” program, if an employee sees anything that is not food safe.
The Management Review Meeting (Quality Assurance Program Review) is held quarterly (EX: 2019-04-11) and meeting minutes were reviewed. There are topics from the previous meeting, customer complaints, internal and external audits, food defense, food fraud, HACCP plan changes new BRC standard changes and regulatory changes.
Quality topics are discussed through mid-year meetings of Quality Assurance Managers via web-ex (2018-04-12). Topics covered included: safety, regulatory update, customer complaints, and goals for the next year. There are also daily meetings that include any relevant food safety topics.
Notifications by the Corporate Quality Assurance via email keep the plant informed of changes in government policies.
The core staff all attended the opening and closing meetings, including the Plant Manager. The Plant Manager and other staff members participated in the audit when their areas of responsibility were examined.
There is an electronic copy of the BRC Standard (version 8) on file.
One minor from the last BRC audit was resolved (clause 3.9.1).

1.2 Organisational structure, responsibilities and management authority

There is an Organizational Chart (2019-04-22). All Plant employees report to the Plant Manager. The coverage for absences is stated on the Organizational Chart (EX: The Production Superintendent is the back-up for the Plant Manager; the Supervisors back up the Plant Superintendent).
Job descriptions for Quality Assurance Manager and Plant Manager were reviewed.
Employees interviewed on the process floor had a clear understanding of their jobs and when to contact management; they were able to identify the chain of command.

2. The Food Safety Plan – HACCP

HACCP team: The HACCP Team is made up of the Quality Assurance Manager-Team Leader (trained in FSPCA 2016-08-24), the Plant Manager, the Production Superintendent, the Production Supervisor, the Maintenance Supervisor, the Process Engineer, the MRP Controller and a QA Technician. Internal resources have trained the remainder of the team.

Products: Product manufactured in this facility: malic acid and fumaric acid, in powdered form

Product characteristics: pH of less than 2.2, moisture of less than 0.5%-powders with up to 5 years shelf life
Packaging is into bags, drums and bulk containers. Distribution states: inspected, secure, cool, dry trucks.
The intended users for all products are defined as: “the food industry and industrial users”.

Process flow steps: Receiving, storage, batching, reaction, precipitation, separation, drying, purification, evaporation, crystallization, screening and packaging
The HACCP Team annual review of flow charts on 2019-02-07; with final corporate approval on 2019-04-10.

Hazard analysis and Hazards: Each step of the process was evaluated in the hazard analysis. All steps were evaluated for:
Chemical (Allergens are addressed)
Physical (metal)
Biological risks (Salmonella, Coliform, yeast and mold)
Radiological risk (this has been considered in a corporate study and found to be not a risk factor)
A decision tree system was used to assess the likeliness and severity of risk.

CCPs and critical limits: There are 4 CCPs:

CCP 1 3.0 mm screen
CCP 2 3.0 mm screen
CCP 3 Metal detection on the bagging line (2.0 mm Ferrous, 2.0mm non-ferrous, 3.0 mm stainless steel)
CCP 4 Metal detection on the tot line (2.0 mm Ferrous, 2.0mm non-ferrous, 3.0 mm stainless steel)
If metal detector or screens fail then product is held from the last good check. Screens are checked twice per shift and metal detector once per shift.
For the screens, critical limits are: “Screen not in place, any tears or signs of screen breakage, or screen with openings greater than 3 mm.” For the metal detector, the critical limit states: “Metal Detector does not trip or reject the bag.”

The screens are placed just before the metal detectors. The metal detectors are the last process before packaging

Validation methods of CCPs The validation of the CCPs is done with a review of Deviation Reports, customer complaints and non-conforming product as a result of foreign material.

Monitoring and corrective actions: CCP monitoring is done by the “Dry-side Operator”. The Screens are inspected by visual inspection twice per shift (every 8 or 12 hours depending on the day of the week). The Dry-side Operator checks the metal detectors once a shift. The corrective action for the metal detectors states: “If metal detector fails to detect the test piece, stop packing, contact the Supervisor, place product on hold from the last good check. If the detector fails to detect the test pieces, contact Maintenance to investigate and correct by adjusting the sensitivity or repair.”
The auditor observed the Operator while he was performing his checks during the plant tour on the first day of the audit.

The PRP and HACCP plan were last reviewed on 2019-02-07.

