Updated: 01/19/2023 SM

Berry Global Anaheim

We are a Packaging component Manufacturer – No drugs, drug components of finished Pharmaceutical product.

Please contact your sales Representative or Customer Service Representative concerning Regulatory inquiries.

This Document is provided to answer the most frequently asked questions listed on the questionnaires of Customers seeking to Audit the Anaheim facility.

Corporate Headquarters:

Full Street Address: Berry Global
101 Oakley Street
Evansville, IN 47710
www.berryglobal.com

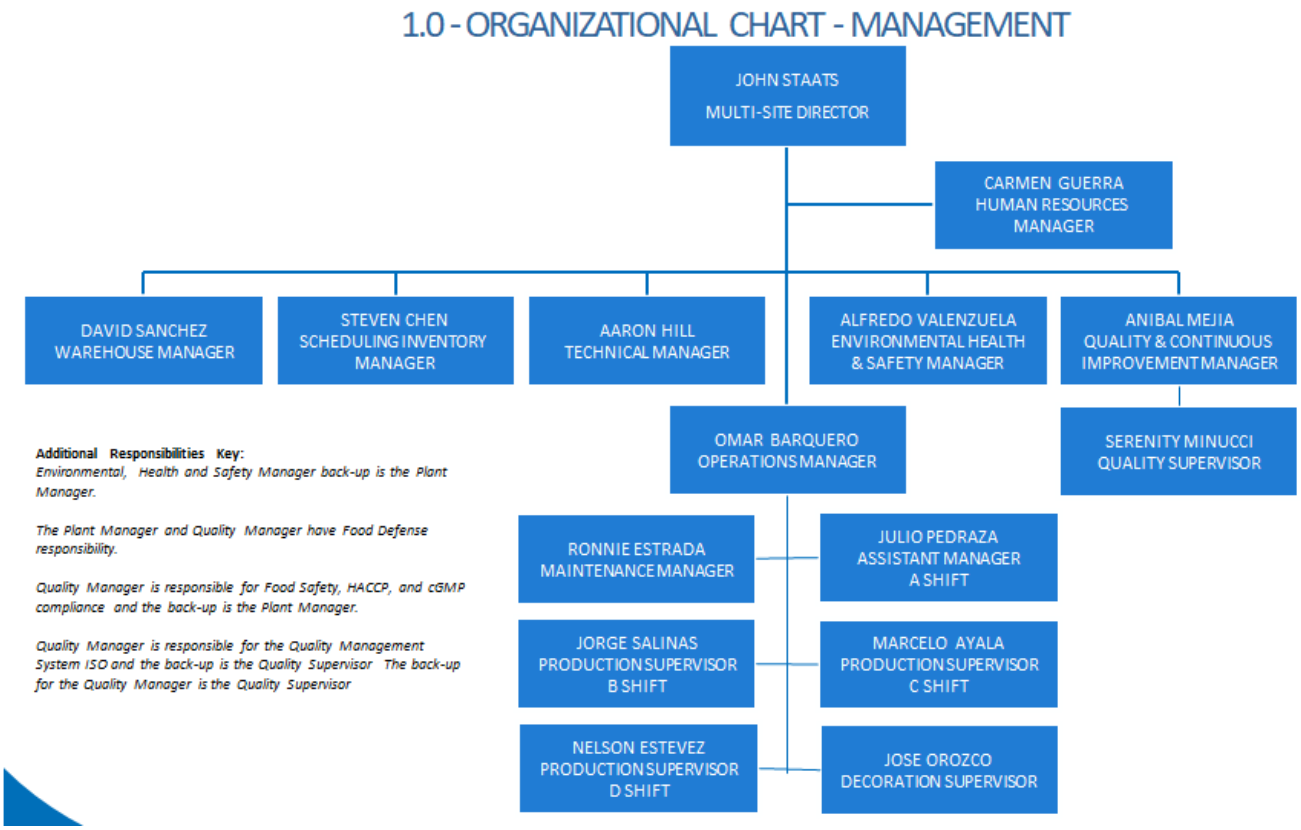
Manufacturing Site:

Full Street Address Berry Global
4875 E Hunter Ave
Anaheim CA 92807

Telephone Number: (714) 777-5200

MANUFACTURER OF: Healthcare; Personal Care ~ Pharmaceuticals ~ Nutraceuticals ~ Food ~ Beverage & Spirits ~ Household Chemicals ~ Distribution.

