QUALITY DOSSIER

Rev 02 | September 2021

INDEX

SELF-AUDIT QUALITY QUESTIONNAIRE

1. Company Information

SOLUTEX GC, S.L.
Global Headquarters: **Av. de la Transición Española ºº24, 3ª Pl., Edificio Gamma. 28108 Alcobendas, Madrid, Spain** **Phone: +34 918.060.477** **Fax: +34 918.060.605**
Manufacturing plant **Polígono Industrial El Zafranar, Calle Rioja, 6, 50550 Mallén, Zaragoza, Spain** **Phone: +34 976.866.314** **Fax: +34 976.850.123**

2. General Information

			YES	NO	NA
2.1.	Are customer audits and/or inspections by agencies permitted?		☒	☐	☐
2.2.	Is the decision to release or reject a product for sale independent from production?		☒	☐	☐
2.3.	Who is signing the Certificate of Analysis?	*QA MANAGER (RAQUEL YEREGUI)*			
2.4.	Who is responsible for the final product release?	*QA MANAGER (RAQUEL YEREGUI)*			
2.5.	Who is responsible for quality matters?	*HEAD OF QUALITY (RAFAEL GRACIA)*			
2.6.	What kind of product do you manufacture				
	• Bulk raw materials?		☒	☐	☐
	• Bulk raw materials for pharmaceuticals?		☒	☐	☐
	• Active pharmaceutical ingredients?		☒	☐	☐
	• Technical products?		☐	☒	☐
	• Packaging material?		☐	☒	☐
	• Others? Please, specify:		☐	☒	☐

2. General Information

		YES	NO	NA
2.7.	Has the facility been registered with the FDA (Food Facility Registration Number)?	☒	☐	☐
2.8.	Is a cGMP program in place?	☒	☐	☐
2.8.1.	If yes, does it conform to a government regulation, i.e. Part 111, Part 117, etc.?	☒	☐	☐
2.9.	Does the company/facility have programs in place for the following?			
	• Allergen(s)	☒	☐	☐
	• GMO/IP	☒	☐	☐
	• HACCP/Food Safety	☒	☐	☐
2.10.	Does the company/facility have programs in place for the following?			
	Are incoming materials inspected for damage, contamination, etc.?	☒	☐	☐
	Is rejected material identified, segregated and dispositioned?	☒	☐	☐
	Are records kept showing material disposition?	☒	☐	☐

3. Personnel, Training and Education

		YES	NO	NA
3.1.	Do you have written job descriptions for all personnel?	☒	☐	☐
3.2.	Do you have procedures that document how you perform training?	☒	☐	☐
3.3.	Do you maintain records of the training?	☒	☐	☐
3.4.	Are personnel aware that products are used for the manufacturing of food products?	☒	☐	☐
3.5.	Does the Training Program in place have the following elements?			
	• Formal Introduction to Regulatory Guidance (GMP, ISO, etc.)	☒	☐	☐
	• New Hire Program	☒	☐	☐
	• Specific training e.g. clean room or handling hazardous materials?	☒	☐	☐
	• Periodic assessment of practical effectiveness?	☒	☐	☐
	• Periodic refresher training programs for established employees?	☒	☐	☐
	• At the start of new product manufacturing?	☒	☐	☐
	• When new methods are used?	☒	☐	☐
	• Quality techniques for production people?	☒	☐	☐
3.6.	Does your training program emphasise?			
	• Product integrity?	☒	☐	☐
	• Hygiene?	☒	☐	☐
	• Cleanliness?	☒	☐	☐

4. Facility and Utilities

		YES	NO	NA
4.1.	Do you have written job descriptions for all personnel?	☒	☐	☐
4.2.	Are there separate areas for:			
	• Handling of starting materials?	☒	☐	☐
	• Manufacturing?	☒	☐	☐
	• Quarantined finished products or are other control systems in place?	☒	☐	☐
	• Approved finished products?	☒	☐	☐
	• Packaging and dispatch?	☒	☐	☐
	• Rest and eating?	☒	☐	☐
4.3.	Does the present design prevent:			
	• Chemical contamination?	☒	☐	☐
	• Physical contamination?	☒	☐	☐
	• Microbial contamination?	☒	☐	☐
4.4.	Are your working-rooms:			
	• Of proper size for the intended functions?	☒	☐	☐
	• Satisfactorily lighted, air-conditioned?	☒	☐	☐
	• Clean and cleaned-up?	☒	☐	☐
	• Designed to avoid (cross-) contamination?	☒	☐	☐
	• Supplied with security and fire protection measurements?	☒	☐	☐
4.5.	Do you have written Good House Keeping Procedures?	☒	☐	☐
4.5.1.	If yes, do you maintain follow-up records of these procedures?	☒	☐	☐
4.6.	Do your manufacturing locations follow Good Manufacturing Practices?	☒	☐	☐
4.7.	Are your sites inspected by the FDA or national (health) authorities?	☒	☐	☐
4.8.	Are plant supply pipelines identified and labelled?	☒	☐	☐
4.9.	Do you monitor the quality of the water used to prepare standards and reagents?	☒	☐	☐
4.10.	Do you monitor the quality of the water used during the manufacturing process?	☒	☐	☐
4.11.	What are the normal hours of operation of the facility?	24 h/d, 7 d/w and 350 d/y		