Shelf Life Validation: 5 years with controlled temperature and humidity. Shelf life studies are ongoing (testing is performed at 75% of shelf life, 100% of shelf life and 125% of shelf life)

3. Food safety and quality management system

3.1 Food safety and quality manual

There is an electronic version of the Food Safety documents (this is on a shared drive and includes corporate and plant policies; Share-point). The computer system is backed up off site (at the home office in Decatur, IL). There are Standard Operating Procedures (EX: HACCP Sweeco and Vibra Feed Screen Checks S.9.17.0, r7), and general policies and procedures (EX: document control, Good Manufacturing Practices). The standard operating procedures are available to operators through Share-point, which is available through the computers in each department. The revisions are tracked through the Share-point system.
Corporate policies And procedures covered in the head office audit.

3.2 Document Control

The “Document Control Policy” defines the document control procedures; documents are in Share-point computer system. There are plant and corporate documents in binders that comprise the food safety documents. The plant issues Standard Operating Procedures and policies that further define the policies that are issued by the Corporate office (There is a corporate document control policy; this was covered in the corporate head office audit).

There are Standard Operation Procedures (EX: Procedure for Restarting After Opening the Guard Gate, S 9.1.43E, rev 0. This same revision number was found in the master document system.) for the operators to use that are controlled through the Quality Systems Record List of documents (these are reviewed annually by the Quality Control Manager).

3.3 Record completion and maintenance

Records were retrieved from 2018-05-01, 2018-08-01, and 2019-02-01 for sanitation, batch records, laboratory results and shipping records. These records were gathered in a reasonable time, and were complete, neat and orderly (this information was stored in the computer). The operators initial forms, supervisors review and initial forms (this is done through the computer, all personnel use passwords for identification). Production and laboratory records are retained for an indefinite period; these are on the computer and are backed up. Shipping and receiving records are retained for 3 years (some records are retained longer as they are electronic records). Quality Assurance records are retained indefinitely on the computer. Electronic records are backed up in the cloud-covered in the head office audit.

3.4 Internal audits

Internal audit Programme: Head office BRC audit covered topics that were reviewed (management commitment food safety, food defence and supplier quality) There is an audit schedule annually, performed monthly. There are internal audits which are performed by the Director of Global Quality and the Quality Assurance Manager. Each finding from audits was discussed in Management Review Meetings...

Auditor competence and training: The Director of Global Quality and the Quality Assurance Manager audited this site against the BRC Standard. The Quality Assurance Manager audited sections 3-7 of the BRC Standard (some topics are covered each month). The Quality Assurance Manager was trained for internal auditing on 2015-12-19.

Site Inspections: There are monthly GMP inspections (performed by management personnel). These audits from 2019-02-22 and 2019-04-29 were reviewed. The items cited 2019-02-22, required repair to the insulation. A work order has been placed for this repair). The results of the inspections are shared with all staff through email and posted in the discussed in staff meetings.
Quarterly glass and brittle plastic inspections and an annual plant security audits are also performed.

3.5 Supplier and raw material approval and performance monitoring

3.5.1 Management of suppliers of raw material and packaging

Supplier approval is performed at the corporate headquarters and was covered in the head office audit.

3.5.2 Raw material and packaging acceptance, monitoring and management procedures

All materials must come in with Certificates of Analysis (Certificates of Analysis were on file for sulfuric acid, last load received on 2019-02-05). All incoming materials have a visual inspection.
At receiving, the plant uses a form (Tank Truck/Railcar Receiving Form) to evaluate and document the conditions of materials. If there are any issues, the material is put on Hold. Issues are communicated to the Corporate Purchasing group through the Plant Coordinator.

3.5.3 Management of suppliers of services

There is a list of service suppliers; these contracts are managed from the home office. This was covered in the head office audit.

3.5.4 Management of outsourced processing

There is no outsourced processing or packaging at this site.

3.6 Specifications

Specifications are handled through the purchasing department at corporate headquarters; this was covered in the head office audit.

3.7 Corrective and preventive actions

Data bases are used to record any incidents leading to out of specification product (these are in Share-point; FY20 Non-Conformances). (Customer complaints an internal audits have separate databases and are not in this one)

The FY19 Non-Conformities database includes a Root Cause analysis is included in the description of the resolution. (EX: on 2018-06-25, fumaric acid fine grain was not sufficiently fine at 30 mesh testing. A leak in the cooler bed was found and welded up).

