
S.A. Citrique Belge N.V.

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Subject Tienen,
Standard answers to FAQs of customer questionnaires May 2009

Citrique Belge/ Tienen, Belgium
Production Site
Standard answers to FAQs of customer questionnaires

Part One: Corporate information

	<u>yes</u>	<u>no</u>
Quality Policies		
What quality policies have been defined:		
▪ Mission & Vision	X	
▪ Quality Policy	X	
Quality Systems	<u>yes</u>	<u>no</u>
Quality systems and standards meet the following regulations:		
▪ ISO Standard 9001:2000	X	
▪ ISO Standard 14001:2004	X	
GMP/POP/HACCP	<u>yes</u>	<u>no</u>
Quality systems and standards meet Good Manufacturing Practices (GMP)	X	
Is the implemented food safety control plan based on the HACCP concept?	X	
What does the HACCP-plan contain?		
▪ Definition of hazards and risks for health quality and cost calculation	X	
▪ Documented Critical Control Points (CCP)	X	
▪ Critical Limits of each CCP	X	
▪ Description of the monitoring procedure for each CCP	X	
▪ Description of corrective actions when there is a non-compliance at a CCP	X	
▪ An effective record system	X	
▪ Regular audits	X	
Recall of products	<u>yes</u>	<u>no</u>
Are there appropriate recall procedures in place?	X	
Granting that documents can be traced back via product-, packaging- and batch-code	X	
Complaint Management	<u>yes</u>	<u>no</u>
Do you have a formal customer complaint process that guarantees commitment and responsibility?	X	
▪ Regardless of the nature of the complaint	X	
▪ Covering all products	X	
▪ Covering all logistics	X	
Approval procedure of changes to manufacturing processes	<u>yes</u>	<u>no</u>
Is there an approval and notification-of- changes program regarding major changes in manufacturing processes in place?	X	
Stability Testing	<u>yes</u>	<u>no</u>
Is there a stability-testing program (storage conditions, re-test periods, and re-test dates) in place?	X	

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Product Labelling

Are finished product labels printed with text details in-house, showing the following information:

- | | <u>yes</u> | <u>no</u> |
|--|-------------------|------------------|
| ▪ Name of the supplier | X | |
| ▪ Name and batch number of the product | X | |
| ▪ Quantity per unit | X | |
| ▪ Best-use-before date (re-test date) | X | |
| ▪ Storage conditions | X | |
| ▪ Safety warning | X | |

Product Info

For specific product information following documents are available:

- | | <u>yes</u> | <u>no</u> |
|---------------------------------|-------------------|------------------|
| ▪ Product Data Sheet | X | |
| ▪ Safety Data Sheet | X | |
| ▪ Specification and Tests | X | |
| ▪ GMO statement | X | |
| ▪ Allergens statement | X | |
| ▪ BSE/TSE statement | X | |
| ▪ Residual solvents | X | |
| ▪ Halal and kosher certificates | X | |
| ▪ Composition Sheet | X | |
| ▪ Nutritional values | X | |
| ▪ GMP Food | X | |

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Part two: Site information

General information

Name of the production site: S.A. Citrique Belge N.V.
Address (general address): Pastorijsstraat 249, 3300 Tienen
Belgium – EU member state
Internet address: <http://www.citriquebelge.com>

Product Info

	<u>yes</u>	<u>no</u>
Is the site a mono production site?	X	
Has the facility/product/process been inspected by local (national) health inspection agency?	X	
Does your site perform:		
▪ planning	X	
▪ production	X	
▪ packaging	X	
▪ storage	X	
▪ sales and marketing	X	
▪ distribution	X	
Does the site guarantee		
▪ On-site Quality Control and -Assurance	X	
▪ Security-, Safety- and Environment Management	X	
▪ Facility Management	X	
▪ Research & Development	X	
Do the quality systems and standards at the production site meet the following:		
▪ GMPplus:2006 (Animal feed; enclosed HACCP-system)	X	
▪ ISO Norm 9001:2000	X	
▪ ISO Norm 14001:2004	X	
▪ FDA-Registration		X
▪ HPFB-Registration		X
Does the site provide a training program to its personnel, covering:		
▪ Standard operating procedure for training	X	
▪ GMP guidelines and SOPs	X	
▪ Regular updates of training documentation	X	