5. Machines and Equipment

		YES	NO	NA
5.1.	Is the production line single purpose?	☐	☒	☐
5.2.	Is the production line multi-purpose?	☒	☐	☐
5.3.	Is there a maintenance and preventative maintenance program?	☒	☐	☐
5.4.	Do you have written maintenance and calibration procedures for critical equipment?	☒	☐	☐
5.5.	Is equipment calibrated, e.g., calibration stickers are present?	☒	☐	☐
5.6.	Are these calibrations traceable back to national standards?	☒	☐	☐
5.7.	Do you retain records of calibration as evidence of control?	☒	☐	☐
5.8.	Is there a cleaning plan/procedure for production machines, equipment?	☒	☐	☐
5.9.	Have the cleaning and sterilisation processes been validated?	☒	☐	☐
5.10.	Is any manufacturing equipment software controlled?	☒	☐	☐
5.11.	Are equipment and tests validated?	☒	☐	☐
5.12.	Do you retain records of validation as evidence of control?	☒	☐	☐
5.13.	If yes,			
	• Is the software validated?	☒	☐	☐
	• Are software modifications implemented by manufacturing personnel?	☐	☒	☐
	• Is there a procedure concerning change of software and its copying?	☒	☐	☐
	• Is the security of software controlled?	☒	☐	☐
5.14.	Do you contract out any of the following services?			
	Instrument Calibration?	☒	☐	☐
	Preventative / Breakdown Maintenance?	☒	☐	☐

6. Production and Process Control

			YES	NO	NA
6.1.	Is your manufacturing process validated?		☒	☐	☐
6.2.	How do you define your lot/batch?	*Depends on the product, normally the batch is defined by the customer's order.*			
6.3.	How and by whom are lot/batch numbers assigned?	*Traceability System*			
6.4.	What is your normal lot/batch size?	*760 kgs*			
6.5.	Does each lot/batch have an identification number?		☒	☐	☐
6.6.	Please, describe your batch numbering system and provide an example: *Assigned by software, P-XXXXX- acronym. Where XXXXX belongs to identification of the manufacturing process followed by acronym. Example:P-12345- 51175Omegatex4618*				
6.7.	If, for capacity reasons, more than one lot of material is used per lot/batch:				
	• Is the lot/batch being homogenised prior to packaging?		☒	☐	☐
	• Is the homogenisation operation validated?		☒	☐	☐
6.8.	Do you use written procedures for each product supplied to the market?		☒	☐	☐
6.9.	Are these procedures approved by QA?		☒	☐	☐
6.10.	Do you have a batch record for each batch/lot manufactured?		☒	☐	☐
6.11.	Does each batch/lot contain the following:				
	• Description, Lot Number & Quantities of Material used?		☒	☐	☐
	• Processing Conditions (Temperature, Times etc)?		☒	☐	☐
	• The identification of the Person who performed the particular step?		☒	☐	☐
	• Results of any In-process tests?		☒	☐	☐
	• All deviations from standard conditions?		☒	☐	☐
	• All cleaning operations carried out before & after batch manufacture?		☒	☐	☐
	• If yes, are these records formally checked and approved by QA?		☒	☐	☐
	• If yes, for how long do you keep the batch records?		7 years		
6.12.	Do you maintain lot separation during the following:				
	• Manufacturing?		☒	☐	☐
	• Packaging?		☒	☐	☐
	• Storage?		☒	☐	☐
6.13.	Do you maintain cleaning, use & maintenance records/logs?		☒	☐	☐
6.14.	Are computers used to store records of manufacture, testing, storage or distribution?		☒	☐	☐
	• If yes, have these computer systems been validated?		☒	☐	☐
6.15.	Is an electronic system used to control the status of materials and products?		☒	☐	☐