3.8 Control of non-conforming product

There was no product on Hold during the audit. (Product that is on Hold is blocked in the SAP materials management system and is not shippable). Product is to be reprocessed is listed in a file and tagged with yellow orange “Reprocess” stickers. Product from cleaning at change-overs is reprocessed. Any member of the Quality Assurance staff can put product on “Reprocess” and release-it.

3.9 Traceability

Site trace system: At least three trace exercises are conducted annually, per the corporate policy “Global Policy Recall Food and Feed Products”. One on food contact packaging and one on an ingredient and one for finished product.
The site uses a materials management system (SAP) to track all materials. Trace exercises are performed annually. Most of the required information is stored in the SAP materials management system.

Trace exercises were reviewed (EX: on 2018-06-26 a trace was performed on the malic anhydride (lot# HMAX41112) raw material (187990 pounds). This was accomplished in 30 minutes, with 100%.

A trace exercise was conducted during the audit:
The raw material sodium hydroxide Lot # UTLX630147, was traced. 191,240 pounds were received on 2018-10-16. The sodium hydroxide was used in 56 production runs. 1,976,570 pounds shipped to customers. 95,800 pounds are still in stock. The product was traced from the receipt to the final customer in one hour; 100% of the sodium hydroxide was accounted for.

3.10 Complaint handling

There is a corporate Customer Advocacy handles complaints and tracks them in a database on the shared drive. This portion was covered in the head office audit.
The Quality Assurance Manager at the site oversees the investigation at the plant level. Current complaints were reviewed; lumps and caking were the issues. (EX: on 2019-03-20 the customer reported lumps in product, from lot DU18G92812; in Indonesia Retained samples were not clumpy). Complaint reports are documented and reviewed in the management meetings.

3.11 Management of incidents, product withdrawal and product recall

There have been no recalls in the last 12 months. There are crisis plans (Emergency and Distress Plan; includes natural disasters, fire and explosions). This is a corporate policy and was reviewed in the head office audit.
There is a corporate level procedure for recalls (Global Recall policy for Food and Feed Products). This is a corporate policy and was reviewed in the head office audit.

4. Site standards

4.1 External standards

The Duluth Plant is located on a site on the St. Louis River (a tributary to Lake Superior). A boat storage company is located to the south side of the plant. A rail track is located along the east side of the plant and the river is on the north and west side. The entire site is fenced. The environment around the plant does not pose a risk to the product. The grounds are well-maintained. There is concrete, gravel and asphalt adjacent to the walls and the areas are in good condition. Inspections are regularly conducted of the grounds.

4.2 Site security and food defence

There is an annual food defence audit performed at this site (through the FDA Plan Builder tool--2018-05-24). Security measures were observed during the plant tours, including a fence, guard house and locked chemical intake ports.
Food Safety/food fraud is monitored from the corporate office. This was reviewed in the head office audit.
All visitors, drivers and contractors sign in at the guard house. Long term contractors are provided electronic access and enter the site through the guard house. Once on-site, there are not any restrictions for employees and contractors. The offices are secured after business hours.
FDA Bioterrorism # xxx6561

4.3 Layout, product flow and segregation

The plant has a documented risk assessment that has identified the risks associated with all areas of the plant. The processing areas have been determined to be either enclosed areas or low-risk areas. The highest risk areas (referred to at the plant as open-product zones) are the bag filling/tote filling areas (these are “low risk” area). There are Site Maps (dated 2019-05-01) that are used to identify the traffic flow around the site. Contractors, visitors and drivers sign in at the guard house located at the plant entrance. There is sufficient working space and storage to operate in a hygienic manner. There were no temporary structures at the site.

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

Walls are made of insulated corrugated metal panels and concrete. Structural I-beams observed during this audit were free of dust and accumulation. No mold growth was observed on the walls. Floors in the plant are in very good condition (there are new floor coverings applied in many areas of the both the wet-side and the dry-side of the plant). There is a mix of circular drains and grate covered trough drains on the first floor. All or the floors are properly sloped to bring water to the drains. The ceiling insulation in the entire plant is in very good condition. There are not any glass windows in the Duluth Plant. There are windows located in remote Control Rooms and the glass is shielded. The windows are in good condition and the product in areas adjacent to the windows is completely enclosed. All of the doors observed on this audit were in good condition and were adequately sealed to prevent pest entry. The lights are shielded to reduce the risk of breakage. All of the upper level doors were covered with screens to allow for ventilation of the building.