KEY PERSONNEL:



Contact Personnel:

Position/Title	Name	Phone Number	E-mail
Plant Manager	**John Staats**	**Site Specific**	**JohnStaats@berryglobal.com**
Quality Assurance Manager SQF Practitioner	**Anibal Mejia**	**(714)777-5386**	**anibalmejia@berryglobal.com**
Quality Assurance Supervisor SQF Practitioner	**Serenity Minucci**	**(714) 777-5320**	**serenityminucci@berryglobal.com**
Operations Manager	**Omar Barquero**	**(714) 777-5394**	**omarbarquero@berryglobal.com**

Number of Staff Employed: 245

PERSONNEL

Has there been any change to the following elements: Standards, Organization of Quality Unit, Ratio of Quality Unit Staff to Production Staff?

Answer: No

	QUALITY MANAGEMENT SYSTEM (QMS)	ANSWER
1	Is there a Quality Manual (QM)?	CORPSOP-0129 Quality Manual
2	Does the QMS contain a Quality Policy?	CORPSOP-0226 Berry Global Quality Policy
3	Does the QM define the responsibility and authority of all employees?	Various Procedures – Job Descriptions
4	Does the QM give the Quality Unit authority to review records and conduct investigations?	Yes
5	Is there a periodic review of the QM and QS required? If so, how often?	ANASOP-0044 Plant Management Business Review – Minimum annually
6	During the past three (3) years, has the facility been involved with "Quality Management Systems", either ISO 9000 or an equivalent system?	Yes

Details of the past three (3) years				
Registration Body	**Inspection Date(s)**	**Certification**	**Certification Granted**	**Certification #**
Eagle Registrations Inc	December 6, 2019	ISO 9001:2015	Yes	4255
Eagle Registrations Inc	June 21, 2021	ISO 15378:2017	Yes	6235I
Eagle Registrations Inc	June 30, 2022	SQF Code Edition 9	Yes	11611

	FOOD SAFETY SYSTEM (FSS)	ANSWER
1	Is there a documented food safety program?	ANAWI-00216 SQF and Food Safe Culture
2	Is there a documented Food Safety Policy?	CPNAPOL-00001 Berry Global Food Safety Policy Statement
3	Does the FSS define the responsibility and authority of all employees?	Yes, attached below.
4	Does the FSS give the Quality Unit authority to review records and conduct investigations?	Yes
5	Is there a periodic review of the FSS required? If so, how often?	Yes, annually
6	Is there a documented food safety plan?	ANAWI-00178 Food Fraud Program
7	Is there a documented allergen program?	ANAWI-00096 Allergen Program
8	Is there an environmental monitoring program? (List environmental factors that are monitored and how often)	ANAWI-00170 Pathogen Environmental Monitoring Program Product Contact Surface Testing – Quarterly, Biannually, Annually (Zone Dependent) ANAWI-00181 Compressed Air Monitoring Program Air Sampling - Annually Water Sampling – Biannually
9	Is there a documented traceability program?	ANAWI-00090 Identification, Traceability and Inspection Status
10	Is there a GMP Program in place?	ANAWI-00077 Good Manufacturing Practices
11	Is there a complete food safety risk assessment?	ANAWI-00078 HACCP Program
12	Is there as documented sanitation program?	ANAWI-00112 Cleaning and Sanitation – Plant, Machine, Grounds
13	Are raw materials stored separate from finished product?	Yes

14	Is there a documented trace program?	ANAWI-00090 Identification, Traceability and Inspection Status
15	Is there documented maintenance and Preventative maintenance programs?	ANAWI-00122 Preventative Maintenance Program
16	Is there a documented food defense plan?	ANAWI-00198 Food Defense Program
17	Is there a documented crisis management plan?	ANAWI-00206 Product Crisis Management Team
18	Is there a documented food fraud program?	ANAWI-00178 Food Fraud Program

	INDEPENDENCE/AUTHORITY/TRAINING	**ANSWER**
1	Is Quality Assurance independent of Manufacturing?	Yes
2	Does QA/QC have independent authority to approve and reject materials (raw materials, components and finished goods)?	Yes
3	Is there a documented training program including GMPs?	Yes - Good Manufacturing Practices (GMP) Manual ANAWI-00077
4	Is there a means for verifying trainee competency?	Yes – Various Training Modules
5	Do GMP training materials address facility cleaning, personal hygiene and record keeping?	Yes – ANAWI-00077 GMP
6	Do employees practice good hygiene in the manufacturing operations?	Yes
7	How do you assure that departmental staff are trained to follow new versions of documents (procedures, batch records, test methods, etc.)?	Training Database
8	Briefly describe the Company's Training Program:	ANAWI-00026 Anaheim Training Program
9	Are job specific training relevant to tasks to be performed?	Yes