6. Production and Process Control

		YES	NO	NA
6.16.	If so, has this system been validated to comply with 21 CFR 21, Electronic Records, Electronic Signature?	☒	☐	☐
6.17.	Do all product containers bear labels, e.g., batch/lot number, product name etc.?	☒	☐	☐
6.18.	Is there expiry or retest dates defined for all material?	☒	☐	☐
6.19.	Are there storage conditions defined for all material?	☒	☐	☐
6.20.	Is the facility continually monitored for temperature?	☒	☐	☐
6.21.	Is the product identifiable throughout the manufacturing process?	☒	☐	☐
6.22.	Is traceability of all raw materials used, maintained throughout manufacture?	☒	☐	☐
6.23.	Is there a procedure in place to prevent cross-contamination?	☒	☐	☐
6.24.	Are line clearances undertaken between product changes?	☒	☐	☐
6.25.	Do you use dedicated equipment for the production of the product in question?	☐	☒	☐
	If no, please provide details of other product types manufactured using this equipment:			
	Other concentrates Omega3 from fish oil and Algae oil			
6.26.	Is testing or inspection performed between processes or manufacturing stages?	☒	☐	☐
6.27.	Is testing or inspection performed on finished products?	☒	☐	☐
6.28.	Are rejected lots identified as such and separated?	☒	☐	☐
6.29.	Do you perform a failure investigation in case of a reject?	☒	☐	☐
6.30.	Is reprocessing of rejected lots documented?	☒	☐	☐
6.31.	Do you have a procedure covering rework/reprocessing or recovery of material?	☒	☐	☐
6.32.	Is non-conforming product blended with conforming product to meet specification?	☒	☐	☐
6.33.	Is there a procedure that defines when blending of non-conforming product is allowed?	☒	☐	☐
6.34.	How long do you keep the analytical and production records (number of years)?	☒	☐	☐
6.35.	Do you have plant shutdowns (holidays, maintenance)?	☒	☐	☐
	Yes, by maintenance			☐
6.36.	Do you have procedures for pest control?	☒	☐	☐
6.37.	Do you use a qualified and certified pest controller	☒	☐	☐

SELF-AUDIT QUALITY QUESTIONNAIRE

7. Materials Control

		YES	NO	NA
7.1.	Do you have an approved supplier list?	☒	☐	☐
7.2.	Do you have supplier agreements that require notification of any change?	☒	☐	☐
7.3.	Do you have written specifications for all incoming raw material?	☒	☐	☐
7.4.	Who is responsible for establishing and approving the specifications of raw materials?	QA Department		
7.5.	Do you require a manufacturer's certificate of analysis for all material received?	☒	☐	☐
7.6.	Are Certificates of Analysis routinely compared against a written specification?	☒	☐	☐
7.7.	Do you routinely test received materials to verify conformance with specifications?	☒	☐	☐
7.8.	Do you have procedures for the control of raw materials?	☒	☐	☐
7.9.	Are records kept that show full traceability of raw materials?	☒	☐	☐
7.10.	Do you maintain information records for raw materials which include the following:			
	• Lot Identity?	☒	☐	☐
	• Suppliers Lot Number?	☒	☐	☐
	• Date of Receipt?	☒	☐	☐
	• Quantity?	☒	☐	☐
	• Supplier's name?	☒	☐	☐
	• Shelf Life?	☒	☐	☐
	• Test Results?	☒	☐	☐
	• Specification?	☒	☐	☐
	• Accepted/Rejected?	☒	☐	☐
	• Retained Sample?	☒	☐	☐
7.11.	Please describe how material is issued from stock: *FIFO*			
7.12.	Do you have defined areas for material Receipt, Identification, Sampling and Quarantine?	☒	☐	☐
7.13.	Are scheduled stock checks performed?	☒	☐	☐
7.14.	Do you have a rework/reprocess policy?	☒	☐	☐

8. Quality Control

		YES	NO	NA
8.1.	Is Quality Control (QC) independent of Production?	☒	☐	☐
8.2.	Does the facility have in-house laboratory that performs raw material, in process control and finished material testing?	☒	☐	☐
	Our quality control laboratory is located near the city of Zaragoza at Utebo (Zaragoza). It is 40 kms from manufacturing plant. The laboratory is accredited according to ISO/IEC 17025			
8.3.	Are records kept of all samples that are submitted to the laboratories?	☒	☐	☐
8.4.	If Yes, do these records include the following:			
	• Date sample received?	☒	☐	☐
	• Identity of samples?	☒	☐	☐
	• Results of testing?	☒	☐	☐
	• Date sample taken?	☒	☐	☐
8.5.	Are there formal written procedures for all performed tests?	☒	☐	☐
8.6.	Are the analytical methods validated?	☒	☐	☐
8.7.	Are control samples routinely run with assays?	☒	☐	☐
8.8.	Are analytical calculations checked by a second person?	☒	☐	☐
8.9.	Do you perform trend analysis on analytical results?	☒	☐	☐
8.10.	Are the results of reference standard testing maintained on file?	☒	☐	☐
8.11.	Is there a procedure for documenting and investigating out-of-specification results?	☒	☐	☐
8.12.	Do you use any contract laboratories?	☒	☐	☐
8.13.	Have you qualified/evaluated these contract laboratories?	☒	☐	☐
8.14.	What types of testing is contracted out?	*Mainly contaminants and micro not tested in our laboratory: Dioxins & PCBs, pesticides, some micro analysis, etc.*		
8.15.	Are quality standards or written control procedures available for:			
	• Starting materials?	☒	☐	☐
	• In-process control?	☒	☐	☐
	• Physical identification at all stages (e.g. labelling of semi-finished products)?	☒	☐	☐
	• Finished products?	☒	☐	☐
	• Microbiological control?	☒	☐	☐
8.16.	Are records kept of all control results?	☒	☐	☐
	• If yes, for how long do you keep those records? *7 years*	☒	☐	☐
	• Is your critical analytical laboratory equipment fully qualified?	☒	☐	☐
	• Is there a maintenance plan/procedure for laboratory equipment?	☒	☐	☐