Quality Unit

	<u>yes</u>	<u>no</u>
Does the site have a separate QC/QA unit that is independent		
▪ in approval/rejection process (raw material/packaging components / product batches)	X	
▪ specifications	X	
▪ process changes	X	
Is the site-QA unit responsible for		
▪ the evaluation, selection, approval and rejection of new suppliers (Vendor Evaluation program; together with related departments)?	X	
▪ the process deviation procedure, the investigation of failures and complaints?	X	
▪ the release of products (Certificate of Analysis)?	X	
▪ the rejection of non-conforming raw material and intermediates?	X	
▪ the return of non-conforming products?	X	
▪ the documentation and investigation of and response to customer complaints?	X	
▪ ensuring compliance to updated compendia test methods?	X	
Is the site-QA unit responsible for quality audits:		
▪ Internal audits	X	
▪ Supplier audits	X	
▪ Customer audits	X	

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	<u>yes</u>	<u>no</u>
Does the quality audit procedure guarantee pre-audit planning and post-audit documentation with respective corrective action to be taken?	X	
Are there independent Quality Control Laboratories on-site	X	
Do the Quality Control laboratories incorporate the use of scientifically sound test procedures and standards:		
▪ USP	X	
▪ Ph. Eur.	X	
Or other standards:		
▪ Reagent grades		X
▪ Commercial grades		X
▪ Food grades	X	
Which analyses are performed at these on-site laboratories?		
▪ GMO-analysis		X
▪ Pesticides residues		X
▪ Microbiological analyses		X
▪ Heavy metals	X	
Are the specifications of the products purchased in place?	X	
Are written and approved specifications, sampling plans and validated test methods in place (for raw and finished products)?	X	
Do the specifications of finished products include tests and limits for residues of solvents?		n.a. – no solvent used
Is there a written procedure for handling OoS results?	X	
Are samples retained from each production batch (minimum shelf life period)?	X	
Does the site have a written policy for retained samples with regards to the definition of		
▪ storage container?	X	
▪ storage condition?	X	
▪ storage time?	X	
Raw Materials	<u>yes</u>	<u>no</u>
Does the site have a Vendor Evaluation program for the suppliers and ingredients used in the process, covering:		
▪ Raw material specification	X	
▪ Inspection and analysis	X	
▪ Periodic supplier audits (planning, documentation, follow-up)	X	
▪ CoA or CoC	X	
▪ Notification from the supplier in case of significant process and specification changes	X	
Does the site have written procedures in place for receipt, inspection, storage, identification, representative sampling, testing and disposition of raw materials?	X	
Is there a separate quarantine area for raw materials/rejected materials?	X	
Does the site have an internal sampler (department) trained for specific sampling techniques according to sampling plans for raw materials?		X
Can the site guarantee that raw material is not used in production prior to completed testing and approval by the Quality unit?	X	
Does the site have a system in place to ensure that stored raw materials are not used beyond their best-use-before date?	X	

Manufacturing Process:	<u>yes</u>	<u>no</u>
- Equipment		
Do the following instructions account for the site's production equipment:		
▪ Unique numbering of equipment	X	
▪ Batch records equipment indications	X	
▪ Validated cleaning program		X
▪ Validated calibration program	X	
▪ Procedure for the notification of production changes	X	
▪ Preventive Maintenance program	X	
- Water	<u>yes</u>	<u>no</u>
Does the site have a water purification system in place?	X	
What types of water are used for manufacturing:		
▪ Spring water	X	
▪ Potable water	X	
▪ Softened water		X
▪ Purified water	X	
▪ Distilled water		X
▪ Does the site regularly check the water quality?	X	
- Air	<u>yes</u>	<u>no</u>
Does the site have an air-handling system in place?		
▪ In the manufacturing rooms?		X
▪ In the packaging rooms?	X	
Does the site regularly check the air quality (e. g. contamination, dust, and spray)?	X	
- Instructions	<u>yes</u>	<u>no</u>
Does the site have written procedures in place regarding		
▪ Operation instructions and records?	X	
▪ Process control instructions and records?	X	
▪ Calibration instructions and records?	X	
▪ Maintenance instructions and records?	X	
▪ Cleaning instructions and records?	X	
▪ Building sanitation and records?	X	
▪ Pest control and records?	X	
▪ Environmental monitoring system (temperature, humidity and microbiology)	X	
Does the site have written and validated manufacturing process instructions/specifications in place in order to assure process repeatability and control		
▪ In-line process control (IPC)?	X	
▪ Statistical Process Control (SPC)?	X	
▪ Re-process Control?	X	
- Batch System	<u>yes</u>	<u>no</u>
Are the products manufactured		
▪ continuously	X	
▪ batchwise		X
Please indicate how long the site keeps its batch records: ____ 10 ____ years.		
- Batch tracing	<u>yes</u>	<u>no</u>
Can a batch be traced back to		
▪ its raw material?	X	
▪ its IPC?	X	
▪ its release control?	X	
Does the site have written procedures for holding, testing and reprocessing of returned products?	X	