4.5 Utilities – water, ice, air and other gases

Water is provided to the plant by the City of Duluth, MN. The plant has a Water Quality Report from the City of Duluth (2016). The plant submits annual water samples to a third party laboratory (NELAP accredited, samples submitted 2017-06-28) which are tested for Coliforms, Total Plate Count and for E. Coli. A detailed water flow diagram was examined (2015-04-27). The diagram shows how water is distributed in the plant.
Compressed air or steam are not used in contact with the product.
Nitrogen is used to blanket the unloading of Maleic anhydride from rail care and the outside Storage Tank. The blanketing is done for safety, not for a quality function. Nitrogen is purchased to meet a Tate & Lyle specification of 99.95% purity. (Nitrogen is used to force the maleic acid out of the rail cars into the storage tank; this was observed during the first day of the audit; the Certificate of Analysis showed that the material was within specifications, dated 2019-03-14).

4.6 Equipment

The equipment at this site is suitable for use in a food processing plant operation (constructed of stainless steel and rubber conveyor belts).

4.7 Maintenance

There is a preventive maintenance program in the SAP system that undertakes regular checks and repairs. (EX: the preventive checks of the P202 transfer pump were reviewed. The seals and guards received their six month check on 2019-04-24). There is a program for tool cleaning, tool accountability, clean up after maintenance repairs (documented on the Work Order forms). Food grade lubricants and non-food grade lubricants are used in the processing areas at this site (these are stored separately in a locked and labelled cabinet). Non-allergenic, statements are on file (EX: Cassida Grease RLS 2 is used, and there is a letter on file from the manufacturer stating that these are non-allergenic). Monthly Good Manufacturing audits check on the condition of equipment and the building exterior and interior. No temporary repairs were seen in the plant. Backflow devices are tested annually (2018-08-08). The maintenance shop was tidy.

4.8 Staff facilities

The staff support areas are clean and sufficient in size for the number of employees. There is a microwave oven, a sink with warm water for washing utensils, a refrigerator, tables and chairs, plenty of light and ventilation in the lunchroom. The rest rooms were clean, with warm water, soap, paper towels, waste bins and signs to remind employees to wash their hands. There are lockers are provided for employees personal items. Separate uniform storage is provided.
There is no smoking allowed on the site. Smoking may only be practiced off of the company grounds.
There is no catering service at this site. There are no high risk or high care areas.

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

4.9.1 Chemical control

In-process chemicals are purchased from a chemical supplier from an approved list. Cleaning chemicals are stored in a locked room. Inventory and chemical ordering is performed by the Inventory Manager. The sanitation operators are trained in the use of chemicals. No cleaning chemicals are used here.
“pH 4 buffer” is a chemical used at this site; and the SDS for it is in Share-point (the shared drive that is on all company computers throughout the site). There are no strongly scented chemicals at this site.

4.9.2 Metal control

Knives are utilized on the site for reprocessing bagged materials. These are signed out at the start of a shift, returned at the end of the shift and tracked through the Utility Knife Inspection and Sewing Needle List Replacement Sign Out Check Sheet (records for 2019-03-07 to 2019-04-20 were reviewed). There are no staples or other foreign-body hazards used as part of the packaging materials. Staples, paper clips and drawing pins are not used in open product areas.

4.9.3 Glass, brittle plastic, ceramics and similar materials

There is a policy for Glass, Hard Plastics, Ceramic Material and Wood Control, (2016-12-30), which includes practices and details on cleaning up after a breakage. There is an inspection and it is done quarterly, section by section (January, 2019 and April, 2019 records were reviewed). Work orders were written to replace four items.

4.9.4 Products packed into glass or other brittle containers

There is no product packed into glass or brittle containers at this site.

4.9.5 Wood

The “Global Detection and Control of Foreign Material” includes wood control. Wood is limited to pallets only. The only wood seen in the plant processing area was wooden pallets (new wooden pallets are used; these are stored indoors).

4.9.6 Other physical contaminants

This process is a completely closed system. The only additions are reprocessed materials; there is a screen at the dump station and filters further along in the process.