8. Quality Control

		YES	NO	NA
8.16.1.	If yes:			
	• Do you have a calibration scheme?	☒	☐	☐
	• Do you have calibration instructions?	☒	☐	☐
	• Do you keep all records of calibration performances?	☒	☐	☐
	• Does any laboratory equipment have software control?	☒	☐	☐
8.16.2.	If yes:			
	• Is the software validated?	☒	☐	☐
	• Are modifications of software (or its use) implemented by laboratory personnel?	☒	☐	☐
	• Is there a procedure concerning change of software and its copying?	☒	☐	☐
	• Is the security of software controlled?	☒	☐	☐
8.17.	Are samples of end product taken by appropriate trained personnel?	☒	☐	☐
8.18.	Which sampling plan do you use:			
	• For starting materials? *Each batch*			
	• For finished products? *Each batch*			
8.19.	Do you analyse each sample?	☒	☐	☐
8.20.	Do you keep retain samples of each lot?	☒	☐	☐
8.21.	How long do you keep retain samples? *2 years*			
8.22.	Is there a procedure in place to establish and manage reference standards?	☒	☐	☐

9. Quality Assurance

		YES	NO	NA
9.1.	Is there an independent Quality Assurance (QA) department within the company?	☒	☐	☐
9.2.	Who is responsible for evaluation and approval?			
	• of specifications of end products?	*QA MANAGER*		
	• of critical manufacturing process parameters?	*QA MANAGER*		
9.3.	Do you have procedures covering the release or rejection of material?	☒	☐	☐
9.4.	Who is responsible for release and reject of your end product?	*QA MANAGER*		
9.5.	On which quality data do you base the release of the product? *Specification*	☒	☐	☐
9.6.	Are batch records reviewed / approved before the batch is dispatched?	☒	☐	☐
9.7.	Are deviations and non-conformances investigated, documented and filed?	☒	☐	☐
9.8.	Do you communicate doubts regarding the quality of the product to the customers?	☒	☐	☐
9.8.1.	Even when the product is still within specification?	☒	☐	☐
9.9.	Would you notify your Customer of significant deviations during manufacturing?	☒	☐	☐
9.10.	Do you introduce changes according to a written procedure?	☒	☐	☐
9.11.	Do you inform your customers about changes? *Major changes*	☒	☐	☐
9.12.	Do you wait for approval of customers on major changes?	☒	☐	☐
9.13.	Would you notify your Customer in writing prior to implementing significant changes?	☒	☐	☐
9.14.	Would you notify your Customer in writing prior to implementing major facility changes?	☒	☐	☐
9.15.	How is senior management informed of related issues?	weekly department meeting		
9.16.	Do you supply a Certificate of Analysis with each batch?	☒	☐	☐
9.16.1.	If 'YES,' will the Certificate of Analysis include actual analytical results?	☒	☐	☐
9.17.	Will you supply a Certificate of Sterilization with each batch?	☐	☐	☒

