

Supplier Questionnaire

Instructions: Fill in all areas; please do not leave any blanks. Some questions may not be applicable (N/A), especially if the audit pertains to a distributor. Please make this indication.

Nature of audit	X Initial Assessment <input type="checkbox"/> Re-qualification
Description of the business:	X Manufacturer (Complete Section A only) <input type="checkbox"/> Distributor/ Broker (Complete Section B Only)

General Information

SECTION A: FOR MANUFACTURER		
<i>To be completed by Manufacturer</i>		
GENERAL INFORMATION		
1	Manufacturer Name	RED B.V. ("RED Lecithin")
2	Address	Einsteinstraat 37, 3316 GG, Dordrecht, The Netherlands
3	Mailing address if different than above	
4	Contact Person	R.A.G. Blokvoord
5	Phone number & E-mail address	+1 818 730 1200 / blokvoord@redlecithin.com
6	Fax number	n.a.
7	Web site	www.redlecithin.com
8	When was the manufacturing facility established?	2017
9	Total number of employees:	10
10	Number of shifts:	1
11	Provide an organizational chart, reflecting the reporting structure of the company.	X Yes* <input type="checkbox"/> No *Attach a copy at the end of the document

Note: List the ingredients which are pertinent to the questionnaire on page 12

Regulatory Information

1	Provide the FDA Food Facility Registration Number(s) for the facility or facilities manufacturing this product.	FFRN: 11918892328
2	Registration Expiration Date	12/31/2024
3	Does the facility have a license from the state, county and/or city to operate the business as an ingredient manufacturer/supplier?	X Yes* <input type="checkbox"/> No
	*If yes, are the registrations renewed every year or as required?	X Yes <input type="checkbox"/> No
4	License No., Issuing federal/state agency and License description	Dutch food authority (NVWA) does not issue reg numbers; they merely acknowledge our registration
5	Has the facility been inspected by a government or regulatory agency?	X Yes* <input type="checkbox"/> No
	*If yes, list name of agency and date of last inspection below for all that apply.	
	Agency Name: NVWA	Date of Last Audit: 02/21/2021 <input type="checkbox"/> Certification/License X Other (Specify): unannounced regular visit
	Agency Name:	Date of Last Audit <input type="checkbox"/> Certification/License <input type="checkbox"/> Other (Specify):
	Agency Name:	Date of Last Audit <input type="checkbox"/> Certification/License <input type="checkbox"/> Other (Specify):
6	Are all regulatory inspections kept on file?	X Yes <input type="checkbox"/> No
7	Do you have ISO certification?	<input type="checkbox"/> Yes Certification # _____ <input type="checkbox"/> No <small><i>Provide a copy of the certificate</i></small> FSSC22000 certified
8	Is the facility FSMA Compliant	X Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
9	Is there a HACCP (Hazard Analysis and Critical Control Point) program in-place?	X Yes* <input type="checkbox"/> No
	*If yes, provide a copy of the manufacturer's HACCP or HARPC plan (as required by the FDA Food Safety Modernization Act, or FSMA). Company policy to not share copies; can be witnessed during a site audit	
10	Is HACCP or HARPC Training provided?	X Yes <input type="checkbox"/> No
11	How often is HACCP or HARPC Training provided?	Annually
12	Do you have a written Food Defense Program in place?	X Yes <input type="checkbox"/> No
	a. Does it include Food Defense Program Training?	X Yes <input type="checkbox"/> No
	b. How often is the Food Defense Program Training provided?	Annually

13	Do you have a written Food Safety Plan in place?	X Yes <input type="checkbox"/> No
	a. Does it include Food Safety Training?	Yes
	b. How often is the Food Safety Training provided?	Annually
14	Products manufactured/distributed	<input type="checkbox"/> Vitamins <input type="checkbox"/> Minerals <input type="checkbox"/> Amino acids <input type="checkbox"/> Herbal Products <input type="checkbox"/> Probiotics X Others lecithin, lecithin-based compounds, and vegetable oils
15	Is the material manufactured under cGMPs?	<input type="checkbox"/> Yes X No
16	Under which cGMPs is the material manufactured?	<input type="checkbox"/> Dietary Supplement (U.S. 21 CFR Part 111) <input type="checkbox"/> Food (U.S. 21 CFR Part 117) <input type="checkbox"/> Drug (U.S. 21 CFR Parts 210 & 211) <input type="checkbox"/> Other:

Note: Information may be provided by the distributor/ broker, however all manufacturing information pertinent to the questionnaire is required.