4.10 Foreign-body detection and removal equipment

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

Foreign body risk assessment conducted in association with the HACCP study and controls include:
Risk controls include filters to verify that there are not any foreign materials present. Sifters, magnets and metal detectors are used in the processes.
The baggers and the tote filling stations will shut down the filler and the bagger if metal is found with the metal detectors. The frequency of checking the sifters is every 6 hours; checks are every 12 hours for metal detection. The metal detector on bagging line rejects the product, using a push arm. The Team Coordinator will fill out a Metal Detection Deviation Notification is there is a failure of the sifters or the metal detectors. Deviations have been recorded on 2019-01-28 and 2019-04-04; the 3 mm screens were intact.

4.10.2 Filters and sieves

Filters are located on the unloading lines for processing aids and in the Wet Side. Filters are inspected and cleaned weekly. All checks and changes are documented in MDE and Log Book. The Scalping Screens are identified as CCPs and challenged according to the HACCP Plan. The sifter screens in dry processes are changed out when signs of wear appear. Changes are documented in the Maintenance Portion of SAP. Failures for other than wear are reported in the HACCP Plan.

4.10.3 Metal detectors and X-ray equipment

All dried product passes through a metal detector before to release for shipment. The in-line metal detectors are located on the filling lines for totes and on the bag line. Kraft bags are used to pack powdered product and they are run through metal detectors after they have been filled (this was observed and explained during the audit). The reject mechanism is a divert valve on the tote lines and a push arm and alarm on the bagging line. All CCP monitoring is done by the operators. Test pieces containing 2.0 mm Ferrous, 2.0 mm non-Ferrous and 3.0 mm stainless steel spheres are passed through the metal detectors every twelve hours. The metal detector checks and the sifter inspections are verified by the Team Coordinator every shift (there is also a weekly direct observation by the Supervisor). The corrective actions for metal detector failures are documented in the HACCP Plan.

4.10.4 Magnets

There are 14 magnets located in the process and under the Scalping Screens over the bag filling hoppers and on the tote filling line. The magnets are checked every 12 hours. The results are recorded in MDE. A third-party company conduct pull-tests annually (last on 2018-08-16) and the report was reviewed by the auditor. All magnets are within expected limits (minimum is 7 pounds, all magnets are over 9 pounds of pull strength).

4.10.5 Optical sorting equipment

There is no optical sorting equipment in use.

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

There are no rigid containers in use.

4.11 Housekeeping and hygiene

A Sanitation Policy is implemented and all SSOPs is available for the employees through the Production Superintendent (the Standard Operating Procedure for Washing from D-702 to 400 screener cyclone was reviewed; this includes Personal Protective Equipment, tools needed, chemicals needed and procedure). Most of the cleaning at this site is performed with hot water; no chemicals are used. When the acids are washed out of the equipment, the pH will return to 7—this is the cleanliness check. The area supervisors visually inspect the work and sign off on the paperwork (Production and Equipment Cleaning Checklist, records were reviewed in 3.3).
There is a third party service that cleans the rest rooms, breakrooms and offices.
The site is mostly a dry site, with much of the cleaning comprising vacuuming (there is a significant emphasis on cleaning). During the plant tours, all areas were well cleaned. Operators clean their areas at the end of their shifts. Wet cleaning is performed about every 6 weeks.
Sanitation Standard Operating Procedures for cleaning are on file in the computer (in Share-point).

4.11.7 Cleaning in place (CIP)

The plant does not CIP equipment.

4.11.8 Environmental monitoring

No environmental monitoring is performed. The site is totally an enclosed process, handling chemicals that are used as an ingredient in food processing (pH 2.2) A risk assessment was performed 2016-10-06 that states the products made at this site are anti-microbial (pH of less than 2).

4.12 Waste / waste disposal

Trash is picked up in a dumpster weekly (more frequently if needed) and taken to the landfill. Close-topped dumpsters are used to contain trash until they are picked up. There is a dumpster located the east side of the plant. The dumpster observed during this audit was clean and closed. All bags and totes are labeled with the Tate & Lyle name and the product name. Bags of non-conforming product are opened up and the material is reprocessed.
Waste water is neutralized before it is sent to the municipal sewer. This site has a waste permit (five year permit, issued 2016-07-15).

4.13 Management of surplus food and products for animal feed

The plant does not make customer-branded products. No product is donated or sold as animal feed from this site.