10. Packaging, Labelling and Shipping

		YES	NO	NA
10.1.	If containers are reused, are they cleaned and inspected before use?	☒	☐	☐
10.2.	Are container labels reconciled and the labels printed, used and destroyed recorded?	☒	☐	☐
10.3.	Is each bag/container labelled with the lot/batch number?	☒	☐	☐
10.4.	Will each bag/container on a pallet have the lot/batch number and description?	☒	☐	☐
10.5.	Do you keep records of all shipments, including batch number and quantity?	☒	☐	☐
10.6.	Is a contractor used for shipping?	☒	☐	☐
10.6.1.	If you use a contractor, do you have a supplier contract?	☒	☐	☐
10.6.1.1.	If yes, have they been evaluated?	☒	☐	☐
10.7.	Is the shipping temperature controlled?	☒	☐	☐
10.8.	Have stability studies for temperature-controlled shipments been performed?	☒	☐	☐
10.9.	Are written instructions available for:			
	• Packaging components?	☒	☐	☐
	• Packaging operation?	☒	☐	☐
	• Labels and labelling?	☒	☐	☐
10.10.	Does the labelling procedure have special precautions to prevent unintentional mix-ups?	☒	☐	☐
10.11.	Do you maintain lot separation during packaging?	☒	☐	☐
10.12.	Are you prepared to meet packaging and labelling requirements from your customers?	☒	☐	☐
10.13.	Does your labelling indicate:			
	• Name and quality?	☒	☐	☐
	• The site of manufacturing?	☒	☐	☐
	• The lot number?	☒	☐	☐
	• Customer order number?	☒	☐	☐
	• Customer code number?	☒	☐	☐
10.14.	Do you use re-usable containers?	☒	☐	☐
10.14.1.	If yes: Do you have procedures to take special precautions to avoid cross-contamination?	☒	☐	☐
10.15.	Do you have your own transportation system?	☐	☒	☐
10.16.	Do you have a Quality/Safety selection system for contracting carriers	☒	☐	☐
10.17.	Do you have a regular carrier for your goods?	☒	☐	☐
10.18.	Do you contact your customer in case of delay?	☒	☐	☐

10. Packaging, Labelling and Shipping

		YES	NO	NA
10.19.	Does your transport system make use of a tracking report?	☒	☐	☐
10.20.	Does your carrier have a Quality Manual?	☒	☐	☐
10.21.	Does your carrier have a SQAS assessment report?	☐	☒	☐
10.22.	Are transportations insured?	☒	☐	☐
10.23.	Do you have one or more substitute carriers?	☒	☐	☐
10.24.	Does the Safety Advisor make annual reports about transport of dangerous materials?	☒	☐	☐
10.25.	In case of liquid products			
	• Do you use dedicated tankers?	☒	☐	☐
	• Do you require cleaning of road tankers after every use?	☒	☐	☐
	• Are cleaning certificates kept by the driver?	☒	☐	☐
	• Are cleaning certificates available for inspection by us?	☒	☐	☐

11. Safety, Health and Environment (SHE)

		YES	NO	NA
11.1.	Do you have operational management systems for Safety, Health and Environment (SHE)?	☒	☐	☐
	If so, are these systems			
	• Based on an international standard (ISO 9001/14001/18001)? *ISO 9001*	☒	☐	☐
	• Certified by an accredited third-party auditing body? *AENOR*	☒	☐	☐
11.2.	Do you have a dedicated organization for safety, health and environment?	☒	☐	☐
11.3.	How many people are employed in this organisation? 3	☒	☐	☐
11.4.	Have you identified all relevant SHE aspects and all legal requirements?	☒	☐	☐
11.5.	Do you have a structured SHE program which is regularly monitored and updated?	☒	☐	☐
11.6.	Does your site comply with all relevant laws (EPA, Pollution Prevention, etc.)?	☒	☐	☐
11.7.	Are the following subjects regulated by law and/or specific standards?			
11.8.	• Emissions to air	☒	☐	☐
11.9.	• Discharge of wastewater	☒	☐	☐
11.10.	• Disposal of hazardous waste	☒	☐	☐
11.11.	• Protection against/remediation of soil pollution	☒	☐	☐
11.12.	• Risk control and reduction	☒	☐	☐
11.13.	• Nuisance by noise/odor	☒	☐	☐
11.14.	• Occupational safety	☒	☐	☐
11.15.	Does your site operate its own wastewater treatment installation?	☐	☒	☐
11.16.	Is your site controlled by regular inspections of safety, health and environment?	☒	☐	☐
11.17.	Are your personnel instructed on the handling of any kind of hazardous materials?	☒	☐	☐
11.18.	Do you have an adequate emergency response plan and organization?	☒	☐	☐
11.19.	Do you run SHE (compliance/performance) audits?	☐	☒	☐
11.20.	Do you have a certified: “Safety-Advisor transport dangerous materials (road/rail)”?	☐	☒	☐
11.21.	Does the Safety-Advisor make annual reports with respect to dangerous materials?	☐	☒	☐

12. Food Defense

		YES	NO	NA
12.1.	Is there a Food Defense program in place?	☒	☐	☐
	We have a written procedure in place for the requirements of Food Defense. All doors are locked, and we have an automatic gate system monitored by personnel. All keys are controlled by our personnel with limited/ authorized access. The main door and offices are monitored by cameras and intercom 24 hours a day, year-round. All employees have a registration card. When the workers enters / leaves the factory, they must register their entry / exit on the device, signing with their cards. All visitors must fill out a registration form with their details, and we assign an identification card which must be displayed on their clothing at all times.			
12.2.	Is there limited access control for employees and visitors to the facility and the production rooms?	☒	☐	☐
12.3.	Is there CCTV video monitoring present at the facility?	☒	☐	☐