	INTERNAL AUDITS/CAPA	**ANSWER**
1	Is there a documented written procedure for conducting internal audits?	ANAWI-00110 Internal Audits ANAWI-00109 ISO Internal Audit Schedule
2	Are internal audits being conducted according to the procedure?	Yes
3	Are responses to the audit findings/observations in the form of corrective and/or preventative actions (CAPA) addressing root cause?	ANASOP-00151 Preventive Action Plant Level Procedure
4	Is there a follow up to determine if the appropriate CAPA has been completed?	Yes, CAPA Database prompts follow up.
5	Does QA conduct a documented review of production batch records?	ANAWI-00089 Batch Record Review

	COMPLAINT HANDLING	**ANSWER**
1	Is there a written procedure for handling Customer Complaints?	ANASOP-0151 TICs in JDE Status for Anaheim
2	Are each complaint/event uniquely identified?	Yes
3	Does the procedure require that the complaint be resolved/investigated within a specific timeframe?	Yes
4	Does the investigation involve a review of the batch records for the product related to the complaint?	Yes
5	Are samples examined or tested as necessary during a complaint	Yes

	investigation?	
6	Is there a program in place for recording, tracking and resolving customer complaints?	TICs Database

	FAILURE/DEVIATION INVESTIGATIONS	**ANSWER**
1	Is there a documented procedure regarding the investigation of the finished products, raw materials or components which fail to meet required specifications?	ANAWI-00082 Production Samples and Defect Containment ANAWI-00093 Control of Non-Conforming Product
2	Are investigations completed within a reasonable timeframe?	Yes
3	If necessary, do investigations include a review of production events which may contribute to or be the cause of the failure?	Yes
4	What is the timeframe?	30 days is our target
5	Do all of the investigations include an actual or probable cause for failure?	Depending on the failure
6	Are corrective actions being implemented when the root causes have been identified?	Yes
7	Does Quality Assurance conduct or adequately review the failure investigations?	Yes
8	How do you handle OOS results?	ANAWI-00080 Non-Conforming Material Report
9	In the past twelve (12) months, on how many occasions have you had an OOS result?	2 found from customer
10	Who is responsible for the investigation reports?	Production & Quality
11	Are investigation reports extended to other batches/lots of the same product?	Yes

	CHANGE CONTROL	**ANSWER**
1	Are SOPs written identified and approved for compliance?	ANAWI-00165 Control of Documents
2	Are SOPs reviewed periodically to ensure their applicability to actual practices? What is the timeframe for review?	Yes – 3 years
3	Are change control procedures in place?	Yes
4	Will you notify the Customers of changes to manufacturing or materials prior to such changes being implemented?	ANAWI-00002 Customer Notification of Change
5	Are changes relating to manufacturing/packaging processes and or equipment adequately approved where necessary?	Yes

	RECALLS/RETURNS	**ANSWER**
1	Is there a written procedure for conducting a recall?	ANAWI-00086 Product Traceback or (Mock) Recall Procedure
2	Does the procedure require conducting mock recalls or some other means to verify the adequacy and effectiveness of the procedure?	Yes
3	Do you perform mock recalls?	Yes
4	Describe your recall procedure:	Team is assembled, item and WO is identified, Mock recall is performed, summary report is issued when complete.
5	Does the summary recall report indicate that the manufacturer was	Yes, where product was shipped.

	able to account for the distributed product?	
6	Describe the company's procedure for handling returned goods:	ANAWI-0326 Receiving – Customer Returns
7	Is there evidence that the returned products are being processed according to the procedure?	Yes

	VALIDATION	ANSWER
1	Is there a Process Validation Master Plan?	ANASOP-00111 IQ OQ PQ ANAWI-0226 IQ ANAWI-0227 OQ ANAWI-0228 PQ
2	Does the plan require there to be an approved process validation protocol developed for each product?	Yes CQV
3	Does validation reporting provide evidence that the study is conducted per protocol and the process is consistent?	Yes
4	Are deviations to the approved protocol appropriately documented and approved by QA?	Yes
5	Does the Validation Master Plan address re-validation?	Yes
6	Please describe your site's on-going equipment calibration and preventative maintenance programs:	Quality instruments are serviced calibrated and managed by US Calibration – ANAWI-00111 Control of Monitoring and Measuring Devices
7	What is the scope of the validation program?	Ensure process and equipment is repeatable and reproducible.
8	Is there a formal program to determine product safety?	Yes HACCP