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	<u>yes</u>	<u>no</u>
- Foreign bodies		
Can the site guarantee that windows / other openings to the outside are adequately screened?	X	
Can the site guarantee that vents in silos, tanks or other large containers are protected in order to prevent the entry of foreign bodies, insects and water?	X	
Does the site undertake the following measures to fight against the risk of foreign bodies connected with wood, fibers, fur, hair and plastic:		
▪ Filters	X	
▪ Sieves	X	
▪ Metal detectors	X	
Does the site carry out routine checks in order to verify the good condition of its protection against foreign bodies?	X	
- Cleaning and Hygiene	<u>yes</u>	<u>no</u>
If the equipment is used for multipurpose production, can the site guarantee that the equipment train is regularly cleaned between the different products (CIP)?	X	
If the equipment is used for blending production, can the site guarantee that the equipment is completely emptied between product campaigns?		n.a. – no blending
Does the site's Hygiene Program in the production area cover the following points:		
▪ Usage of clothes and caps	X	
▪ Garment instructions (including jewelry and objects)?	X	
▪ Definition of eating, drinking, chewing and smoking/non-smoking areas?	X	
▪ Regular drain cleaning to prevent back siphoning?	X	
▪ Location of hand washing- and toilet facilities?	X	
▪ Periodical medical check-up of employees?	X	
Do operators and maintenance personnel receive training on the above Hygiene Program?	X	
- Documentation	<u>yes</u>	<u>no</u>
Does the site's documentation system cover the following types of documentation:		
▪ Raw material specification	X	
▪ Standard Operating procedures (SOP) production and laboratory	X	
▪ Validation protocols	X	
▪ Facility engineering drawings	X	
▪ Policies (Corporate/Departmental)	X	
▪ Finished products specifications	X	
▪ Stability protocols	X	
▪ Product assembly (sub-assembly) drawings	X	
▪ Batch productions and packaging records	X	
Does the site keep records of significant changes and reason for change?	X	
Are deviations, incidents and rework of batches		
▪ investigated	X	
▪ evaluated	X	
▪ reviewed	X	
▪ approved	X	
▪ released	X	
by Quality Unit?		

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Packaging and Labelling

	<u>yes</u>	<u>no</u>
Does the site have written specifications, examining methods and cleaning procedures (where required) for packaging and labelling?	X	
Are packaging and labelling materials examined for suitability and correctness before packaging operations?	X	
Is the used packaging suitable for the contact with food?	X	
Does the site exclusively use _____ for primary packaging?		
▪ non-returnable package	X	
▪ reusable package		X
Does the site check the compatibility of the packaging used with the products contained?	X	
Does the site perform inspections on the labelling operation?	X	
Does the site perform inspections of packaging and labelling facilities immediately before use in order to assure that all previous material has been removed?	X	
Is labelling reconciliation performed at the end of an order?	X	

Storage

	<u>yes</u>	<u>no</u>
Does the site have a suitably equipped area for		
▪ Raw material?	X	
▪ Intermediates?	X	
▪ Finished products?	X	
▪ Packaging material?	X	
▪ Rejected materials?	X	
▪ Sampling?	X	
Do any of the following environmental conditioners apply when storing raw material, intermediates or finished products (covering a monitoring system):		
▪ Temperature conditioning (only monitoring)	X	
▪ Humidity conditioning (only monitoring)	X	
▪ Particle conditioning		X
▪ Microbial contamination		X
How are the quarantine areas for material awaiting final release organized:		
▪ By physical separation		X
▪ By automatic separation (SAP)	X	
Does the site apply the "First-in-first-out" - or "First-expiry-first-out"-principle?	X	

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Shipping

	<u>yes</u>	<u>no</u>
Does the site have written procedures for inspection of equipment before loading (cleanliness, absence of smell etc.)?	X	
Does the site have written procedures in place in order to verify shipping requirements?	X	
Is documentation enclosed in each shipment?	X	
Is the site capable and willing to provide customer with a Certificate of Analysis for every lot of product supplied to customers?	X	
Does the site keep records of delivery		
▪ by customer?	X	
▪ by batch number?	X	
▪ order number?	X	
Can the site trace every shipment back to a specific batch or lot number?	X	
Does the site have its own logistic department responsible for the transport of finished products?	X	
After loading, does the site seal the vehicles automatically?		
▪ for trucks (on customers` request)	X	
▪ for containers	X	



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