STATE OF THE ART

Solutex actively implements a Quality and Food Safety Management System, based on ISO 9001:2015, ISO 22000:2018, and HACCP requirements. Current Good Manufacturing Practices according to ICH-Q7A are in place for Active Pharmaceutical Ingredients and their intermediates, pursuant to 21 CFR Part 111 for Dietary Supplement Ingredients, Dietary Supplements, and Medical Food purposes.

Solutex GC, Mallén has the sanitary authorization corresponding to the plant and its activity. It is registered in the General Registry of Food and Food Companies with NºRGSEAA 16.003705/Z and 26.013729/Z.

On 18th and 19th September of 2014, an inspection by the FDA was conducted under CPGM 7303.803 to cover CPGM7321.008 Dietary Supplements. As a result, FDA Form 483, Inspectional Observations was not issued.

Raquel Yeregui
QA Manager

NON-GMO STATEMENT

To Whom It May Concern:

We hereby inform you that our products are made from Fish Oil or Algal Oil. These products are neither organism nor genetically modified per the regulations enforced. They also contain antioxidants from natural sources also considered non-GMO.

Therefore, our products are not subject to GMO labelling in reference to EU regulations 1829/2003 and 1830/2003.

Raquel Yeregui
QA Manager

BSE/TSE STATEMENT

To Whom It May Concern:

We hereby inform you that our products do not contain, nor are they manufactured using any animal fats or by-products from Bovine, Ovine or Caprine – their derivative ingredients, or human blood products.

Only fish and algae are used in manufacturing our products; Fish are not TSE-relevant animals (Official Journal of the European Union 2011/C 73/01, and European Pharmacopoeia 5.2.8).

Raquel Yeregui
QA Manager

CONTAMINANTS STATEMENT

To Whom It May Concern:

By means of this letter, Solutex G.C., S.L. confirms that our Omega-3 oil is produced under strict security limits in order to control the oxidation of the product according to European Pharmacopoeia (Eur. Ph.) and under the limits established by EU Regulation 1881/2006 as amended for metals, dioxins & PCBs, 3-MCPD, 3-MCPD fatty acid esters & glycidyl fatty acid esters & polycyclic aromatic hydrocarbons (PAHs) and nitrates, therefore, control of the food security of the product is guaranteed.

Raquel Yeregui
QA Manager

PESTICIDES STATEMENT

To Whom It May Concern:

By means of this letter, Solutex GC, S.L., confirms that our products have been tested and analyzed for pesticides; the results indicate pesticides have not been detected according to active compounds and limits below European Pharmacopoeia.

Raquel Yeregui
QA Manager

GLUTEN-FREE STATEMENT

To Whom It May Concern:

We hereby inform you that our Omega-3 products/concentrates are gluten-free and the facilities used in the manufacturing process do not manufacture any product containing gluten.

Raquel Yeregui
QA Manager

HISTAMINE STATEMENT

To Whom It May Concern:

We hereby inform you that we analyze the histamine content in our raw materials from fish oil (from crude to refined oils), and the results are below the limit of quantification.

We annually evaluate the content of histamines in our contaminant plan, obtaining results below the limit of quantification.

In addition, the high temperatures in our manufacturing process causes a thermal denaturalization of proteins such as histamine, and the content in our final products is below the limit of quantification.

Therefore, we conclude that our products made from fish oil do not contain histamine in origin.

Raquel Yeregui
QA Manager

RESIDUAL SOLVENTS STATEMENT

To Whom It May Concern:

According to current ICH Q3C Guidelines for Residual Solvents, Solutex certifies that our products contain Class 3 Solvent Ethanol, below the detection limit of 500 mg/kg for Residual Ethanol.

Raquel Yeregui
QA Manager

MELAMINE STATEMENT

To Whom It May Concern:

We hereby inform you that our products are free of Melamine and therefore may be considered Melamine-free.

Raquel Yeregui
QA Manager

AFLATOXINE STATEMENT

To Whom It May Concern:

Aflatoxins are naturally occurring mycotoxins that are produced by *Aspergillus flavus* and *Aspergillus parasiticus*, species of fungi. These toxins typically develop during harvest, storage and/or transit of cereal grains, legumes and tree nuts.

1. The raw material is esterified fish oil or algal oil that is not suitable for the growing and development of fungi.
2. The conditions of the manufacturing process do not allow growth and development of fungi.
3. Cereal grains, legumes and tree nuts or their by-products are not used in the manufacturing process nor are they added during production, storage or packaging.
4. Auxiliar materials used in the manufacturing process do not contain cereal grains, legumes and tree nuts or their by-products.