4.14 Pest management

There is a contract pest control service used at this site (weekly). There is a contract (2019-02-25) that defines the services of the pest control company. There are up to date licenses, insurance, map (2018-01-25), with icons identifying the locations of the devices, pest sighting log, list of approved chemicals and Safety Data Sheets (Tempo Ultra WP was used on 2019-03-03 for crawling insects, the SDS was available online). Hard plastic bait stations are used. There is a plan for a response to pest issues in the front of the pest control computer file; action thresholds are stated.
There are annual in-depth program reviews (records of 2019-02-05 were reviewed). Trend graphs are available through the online tool showing that there is limited pest activity, are updated by the pest company in the pest control file. The records of pest control activities, licenses and review report are all online.

4.15 Storage facilities

All totes and bags are shipped directly to the adjacent contract storage facility; all finished packaged goods are stored on pallets, which are sent to the third party warehouse within a day or two of production. These are loaded directly onto transport trailers.

4.16 Dispatch and transport

The plant uses shuttle trailers to ship finished goods to a third party warehouse a short distance away.
The corporate headquarters has this contract; this was reviewed in the head office audit.
The trailers are inspected prior to loading (documented on the Quality Assurance Trailer Pre-Loading Checklist, records were reviewed during the plant tour). Records were checked in 3.3.

5. Product control

5.1 Product design/development

The company has a process titled the Stage Gate Process that documents the steps that are required for the introduction of new products. This is a corporate policy and was reviewed in the head office audit.
There have been no new products at this site in the last 12 months.
The Management of Change is a corporate function; this is a corporate policy and was reviewed in the head office audit.
Shelf life trials are ongoing at this site. Samples of fumaric acid and malic acid have been held and tested with HPLC for acid content and moisture. Samples are held and tested for 5 years, the shelf life of the products.

5.2 Product labelling

Bagged product is shipped domestically and exported. Bags are pre-printed with company name, company address and net weight. This information is provided from corporate headquarters; this is a corporate policy and was reviewed in the head office audit.
The additional information is ink jetted with a lot #, mfr. Date, best by date, bag number and time. Labels are stuck onto totes, and a label is placed into a holder on the tote.
Tote labels are printed on site; these are brought to the Quality Assurance laboratory and checked at the start of a run.
Finished products are packed into the same bags or totes regardless of the final country's destination.
There is a third party warehouse nearby that would handle any additional labelling of the bags for a specific country or customer.

5.3 Management of allergens

No allergens are handled on site but allergen awareness is part of employee training and refresher training. Allergens in raw materials and processing aids are addressed in the questionnaire that all suppliers must complete. Only non-allergen suppliers are approved. Suppliers are approved at the corporate level (this was covered in the head office audit). The plant has conducted a risk assessment to determine the allergen risk.

5.4 Product authenticity, claims and chain of custody

The food fraud risk assessment was covered in the corporate head office audit.
The plant is currently Kosher (Orthodox Union; certificate expiry is 2019-12-31) and Halal (IFANCA, certificate expiry 2020-01-31). Purchasing records for all raw materials are maintained by the corporate office; this was reviewed in the head office audit.

5.5 Product packaging

Packaging is purchased by the corporate purchasing department; this was reviewed in the head office audit.

5.6 Product inspection and laboratory testing

5.6.1 Product inspection and testing

In process testing depends on the product; operators test for fumaric acid during changeovers (fumaric is insoluble, malic acid is soluble in water).
A sampling plan is used and the product is tested in process-- High Pressure Liquid Chromatography, pH, are tested on in- process product. Finished product is tested for particle size, purity, high pressure liquid chromatography, moisture, and water insolubility and residue on ignition. Each year heavy metals testing is performed on the finished product. All products are on Hold in the SAP system until the tests are successfully completed.
Ongoing shelf life testing is being performed (see 5.1).

5.6.2 Laboratory testing

Third party laboratories are used for annual heavy metals testing (ISO 17025 certified; certificate #2918.01) and water testing (NELAC certified and ISO 9001). Certificates were examined which demonstrated accreditation as current.
On site finished product is tested for particle size, purity, high pressure liquid chromatography, moisture, and water insolubility and residue on ignition.
On 2019-04-19 the three laboratory technicians all tested the same samples, and results were very closely grouped.

5.7 Product release

All finished goods are on Quality Assurance hold (positive release) until the lab completes the testing and Quality Assurance staff release the product for shipment to the third party warehouse.

5.8 Pet Food

This site does not manufacture any product for pet food.