Personnel

1	Are formal, documented job descriptions available for all company positions?	X Yes <input type="checkbox"/> No
2	Do you have a written training program for all employees?	X Yes <input type="checkbox"/> No
	a. Does it include cGMP training?	<input type="checkbox"/> Yes X No
	b. How often is cGMP training performed?	
3	Is a procedure in place for personnel health and hygiene that include appropriate garments, personal hygiene, hand washing, storage of personal items, and reporting illness?	X Yes <input type="checkbox"/> No

Equipment, Facilities, and Utensils

1	Have IQ/OQ/PQ been performed for all major equipment/instruments?	X Yes <input type="checkbox"/> No
2	Is there a written procedure for the cleaning and sanitization of all utensils and equipment?	X Yes <input type="checkbox"/> No
3	Is there an SOP for facility general cleaning and sanitation	X Yes <input type="checkbox"/> No
4	Is the facility or equipment used dedicated to each material?	<input type="checkbox"/> Yes X No*

	a. *If no, what is in place to prevent cross contamination?	Segregation procedures, cleaning procedures, allergen monitoring/analyses, partially dedicated equipment, CIP of filling tank/pipes/equipment after each filling run, new packaging (no recycling)
5	Is there a pest control program?	X Yes <input type="checkbox"/> No
6	Are Restrooms and wash facilities kept clean and are not potential sources of Contamination? Are the cleaning records available for review upon request?	X Yes <input type="checkbox"/> No
7	Is there a Preventive Maintenance (PM) program for all major equipment?	X Yes <input type="checkbox"/> No
8	Are cleaning validation/verification performed on all major equipment?	X Yes <input type="checkbox"/> No
9	Is measuring and test equipment inspected and calibrated prior to use?	X Yes <input type="checkbox"/> No

Production and Process Control

1	Does the manufacturing/packaging facility have a written master manufacturing record in-place for each product code that details the production and process control systems for the product?	X Yes <input type="checkbox"/> No
2	Does each manufacturing batch have a batch record that follows the master production record and is properly identified by product code number and lot number?	X Yes <input type="checkbox"/> No
3	Is the manufacturing process validated/verified?	X Yes <input type="checkbox"/> No <input type="checkbox"/> NA
4	Is there a process flow diagram for the manufacture of the ingredient?	X Yes* <input type="checkbox"/> No *Attach a copy at the end of the document
5	Are validations/verification reports reviewed and approved by the quality unit?	X Yes <input type="checkbox"/> No*
	a. *If no, explain process.	
6	Do you have established Ingredient/Finished product specifications for components, in-process materials and finished products?	X Yes <input type="checkbox"/> No
7	Is water required in the manufacturing process?	X Yes* <input type="checkbox"/> No
8	*If yes, is there a purification system used & what type of system is used? Potable water only	
9	Is water tested?	X Yes* <input type="checkbox"/> No

	*If yes, what is the frequency of the water testing?	Twice Annually
10	Do you have a supplier qualification procedure in-place which includes initial qualification, periodic verification/re-qualification and procedures for disqualification?	X Yes <input type="checkbox"/> No
11	Are components used in manufacturing sampled, tested and the test results verified and approved by Quality Unity prior to use in production?	X Yes <input type="checkbox"/> No
12	Are there separate areas for storage of Quarantined materials?	X Yes <input type="checkbox"/> No
13	Does your facility handle substances which would be considered prohibited in sport (WADA prohibited list available at www.wada-ama.org)?	<input type="checkbox"/> Yes X No
14	Is your facility, to the best of its ability, able to supply raw materials that will not be contaminated with substances banned in sport?	X Yes <input type="checkbox"/> No
15	Is there a written change control system in place for facility/equipment changes?	X Yes <input type="checkbox"/> No
16	Are environmental controls (temperature, humidity) in-place and adequate in the facility?	X Yes <input type="checkbox"/> No