To the best knowledge of Solutex GC, S.L. our products are Aflatoxin free.

Raquel Yeregui
QA Manager

MYCOTOXINS STATEMENT

To Whom It May Concern:

Mycotoxins are naturally produced by different species of fungi. These toxins typically develop during harvest, storage and/or transit of cereal grains, legumes and tree nuts.

1. The raw material is esterified fish oil or algal oil that is not suitable for the growing and development of fungi.
2. The conditions of the manufacturing process do not allow growth and development of fungi.
3. Cereal grains, legumes and tree nuts or their by-products are not used in the manufacturing process, nor are they added during production, storage or packaging.
4. Auxiliar materials used in the manufacturing process do not contain cereal grains, legumes and tree nuts or their by-products.

To the best knowledge of Solutex GC, S.L our products are Mycotoxin free.

Raquel Yeregui
QA Manager

NANOMATERIALS STATEMENT

To Whom It May Concern:

We hereby inform you that nanotechnology is not employed during the manufacturing process of our products.

Raquel Yeregui
QA Manager

PACKAGING CONFORMITY STATEMENT

To Whom It May Concern:

Our products are drummed in 230-liter and 30-liter steel drums inner covered with sanitary lacquer suitable for food contact.

We confirm that the drums used comply with the following legislation:

- Regulation (EC) 1935/2004, of October 27, 2004, on the materials and objects destined to come into contact with food., developed in Regulation (EC) 10/2011, and its amendings.
- Regulation (EC) 2023/2006, of December 22, 2006, on Good Manufacturing Practices for materials and objects intended to come into contact with food.
- Regulation 1895/2005 (concerning the restriction on the use of certain epoxy derivatives in materials and articles intended to come into contact with food products).
- RD 847/2011, of June 17, establishing the positive list of substances allowed for the manufacture of polymeric materials intended to come into contact with food.
- Regulation FDA 21 CFR 175: Resinous and polymeric coatings for food contact.

Related to tests and limits of migration:
According to Regulation (EU) 2018/213., the overall migration limit established in a maximum value of 0.05 mg/Kg of BPA.

Raquel Yeregui
QA Manager

WADA STATEMENT

To Whom It May Concern:

Solutex GC, S.L. does not add as ingredients, substances mentioned in the current “Prohibited List” of the World Anti-Doping Agency (WADA) to our products.

The processing aids used in the manufacturing process are not included in the “Prohibited List” of the World Anti-Doping Agency (WADA).

According to our experience with the manufacturing process as well as the knowledge of the raw materials, processing aids and ingredients, SOLUTEX GC, S.L: does not explicitly test for substances from the “Prohibited List”.

Raquel Yeregui
QA Manager

AENOR ISO 9001:2015

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

AENOR *has issued an IQNet recognized certificate that the organization:*

SOLUTEX GC, S.L.

A)	***A)***	***B)***
PI EL ZAFRANAR PARCELA 22 50550 - MALLÉN (ZARAGOZA)	***Parque EMPRESARIAL OMEGA, EDIF. GAMMA, CR BARAJAS 24, 28109, MADRID 28108 - ALCOBENDAS***	***PQ EMPRESARIAL UTEBO, MIGUEL SERVET 81, NAVE 18 50180 - UTEBO (ZARAGOZA)***

has implemented and maintains a

Quality Management System

for the following scope:

A) The design and production of essential oils, lipids and food suplements for the sectors of Pharmacy, Nutrition and Cosmetics.
B) Sampling and physical-chemical and microbiological analysis of drinking, natural and waste waters.
Physical-chemical and microbiological analysis of foods, soils, fertilizers, chemical products, cosmetics and pharmaceutical products.

which fulfills the requirements of the following standard

ISO 9001:2015

First issued on: ***2010-12-22*** *Last issued:* ***2019-12-22*** *Validity date:* ***2022-12-22***

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number: ***ES-1375/2010***

AENOR

Alex Stoichitoiu
President of IQNet

Rafael GARCÍA MEIRO
Chief Executive Officer

Original Electronic Certificate

IQNet Partners*:
AENOR *Spain* AFNOR Certification *France* APCER *Portugal* CCC *Cyprus* CISQ *Italy*
CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS Holding GmbH *Germany* EAGLE Certification Group *USA*
FCAV *Brazil* FONDONORMA *Venezuela* ICONTEC *Colombia* Inspecta Sertifiointi Oy *Finland* INTECO *Costa Rica*
IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland*
NYCE-SIGE México PCBC *Poland* Quality Austria *Austria* RR *Russia* SII *Israel* SIQ *Slovenia*
SIRIM QAS International *Malaysia* SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* TSE *Turkey* YUQS *Serbia*

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

AENOR *has issued an IQNet recognized certificate that the organization:*

SOLUTEX GC, S.L.