6. Process control

6.1 Control of operations

All of temperatures, pHs, pressures, pump speeds and residence times are monitored electronically and controlled from the Control Rooms (with 8 computer screens). Samples of the product are taken at specified intervals to confirm that the process settings are making product to satisfy the targets at that point in the process (EX: evaporator feed concentration). All of the electronic readings are capable of being reviewed from a historical standpoint using a program on the “S” drive (Trends can be reviewed). Any of the monitored equipment can be alarmed to notify an Operator if a process is not in control or if a valve or pump has failed. Analytical tests are used to verify the equipment is running properly to make an in-specification product. Changes can be made to the process settings to return the product to conformance. The PM program is used to verify that temperature controllers and sensors, pressure indicators and level indicators are providing accurate feedback.

6.2 Labelling and pack control

All bags used in packaging are brown poly-lined Kraft bags without some pre-printed information on them. There are 50 pound bags and 25 KG bags. Coding is ink jetted onto the bags. Totes (1000Kg or 2000 pound totes) are labelled with an 8 x 11 inch tag that contains the label and lot code.
No product changeover was seen during the audit.
The plant prints labels for totes and pallet flags.

6.3 Quantity, weight, volume and number control

Finished product bags are automatically filled on a scale; the finished bags go across check-weighers to verify that all bags attain correct weight. Maintenance Operators verify the check-weighers by weighing a certified 50 pound weight on the check weighers weekly.

6.4 Calibration and control of measuring and monitoring devices

The instruments requiring calibration in the production area are metal detectors and scales. The annual metal detector calibration was performed (2019-03-28).
Scales in the plant are calibrated monthly (records for 2019-04-17 were reviewed; the scales are traceable to the National Institute of Standards and Technology).
Laboratory instruments are calibrated according to the manufacturer’s recommendations (EX: pH meter is calibrated daily; HPLC standardization is performed daily, the moisture tester is calibrated weekly, the laboratory scales are calibrated semi-annually, 2019-02-14).
Process equipment is calibrated by the maintenance department as part of the preventative program. pH meters on the malic purification columns are calibrated monthly; check weighers are tested with certified weights monthly, and thermometers are checked monthly.
If measuring equipment is found to be out of calibration; the material measured since the last good check is put on Hold and re-measured.

7. Personnel

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

Training is managed via a computer aided system called “working bird” for safety training. The operators are trained in food safety through a monthly planned program. The results are tracked by the Quality Assurance Manager. Operators must demonstrate knowledge of processing. They work with other operators and the Area Manager until they are proficient and have management sign-off.
New employees receive orientation training, (EX: on 2018-08-28 a new employee started and was given orientation training. The annual refresher training for HACCP for employees was given through a power-point presentation; employees took the presentation when they had time available ((this included a quiz). Contractors go through an orientation given to program that includes food safety and GMPs (records for a pipe fitter were reviewed, 2019-03-18).

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

There are Personal Hygiene and GMP requirements communicated to all employees through orientation and annual refresher training, contractors and visitors. Communicable diseases are defined, and persons with illness must have a medical release to return to work (per the Global Food Safety Policy). Designated GMP Zones (production rooms, sanitation room and warehouse) require hair restraints when raw materials, finished products or food-contact surfaces are handled. Personal medications are not allowed in the plant and must be kept in employees’ lockers. Compliance to GMPs is verified during monthly sanitation inspections.

Blue bandages are used and a sample from each batch is passed through both bag line metal detectors and the results recorded (EX: on 2019-01-30 lots P018070014 of bandages were tested through the detectors. Metal detectable ear plugs are starting to be used; on 2018-12-04 lots 3301167, 6415, and 340-4007 were tested).

7.3 Medical screening

Prospective employees must pass a drug test and a background test. Visitors and contractors are instructed as to the illnesses and conditions that are not allowed in the plant. Employees are trained on the conditions that would prevent them from working with open product and that they must inform their supervisor if they have any symptoms of an infection or contagious disease.

7.4 Protective clothing: employees or visitors to production areas

Production personnel change into clean, company provided uniforms upon reporting to the plant (this is an enclosed product and low risk site). Visitors are provided with hard hats, hearing protection and protective googles to wear in GMP Zones. Employee work shoes are steel toed shoes. Based upon risk assessment, employees are allowed to wear uniforms into the rest rooms and break room. Uniform shirts and lab coats do not have top pockets and have snap closures. Uniforms and lab coats are provided and laundered by a third party uniform company (HACCP plan on file).