Quality Control System

1	Does your company maintain a documented quality system?	X Yes <input type="checkbox"/> No
2	Are their written procedures for the following activities? <i>Provide a copy of SOP index</i>	
	Records of purchase orders:	X Yes <input type="checkbox"/> No
	Issuance of documents & document control:	X Yes <input type="checkbox"/> No
	Calibration of lab & manufacturing equipment:	X Yes <input type="checkbox"/> No
	Standard operating procedures:	X Yes <input type="checkbox"/> No
	Quality Control testing procedures:	X Yes <input type="checkbox"/> No
	Data review & reporting process:	X Yes <input type="checkbox"/> No
	Item identification & control:	X Yes <input type="checkbox"/> No
3	Indicate the record retention policy (# of years) for the following listed below (NA if not applicable)	
	Manufacturing batch records:	Min. 5 years
	Lab records:	Min. 5 years
	Training records:	Min. 5 years
	Equipment validation/verification	Min. 5 years
	Calibration:	Min. 5 years
	Cleaning logs	Min. 5 years

	Distribution records	Min. 5 years
	Other	
4	Does your company have a Quality Unit?	X Yes <input type="checkbox"/> No*
	Is the quality unit independent from the production department?	X Yes <input type="checkbox"/> No*
	*If not, please explain:	
5	Are changes to documents reviewed and approved by the Quality unit?	X Yes <input type="checkbox"/> No
	Is there a written procedure to ensure that only current documents are used?	X Yes <input type="checkbox"/> No*
	*If not, please explain how they are maintained and by whom.	
6	Does the company have a documented internal cGMP audit program?	<input type="checkbox"/> Yes ** X No*
	** If yes, what is the frequency of the audits and who performs the internal audits?	
	*If no, please detail how adherence to cGMP's is evaluated: We are FSSC 22000 (=GFSI); internal audits is a part of this	
7	Describe your customer complaint handling program? Procedure in place for customer complaints; reference P10-02	
8	Is there a procedure to notify customers of a non-conformance resulting in product quality impact?	X Yes <input type="checkbox"/> No
9	Are returned goods identified and controlled?	X Yes <input type="checkbox"/> No
10	How will Captek Softgel be notified of corrective actions initiated as a result of a complaint submitted by Captek Softgel?	In writing by the Quality Head
11	Has a 3 rd party auditing body evaluated the facility?	X Yes* <input type="checkbox"/> No
	*If yes, indicate the agency and provide copies of certifications obtained (e.g. NSF, UL, NPA, MSC, Halal, Kosher, ISO)	FSSC 22000, GMP+, Kosher, Halal, SKAL (Organic), SGS (Non-GMO IP)
12	Are there procedures for final product inspection, sampling, and testing?	X Yes <input type="checkbox"/> No
13	Is the final review of production documentation and product disposition performed by Quality Unit?	X Yes <input type="checkbox"/> No

14	Is there an Allergen control program in-place	X Yes <input type="checkbox"/> No
15	Are any residual solvents listed as class 1, 2, or 3 under USP <467> used in any part of your manufacturing?	X Yes* <input type="checkbox"/> No
	*If yes, list the solvents used:	Hexane; residual solvent levels well below the 290 ppm maximum concentration listed in Chapter 467