	FACILITIES and EQUIPMENT	ANSWER
1	Are there written procedures to address the maintenance of the facility?	Yes most facility maintenance is contracted out to vendors
2	What kind of security do you have to assure no entry by unauthorized personnel?	ANAWI-00120 Security Program
3	What is the square footage of your facility?	Site – 538,867 sq. ft. Building – 272,510 sq. ft. Manufacturing Area – 100k sq. ft. Outside Warehouse – 117k sq. ft.
4	What are your hours of operation?	24/7
5	How many shifts operate at your manufacturing site?	4
6	Is there a list of approved chemicals for maintaining the sanitation of the facility?	ANAWI-00112 Cleaning and Sanitation – Plant – Machine - Grounds
7	Is there a documented procedure regarding the receipt, handling, storage, use and disposal of chemicals, standards?	ANASPG-00008 Chemical Management Program
8	Is there proper segregation of hazardous materials?	ANAWI-0010 Hazardous Materials Storage Area Inspection
9	Is the facility in acceptable structural condition to perform tasks?	Yes
10	Are there environmental controls for the building?	Building is equipped with air circulators to control temperature.
11	Is the design of the facility adequate to allow for smooth flow of materials and reduce potential for contamination?	Yes

12	Is the lighting adequate for the building?	Yes
13	Is there a pest control program? Please describe:	Contractor – ISO Tech
14	Are the washrooms and toilets clean and in good working order?	Yes – serviced daily
15	Are the washrooms equipped with hot water and hand wash signs?	Yes
16	Are toilet facilities physically separated to prevent a direct opening to the manufacturing areas?	Yes
17	Is there a control system for implementing and tracking changes to equipment?	CORPSOP-00115 Management of Change
18	Does the control system take into account the need for revalidation?	Yes
19	Is there a formal program for ensuring the qualification of all processing equipment with respect to installation, operation and performance (IQ/OQ/PQ)?	ANASOP-00111 IQ OQ PQ ANAWI-0226 IQ ANAWI-0227 OQ ANAWI-0228 PQ
20	Is there a documented procedure for qualifying instruments (IQ/OQ/PQ)?	ANAFCD-0173 Machine Installation Checklist ANAFCD-0174 Machine Operation Checklist ANAFCD-0175 Machine Performance Checklist

	CALIBRATION	**ANSWER**
1	Is equipment properly installed to allow for reasonable cleaning, maintenance and calibration?	Yes
2	Are there written procedures for ensuring the maintenance and calibration of equipment?	ANAWI-00111 Calibration – Control of Monitoring and Measuring Devices
3	Is equipment labeled to readily identify Calibration status?	Yes
4	Are calibrations conducted per procedure and schedule?	ANAWI-00111 Calibration – Control of Monitoring and Measuring Devices
5	Do you perform calibrations internally or by an outside source?	Contractor - xTrak Calibration
6	Is there an effective means to quality outside contractors providing calibration services?	Certified
7	Do outside contractors provide adequate documentation with regards to services provided?	Calibration Certificates
8	Are all data (including graphs, scans, charts and calculations) maintained?	Yes
9	What is the frequency of calibrations?	Varies

	MATERIAL SYSTEM	**ANSWER**
1	Is there a procedure for the receipt, sampling and identification of all raw materials?	ANAFCD-00038 Label Inspection Form ANAFCD-0156 Purepak Corrugated Inspection ANAWI-00148 Verification of Purchased Product
2	Are all components (containers, closures, labels, IFC; and inserts) properly identified?	ANAWI-00148 Verification of Purchased Product
3	Are components and raw materials adequately quarantined until release by QA to Production?	ANAWI-00148 Verification of Purchased Product
4	Are there specifications for all components and raw materials?	Yes
5	Do the specifications include acceptability criteria for each item?	Yes
6	Is there an adequate program to ensure FIFO? What is it?	Enterprise Resource Planning (ERP) JDE System manages inventory in FIFO