Details of non-applicable clauses with justification

Clause reference	Justification
7.4.7	All clothing can be cleaned and clothing does not present a risk to the product.
8.1	There are no high risk, high care or ambient high care products at this site.

8. 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
There are no high risk, high care or ambient high care products at this site.
8.2 Building fabric in high-risk and high-care zones
There are no high risk, high care or ambient high care products at this site.
8.3 Maintenance in high-risk and high-care zones
There are no high risk, high care or ambient high care products at this site.
8.4 Staff facilities for high-risk and high-care zones
There are no high risk, high care or ambient high care products at this site.
8.5 Housekeeping and hygiene in the high-risk high-care zones
There are no high risk, high care or ambient high care products at this site.
8.6 Waste / Waste disposal in high risk, high care zones
There are no high risk, high care or ambient high care products at this site.
8.7 Protective clothing in the high-risk high-care zones
There are no high risk, high care or ambient high care products at this site.

Details of non-applicable clauses with justification

Clause reference	Justification
3.5.1.5	The plant does not currently purchase materials from agents and brokers.
3.5.4	There is no outsourced processing.
4.3.5	There were not any temporary structures.
4.4.6	There are no elevated walkways over product lines
4.4.7	There are not any roof glazings.
4.5.1	All of the water used in the plant is potable.

4.8.8	There is not a catering facility on-site.
4.9.1.2	There are no strongly scented or taint-forming materials in use
4.9.4	Products are not packaged into glass or brittle containers.
4.10.5	There are not any optical sorters.
4.10.6	Products are not packaged into glass, rigid or metal containers.
4.11.7	The plant does not CIP equipment. Tanks, lines and pumps are flushed with water and purged with product after cleaning.
4.11.8	No environmental monitoring is performed
4.12.3	The plant does not make trademarked materials.
4.13.3	There are not any products made in the Duluth Plant that are used for animal feed.
4.14.3	The Plant does not undertake its own pest control program.
4.15.3	There is not a temperature requirement for storage of the products.
4.15.4	There is not a requirement for controlled atmospheric storage.
4.15.5	There is no outside storage
4.16.3	There are not any temperature requirements for transporting the products.
5.2.3	There are not any nutritional or food related claims made on the product made in the plant.
5.3.5 – 5.3.8	The plant does not use or store allergens on-site. Allergens for new materials would be managed through the supplier approval process.
5.4.3	Products are not at risk of adulteration or substitution
5.6.2.1	Pathogen testing is not conducted on-site.

5.8	This site does not manufacture any product for pet food.
6.2.4	There are no on-line bar code devices.
7.4.7	All clothing can be cleaned and clothing does not present a risk to the product.
8.1	There are no high risk, high care or ambient high care products at this site.
8.2	There are no high risk, high care or ambient high care products at this site.
8.3	There are no high risk, high care or ambient high care products at this site.
8.4	There are no high risk, high care or ambient high care products at this site.
8.5	There are no high risk, high care or ambient high care products at this site.
8.6	There are no high risk, high care or ambient high care products at this site.
8.7	There are no high risk, high care or ambient high care products at this site.

CERTIFICATE OF CONFORMITY

SAI Global, accredited Certification Body No Z1440295AS certifies that:

Tate & Lyle Ingredients Americas LLC

110 Spring Street, Duluth, Minnesota 55808 USA

BRC Site Code: 1818906

having conducted an audit for the scope of activities:
The hydrolysis and isomerization of maleic anhydride to make malic acid and fumaric acid, drying the material and packing into bags, drums and super sacks.

Exclusions from scope: None

Product Category: 15 - Dried food and ingredients

Has Achieved Grade: AA

Meets the requirements set out in the

BRC GLOBAL STANDARD FOOD SAFETY ISSUE 8: AUGUST 2018

Audit Programme: Announced

Certificate No.: CERT-0128887

Auditor No.: 123235

Certificate Issue Date: May 16, 2019

Date of Audit: April 30, 2019 To: May 1, 2019

Certificate Expiry Date: June 17, 2020

Re-audit Due Date, From: April 8, 2020 To: May 6, 2020

Kevin Goodwin
General Manager Technical Services SAI Global Assurance

BRC CERTIFICATION BODY

JAS-ANZ

WWW.JAS-ANZ.ORG/REGISTER