Product Information

1	Provide a Safety Data Sheet (SDS).	X Attached
2	Provide Product Specification for supplied material.	X Attached
3	Provide an example Certificate of Analysis (COA).	X Attached
4	Country of Origin Statement	X Attached
5	Allergen Statement	X Attached
6	Kosher Certification	X Attached (if applicable) <input type="checkbox"/> N/A
7	Halal Certification	x Attached (if applicable) <input type="checkbox"/> N/A
8	Non-GMO	X Attached (if applicable) <input type="checkbox"/> N/A
9	BSE/TSE Statement	X Attached (if applicable) <input type="checkbox"/> N/A
10	Gluten certification	X Attached (if applicable) <input type="checkbox"/> N/A
11	Organic Certification	X Attached (if applicable) <input type="checkbox"/> N/A We are Organic certified for our organic lecithins; product; does not apply for the product Captek is interested in
12	Generally, Recognize as Safe (GRAS)	<input type="checkbox"/> Attached (if applicable) <input type="checkbox"/> N/A as per 21 CFR 184.1400 - Lecithin
13	Is this material suitable for vegetarians?	X Yes <input type="checkbox"/> No
14	Is this material suitable for vegans?	X Yes <input type="checkbox"/> No

Quality Control Laboratories

1	Are there Quality Control laboratories located at the manufacturing site?	<input type="checkbox"/> Yes X No
2	Are analysis/ tests contracted out?	X Yes <input type="checkbox"/> No
3	Are the contract laboratories qualified?	X Yes <input type="checkbox"/> No
4	Are test methods verified/validated?	X Yes <input type="checkbox"/> No
5	Is the review of all laboratory documents carried out by qualified Quality Control Personnel?	X Yes <input type="checkbox"/> No
6	Are analytical standards purchased or qualified in-house?	<input type="checkbox"/> Qualified in-house* X Purchased
	*If qualified in-house, is there an SOP to qualify standards?	<input type="checkbox"/> Yes <input type="checkbox"/> No

7	How frequently is the vendor or manufacturer analytical testing performed?	<input checked="" type="checkbox"/> Every Lot/Batch <input type="checkbox"/> Skip Lot * <input type="checkbox"/> Annual <input type="checkbox"/> Other (Specify) _____
	* If skip lot, please explain the skip lot process.	
9	Are the Heavy Metals Specification on the CofA	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Heavy Metals are guaranteed as per TQSS, and are part of annual monitoring program; if desired, lower levels and batch-specific testing can be discussed and agreed. Batch-specific parameters are reported on COA
Contaminants – Residual Solvent		
10	<i>This section must be completed only if an organic solvent is used in the manufacturing process.</i> Residual solvent testing should be performed in accordance with current USP <467>. Note: Class 1 solvents are not permitted for use in Dietary Supplements. Materials found to contain Class 1 solvents will be rejected by Captek Softgel International.	
11	How frequently is this material tested for Residual Solvents?	<input type="checkbox"/> Every Lot/Batch <input type="checkbox"/> Annual <input type="checkbox"/> Skip Lot * <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Other (Specify) _____ see statement attached
	* If skip lot, please explain the skip lot process.	
12	Is this analysis performed by a contract laboratory, or by an internal QC laboratory?	<input checked="" type="checkbox"/> Contract Laboratory – Name: Nofalab; TLR <input type="checkbox"/> Internal QC Laboratory
13	List the method used to test this product for Residual Solvents:	ISO 9832
14	Are retain samples maintained?	<input checked="" type="checkbox"/> Yes* <input type="checkbox"/> No
	*If yes, for how long? 2 years min.	
15	Is there a stability program?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
	Is the product/expiration date supported by the stability study? Has stability of the products being provided to Captek been completed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

16	Does a procedure (SOP) provide for segregation, identification, and documentation of discrepant material?	X Yes <input type="checkbox"/> No
17	Does the Certificate of Analysis include manufacture/expiration date, test specifications, test method, and numerical or description test results? Is the Certificate of Analysis reviewed and approved by the Quality Unit?	X Yes <input type="checkbox"/> No
18	Do you maintain records on the tractability of each botanical material? e.g., Country of origin, State, farm?	X Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