PI EL ZAFRANAR PARCELA 22.
50550 - MALLÉN
(ZARAGOZA)

has implemented and maintains a

Food Safety Management System

for the following scope:

The production of essential oils and lipids.

which fulfills the requirements of the following standard

ISO 22000:2018

First issued on: ***2010-12-27*** *Last issued:* ***2021-02-08*** *Validity date:* ***2022-12-27***

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number: ***ES-SA-0052/2010***

Alex Stoichitoiu
President of IQNet

Rafael GARCÍA MEIRO
Chief Executive Officer

AENOR

IQNet Partners*:
AENOR *Spain* AFNOR Certification *France* APCER *Portugal* CCC *Cyprus* CISQ *Italy*
CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS Holding GmbH *Germany* EAGLE Certification Group *USA*
FCAV *Brazil* FONDONORMA *Venezuela* ICONTEC *Colombia* Inspecta Sertifiointi Oy *Finland* INTECO *Costa Rica*
IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland*
NYCE-SIGE *México* PCBC *Poland* Quality Austria *Austria* RR *Russia* SII *Israel* SIQ *Slovenia*
SIRIM QAS International *Malaysia* SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* TSE *Turkey* YUQS *Serbia*

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

FRIEND OF THE SEA CERTIFICATION

Certificate No. LA0047-2021-A

CERTIFICATE

Friend of the Sea

Issued to:

SOLUTEX GC, SL
Polígono Industrial EL Zafranar Calle Rioja 6
Mallen – Zaragoza 50550 Spain

London Associati declares to have audited the product(s) and/or units of the above mentioned Company and have found to be in conformity with the standard:

FOS CoC, FF, FM FO and 03
Criteria and Indicators for the Certification of the Traceability of Friend of the Sea products rev.5, 2017

FOS 0001 - Certification Procedure FOS-FF, FOS-FM, FOS-FO, FOS-O3 and CoC General requirements rev 9.3.

and that the products mentioned below comply with this standard:

(FISH OIL CONCENTRATE):
Anchoveta (*Engraulis rigens*), Chub mackerel (*Scomber japonicus*), European pilchard (*Sardina pilchardus*), European anchovy (*Engraulis encrasicolus*), Anchoa samasa (*Anchoa nasus*), Atlantic chub mackerel (*Scomber colias*).

This Certificate covers the product(s) and/or unit(s) and/or processes/activities as mentioned further in the authenticated annex of this certificate.

This certificate is valid from 22-02-2021 to 21-02-2024
The current status of this certificate is always displayed at:
http://www.friendofthesea.org/certified-products.asp

First date of Certificate: **22-02-2021**

LONDON ASSOCIATI
20-20 Wenlock Road
N1 7GU London UK
+44 (0) 20 3926 0609
info@associati.london

Place and date:
London (UK), 22-02-2021

FRIEND OF THE SEA
Corso Buenos Aires, 45
20124 Milan, Italy
www.friendofthesea.org
Tel. +39 02 87075166
info@friendofthesea.org

Current audit date: **08-02-2021**

LONDON CERTIFICATIONS

LeadAuditor
Pierluigi Monticini

IFOS CERTIFICATION

IFOS™

Raw Materials Summary Report

Raw Material Brand Name:	Omegatex
Raw Material Summary: OMEGATEX™ PLANT / MARINE SOURCED ★★★★★	★ The manufacturing facility is an approved and registered food/dietary supplement manufacturing facility with an appropriate certification = **YES** ★ The company and/or product has been registered in accordance with the regulatory authorities' requirements where the product is produced = **YES** ★ The analytical methods used have met the IFOS standard of testing = **YES** ★ Each lot of certified IFOS raw material has been individually inspected and reviewed for IFOS program compliance = **YES** ★ The product has met the IFOS Consumer Report 5-Star Rating Criteria = **YES**
Company Name:	Solutex®
Company Phone:	+34 91 806 04 77 (EU) | 800.466.1484 (North America)

Certified SKUs:	
OMEGATEX5025TGD	
OMEGATEX5020IF	
OMEGATEX5020TGNF	
OMEGATEX8000TGINN	
OMEGATEX4921IF	

The IFOS™ Program is provided exclusively by Nutrasource Diagnostics Inc.
120 Research Lane, Suite 203 | University of Guelph Research Park | Guelph, ON CANADA N1G 0B4
www.ifosprogram.com | ifos@nutrasource.ca

MANUFACTURING PROCESS DIAGRAM