7	Are all components and raw materials being tested against appropriate and established specifications?	Yes
8	Is at least one specific identity test conducted on each lot of components?	Yes
9	Are raw materials, in-process and finished products adequately dispositioned when failing to meet established specifications?	Yes
10	Are investigations involving NCM documented?	ANAWI-00080 Non-Conforming Material Report
11	Does QA have full authority to accept or reject all raw materials and packaging materials?	Yes
12	Are finished products adequately controlled until release for shipment?	Yes
13	Is there a documented procedure for in-process materials or finished products that fail to meet the required manufacturing standards/specifications?	ANAWI-00080 NCMR
14	Are the investigations of the NCM being conducted in a manner per written procedure?	Action taken is documented in the NCMR report
15	Does your company have a registered Drug Master File (DMF)?	Yes
16	Describe the sampling plan for the checking, testing and release of the product:	ANAWI-00081 outlines our AQL levels and acceptance criteria
17	Do you supply a Certificate of Compliance or Certificate of Analysis for each batch?	Per Customer Request ANAWI-0183 Generating a COC or COA

	VENDOR QUALIFICATION/TESTING	**ANSWER**
1	Where raw materials are not fully tested against specifications, is there a program for qualifying suppliers?	ANAWI-0298 New Supplier Approval CORPWI-0108 AP Vendor Database
2	Does the program for qualifying suppliers include conducting audits or reliance on historical data?	CORPSOP-0210 Evaluation & Selection of Suppliers
3	Where historical data is used to qualify suppliers, does historical data include information on all the characteristics listed in the specifications?	Suppliers are measured and managed by Corporate purchasing
4	Is there an adequate program to establish the qualifications reliability of suppliers providing raw materials if full testing is not conducted on incoming raw materials?	Suppliers are measured and managed by Corporate purchasing we have 3rd party auditors that audit our suppliers.

	PRODUCTION PROCESS	**ANSWER**
1	Is there a control system for implementing changes in process?	CORPSOP-00115 Management of Change and ANASOP-0256 Changes to Traveler BOM or Parts manage change
2	Does the control system recognize the need for revalidation before processes are changed?	Yes
3	Is there a documented procedure for the retention of batch records for each finished product manufactured?	ANAWI-00089 Batch Record Review
4	Do batch production records contain the required information necessary with respect to assuring the quality of the finished product?	Yes
5	Are batch records reviewed by QA?	Yes
6	Do batch records contain instructions with respect to the manufacture of finished products?	Yes – Traveler
7	If a water system is used, is it operating in the manner designed?	Yes

8	Is a record created for every lot/batch of product produced?	Yes
9	Is there a documented procedure for the retention of reserve samples for each batch of product manufactured?	ANAWI-00144 Sample Retention Procedure
10	Are periodic samples taken during the component manufacturing process to ensure that the component meets specification requirements?	ANAWI-00088 Bottle Inspection During Set-Up – Production and Packing
11	Are retain samples of raw materials, bulk product and finished goods maintained for the required period of time?	ANAWI-00144 Sample Retention Procedure

	PRODUCT ASSEMBLY and PACKAGING	**ANSWER**
1	Are components used in production runs checked for adequacy prior to commencing a packaging run?	ANAWI-00204 Decoration Line Clearance ANAWI-00163 Line Clearance Procedure
2	Is line clearance documented?	ANAFCD-00051 Deco Line Clearance and FA Sheet ANAFCD-00044 Berry Anaheim Line Clearance Sheet
3	Is QA or manufacturing personnel involved in periodically monitoring parameters (counts, torques, coding, etc.)?	Monitoring of Set Up Sheets
4	Describe the controls utilized to assure the products are completely and accurately labeled:	ANAWI-00090 Product Traceability and Label Information
5	Are there documented procedures for ensuring the cleanliness, maintenance and calibration of equipment?	ANAWI-00112 Cleaning and Sanitation – Plant, Machine, Grounds
6	Describe your lot numbering system:	ANAWI-00090 Product Traceability and Label Information
7	Are all lines and hoppers adequately covered to prevent contamination?	Yes and No depending on the product that is been manufactured
8	Are the lines properly identified with the name/description and lot # of the product?	Traveler / Line Clearance
9	Are there documented procedures for label control?	ANAFCD-0405 Product Label Reconciliation Form
10	Describe procedures for labeling, segregation and control of finished product prior to final disposition:	NCMR process documents the management and disposition of held product.
11	Describe your procedure for ensuring that labels are not used until they are proofread for accuracy:	ANAWI-00204 Decoration Line Clearance ANAWI-00163 Line Clearance Procedure

	DOCUMENT CONTROL	**ANSWER**
1	Is there a defined document control program in place?	ANAWI-00165 Control of Documents
2	Do controlled documents use an ID and revision level system?	Revision Numbers
3	Is there a documented procedure for Document Control including record retention?	ANASOP-0046 Control of Records
4	How long are records kept?	Varies (Majority time = 7 years)

Attachments:
Berry Global Food Safety Policy
ISO Certificates
SQF Certificate

Berry Global Food Safety Policy

Provide food safe and high-quality packaging products, and services that meet customers' expectations

Comply with applicable customer and regulatory requirements while continually improving the safety of the food packaging manufacturing system by establishing and reviewing food safety objectives.