Holding and Distributing

1	Are materials properly handled and stored to prevent damage/deterioration?	x Yes <input type="checkbox"/> No
2	Are materials properly identified as to their contents?	X Yes <input type="checkbox"/> No
3	Is there a SOP delineating steps to follow upon receipt of goods and responsibilities?	X Yes <input type="checkbox"/> No
4	Is material adequately identified as to acceptance or rejection?	X Yes <input type="checkbox"/> No
5	Is rejected material adequately controlled?	X Yes <input type="checkbox"/> No
6	Is there a FEFO/FIFO system for materials?	X Yes <input type="checkbox"/> No
7	Are materials supplied to Captek considered sensitive to environmental conditions?	X Yes* <input type="checkbox"/> No
	*If yes, describe the storage and transportation requirements	Store at temperatures between 15 and 35 degrees Celsius. Exposure to cold or frost should be avoided and may promote separation of the phospholipids from the oil; heat and remix the product to a homogenous state to avoid loss of functionality. Store in a clean, dry place, away from (excessive) sunlight. Shelf life is a minimum of 2 years after production date in the unopened original packaging

Responsible Sourcing

This section must be completed for the Manufacturer of this material.

Is there a code of conduct available as to the rules of employment and workers' rights that is posted or available to all employees in their own language and understood by all?	X Yes <input type="checkbox"/> No
Are employees aware of working conditions at hiring including working hours and terms of employment?	X Yes <input type="checkbox"/> No
Are all workers or employees over the age of 15 or over the minimum working age established by the jurisdiction where the facility is located?	X Yes <input type="checkbox"/> No
Is there a documented policy with regards to the minimum age of employees?	X Yes <input type="checkbox"/> No
Are all employees paid at least the minimum wage established by the country, state, providence, or local government	X Yes <input type="checkbox"/> No
Is there a non-discrimination policy in place? (It must account for nationality, age, gender, religion, and race of all employees)	X Yes <input type="checkbox"/> No
Is there a policy against using corporal punishment, physical, mental, or verbal abuse, forced labor, debt bondage or slave labor?	X Yes <input type="checkbox"/> No
Is there a documented overtime program that is communicated to all employees?	X Yes <input type="checkbox"/> No
Are migrant workers or foreign contracted laborers used?	<input type="checkbox"/> Yes X No
Are personal identification documents such as passports or visas, retained by the employer or employment agency, if used?	X Yes <input type="checkbox"/> No
If housing is provided, is it segregated by gender, and provides sufficient toilet and washing facilities to meet prevailing jurisdiction?	<input type="checkbox"/> Yes <input type="checkbox"/> No No housing provided
Are all hazardous materials and chemicals disposed in a manner that is in accordance with local law?	X Yes <input type="checkbox"/> No
Do facilities have a program in place to minimize pollution to the environment? Recycling is encouraged.	X Yes <input type="checkbox"/> No
Are all emergency doors and exits in working conditions and unobstructed at all times?	X Yes <input type="checkbox"/> No
Are workers required to wear personal protective equipment such as eye protection, hard hats, steel-	X Yes <input type="checkbox"/> No

toed shoes, and other types of protective gear where danger may exist?	
Are uniforms or PPE, if required, provided at no cost to workers?	X Yes <input type="checkbox"/> No
If this facility has been audited by a 3rd party responsible sourcing, social responsibility or Ethical sourcing organization indicate below the name of the organization /type of audits/standards and the dates of completion.	
Are you part of Sedex?	<input type="checkbox"/> Yes X No
Provide Sedex Company Reference	ZC #: ZS#:
Who is responsible for the social responsibilities policy and its implementation at your facility?	Name: R.A.G. Blokvoord Title: Director Email: blokvoord@redlecithin.com

List of ingredients

No.	Name	Manufacturer Name	Description/Comments
1	REDLEC™ S Fluid 150 Premium	RED B.V.	High-end Sunflower Lecithin
2			
3			
4			
5			
6			
7			
8			
9			
10			

11			
12			
13			
14			
15			

SECTION B: FOR DISTRIBUTOR/BROKER		
<i>To be completed by Distributor/Broker</i>		
GENERAL INFORMATION		
1	Description of the business:	<input type="checkbox"/> Distributor <input type="checkbox"/> Broker
2	Name of Distributor / Broker	
3	Address	
4	Mailing Address if Different than above.	
5	Please indicate the manufacturer name and address	
6	Products distributed: <input type="checkbox"/> Vitamins <input type="checkbox"/> Minerals <input type="checkbox"/> Amino acids <input type="checkbox"/> Herbal Products <input type="checkbox"/> Probiotics <input type="checkbox"/> Others _____ (Specify)	
7	How long has the facility been established?	
8	Total number of employees:	
9	Approximate square footage of the facility:	
REGULATORY INFORMATION		

10	Is the facility FSMA Compliant?	<input type="checkbox"/> Yes <input type="checkbox"/> No
11	Provide the FDA Food Facility Registration Number.	
12	Registration Expiration Date	
13	Do you meet the requirements of the FDA Rule for Foreign Supplier Verification Program (FSVP) for importers?	<input type="checkbox"/> Yes <input type="checkbox"/> No
14	Name of FSVP Importer on Record	
15	Address	
16	Contact Person (Qualified Individual)	
17	Phone Number and Email	
18	Does the facility have a license from the state, county and/or city to operate the business as an ingredient manufacturer/supplier?	<input type="checkbox"/> Yes* <input type="checkbox"/> No
	a. *If yes, are the registrations renewed every year or as required?	<input type="checkbox"/> Yes <input type="checkbox"/> No
19	License No., Issuing federal/state agency and License description	
20	Has the facility been inspected by a government or regulatory agency?	<input type="checkbox"/> Yes* <input type="checkbox"/> No
	a. *If yes, name of agency and date of last inspection.	
21	Are all regulatory inspections kept on file?	<input type="checkbox"/> Yes <input type="checkbox"/> No
22	Is there a HACCP (Hazard Analysis and Critical Control Point) program in-place?	<input type="checkbox"/> Yes <input type="checkbox"/> No
23	Is HACCP or HARPC Training provided?	<input type="checkbox"/> Yes <input type="checkbox"/> No
24	How often is HACCP or HARPC Training provided?	
25	Do you have a written Food Defense Program in place?	<input type="checkbox"/> Yes <input type="checkbox"/> No
26	Does it include Food Defense Program Training?	<input type="checkbox"/> Yes <input type="checkbox"/> No
27	How often is the Food Defense Program Training provided?	
28	Do you have a written Food Safety Plan in place?	<input type="checkbox"/> Yes <input type="checkbox"/> No
29	Does it include Food Safety Training?	<input type="checkbox"/> Yes <input type="checkbox"/> No
30	How often is the Food Safety Training provided?	
31	Is there an executed Quality Agreement with all the manufacturers?	<input type="checkbox"/> Yes <input type="checkbox"/> No

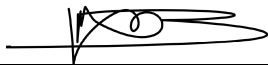
32	Has the manufacturing facility been audited? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, please provide audit report. Audited by: _____ Date of last audit inspection and outcome _____	
PERSONNEL		
1	Are formal, documented job descriptions available for all company positions	<input type="checkbox"/> Yes <input type="checkbox"/> No
2	Do you have a written training program for all employees?	<input type="checkbox"/> Yes <input type="checkbox"/> No
3	Does it include cGMP training?	<input type="checkbox"/> Yes <input type="checkbox"/> No
4	How often is cGMP training performed?	
EQUIPMENT, FACILITIES, AND UTENSILS		
1	Is there an SOP for facility general cleaning?	<input type="checkbox"/> Yes <input type="checkbox"/> No
2	Are Restrooms and wash facilities kept clean and are not potential sources of Contamination? Are the cleaning records available for review upon request?	<input type="checkbox"/> Yes <input type="checkbox"/> No
PRODUCTION AND PROCESS CONTROL		
1	Is there a written change control system in place for facility/equipment changes?	<input type="checkbox"/> Yes <input type="checkbox"/> No
2	Do you have a supplier qualification procedure in-place which includes initial qualification, periodic verification/re-qualification and procedures for disqualification?	<input type="checkbox"/> Yes <input type="checkbox"/> No
3	If manufacturing process changed at manufacturing site, how are you notified? Please describe.	
4	If manufacturing process changed at manufacturing site, how would we be notified? Please describe.	
QUALITY CONTROL SYSTEM		
1	Does your company maintain a documented quality system?	<input type="checkbox"/> Yes <input type="checkbox"/> No