Maintain system effectiveness through utilization of technology, teamwork, and skilled employees.

We are committed to maintaining our established food safety culture.

Plant Manager / John Staats:
Technical Manager / Aaron Hill:
Quality & CI Manager / Anibal Mejia:
Production Manager / Omar Barquero:
Warehouse Manager / David Sanchez:
Human Resources Manager / Carmen Guerra:
Scheduling / Inventory Manager / Steven Chen:
EH&S Manager / Alfredo Valenzuela
Assistant Production Manager / Julio Pedraza:
Quality Supervisor / Serenity Minucci:
Production Supervisor / Nelson Estevez:
Production Supervisor / Don White:
Production Supervisor / Jorge Salinas
Production Supervisor / Marcelo Ayala
Decoration Supervisor / Jose Orozco:
Assistant Production Supervisor / Linda Castrejon:

EAGLE Registrations Inc.
SERVICE • INTEGRITY • VALUE

ANAB ACCREDITED
MANAGEMENT SYSTEMS CERTIFICATION BODY

IAF MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT

Certificate No. 4255X (Recertified September 9, 2021)
September 15, 2021 through September 14, 2024

Certificate of Registration

This is to certify that the Quality Management System of

Berry

Berry Global, Inc.

4875 E Hunter Avenue, Anaheim, California 92807 USA

Has been assessed by **EAGLE Registrations Inc.** and conforms to the following standard:

ISO 9001:2015

Scope of Registration

Manufacturer of Plastic Packaging

Director of Certification

The validity of this certificate depends on the validity of the main certificate
The Management System of this Network of Sites under this Organization has been Certified

40 N. Main Street, Suite 1880 | Dayton, OH 45423 | USA | 937.293.2000 or 800.795.3641
www.eaglecertificationgroup.com

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EAGLE Registrations Inc.
SERVICE • INTEGRITY • VALUE

ANAB ACCREDITED
MANAGEMENT SYSTEMS CERTIFICATION BODY

Certificate No. 6235I
June 21, 2021 through June 20, 2024

Certificate of Registration

Berry

Berry Global, Inc.

4875 E. Hunter Avenue, Anaheim, California 92807 USA

Has been assessed by **EAGLE Registrations Inc.** and conforms to the following standard:

ISO 15378:2017

Scope of Registration

Manufacturer of Plastic Packaging

Director of Certification

The validity of this certificate depends on the validity of the main certificate
The Management System of this Network of Sites under this Organization has been Certified

40 N. Main Street, Suite 1880 | Dayton, OH 45423 | USA | 937.293.2000 or 800.795.3641
www.eaglecertificationgroup.com

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Version 2 – 10/27/2020

EAGLE Food Registrations Inc.
SERVICE • INTEGRITY • VALUE

EAGLE Food Registrations Inc.
40 N Main Street, Suite 1880
Dayton, Ohio 45423

Certificate Of Registration

Berry Global, Inc.

4875 East Hunter Avenue, Anaheim, California, UNITED STATES, 92807
701 Sally Pl,Fullerton, California, UNITED STATES, 92831 (Warehouse)

is registered as meeting the requirements of the

SQF Code Edition 9

Food Safety Code for Manufacture of Food Packaging

Certification Details:

Date of Decision:Aug 11, 2022
Date of Audit: Jun 30, 2022
Certificate Number: 11611

Date of Expiry: Sep 13, 2023
Date of Next Recertification Audit: Jun 30, 2023
Certification Type: Certification

Registration Schedule:
Scope of Registration (Food Sector Categories and Products)

27. Manufacture of Food Packaging: Blown Plastic Bottles

SQF INSTITUTE
One world. One standard.
SQF Institute is a division of FMI.

ANAB
ACCREDITED
PRODUCT CERTIFICATION BODY

Director of Certification

Issuing Officer