2	<p>Indicate the record retention policy (# of years) for the following listed below. (NA if not applicable)</p> <p>Manufacturing batch records: _____ years</p> <p>Lab records: _____ years</p> <p>Training records: _____ years</p> <p>Equipment validation/verification: _____ years</p> <p>Calibration: _____ years</p> <p>Distribution records: _____ years</p> <p>Supplier Qualification Records: _____ years</p> <p>Other(s), please specify: _____; _____ years</p>	
3	Is there a written recall SOP in place?	<input type="checkbox"/> Yes <input type="checkbox"/> No
4	How is product recall handled?	
5	Describe your customer complaint handling program?	
6	How are returned goods identified and controlled? Please describe.	
7	Is there a Non-Conformance SOP in place?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	What is the procedure to notify customers of a non-conformance resulting in product quality impact?	
8	Describe your change control management system?	
	HOLDING AND DISTRIBUTING	
1	Are written procedures describing the receipt, identification, quarantine, sampling, examination and/or testing release, and handling of packaging and labelling materials?	<input type="checkbox"/> Yes <input type="checkbox"/> No
2	How are materials properly handled and stored to prevent damage/deterioration? Please describe.	
3	How are materials identified (e.g. labels, bar code, color coding, etc.)?	
4	Please describe how receipt of goods are processed. How are responsibilities delineated?	

5	Is material adequately identified as to acceptance or rejection?	<input type="checkbox"/> Yes <input type="checkbox"/> No
6	Is there a Rejected Material SOP in place?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	How are rejected material adequately controlled?	
7	Is there a FIFO/FEFO system for materials?	<input type="checkbox"/> Yes <input type="checkbox"/> No
8	Are there temperature & relative humidity controls in the facilities for the storage of all raw materials under the appropriate conditions?	<input type="checkbox"/> Yes <input type="checkbox"/> No
9	Describe how temperature & relative humidity controls in the warehouse are maintained?	
10	Are materials supplied to Captek considered sensitive to environmental conditions?	<input type="checkbox"/> Yes <input type="checkbox"/> No
11	If yes, are special transportation or storage conditions for the raw materials stated on the label.	<input type="checkbox"/> Yes <input type="checkbox"/> No

Manufacturer completes section below.

☐ Not Applicable

All information that is provided in this survey is strictly CONFIDENTIAL and will be handled as PROPRIETARY INFORMATION solely for the use of Captek Softgel Int'l Inc.	
By signing this survey, you agree that, if requested, Captek Softgel representative(s) will be allowed access to your facility for the purpose of verifying supplier compliance to your Self-Audit Survey.	
I certify that all of the information in this survey is correct.	
Company Name	RED B.V.
Title	Director
Email	blokvoord@redlecithin.com
Name (Printed)	R.A.G. Blokvoord
Signature (required)	
Date	01-23-2024

Distributor completes section below.

☐ Not Applicable

All information that is provided in this survey is strictly CONFIDENTIAL and will be handled as PROPRIETARY INFORMATION solely for the use of Captek Softgel Int'l Inc.	
By signing this survey, you agree that, if requested, Captek Softgel representative(s) will be allowed access to your facility for the purpose of verifying supplier compliance to your Self-Audit Survey.	
I certify that all of the information in this survey is correct.	
Company Name	
Title	
Email	
Name (Printed)	
Signature (required)	
Date	

Below for CSI Use Only:

QA Review Name (Print)		<input type="checkbox"/> Approved <input type="checkbox"/> Not Approved* <input type="checkbox"/> Further Evaluation*
*Details/Comments:		
Signature:		Date

Questionnaire Answers