T.3.3b Blueprint

Generic approach for approval, quality assurance and CE marking | Worked example: Kaumera Soil Improver CE status

Project task	T.3.3b - Development of a blueprint for the generic approach of approval/quality for CE marking.
Purpose	Provide a repeatable route for circular resource-recovery products from WWTPs to obtain and maintain CE status as EU fertilising products. *T.3.3a Development of a blueprint for governance structure of public/private cooperation This activity involves crafting a replicable governance model specifically tailoring for public-private cooperation in the valorisation of Kaumera, encompassing both production and sales aspects. The objective is to formulate a comprehensive blueprint that can guide and facilitate effective collaborations between public and private entities involved in Kaumera.* T.3.3b Development of a **blueprint** for the generic approach of approval/quality for CE marking The second activity focuses on creating a standardized blueprint for the generic approach to gain regulatory approval of and to ensure quality standards for Kaumera. The primary objective is to develop an approach that is not only relatively straightforward but also broadly applicable.
Product example	Kaumera soil improver: PFC 3(B) Inorganic soil improver, CMC 9 polymer and CMC 1 preservative.
Use	LIFE/resource-recovery blueprint and as a Kaumera-specific worked example.

1. Executive summary

This blueprint condenses the Kaumera soil improver CE-marking route into a staged route that other (*) wastewater-resource-recovery projects can replicate). The sequence is: define product and claims, resolve waste/end-of-waste and substance status, map the product to the FPR PFC and CMC structure, substantiate the function, build the technical file, complete conformity assessment, release the CE-marked product, and maintain compliance during production, scale-up and replication.

This document should be read as a guide for a new CE registration for Kamera. However, at this stage it is not yet sorted out if there is also a ‘fast-track’ (with limited new “evidence”) for new Kaumera production installations (either within the current cooperative, add new members of the cooperative, or having producers outside the cooperative to use a registration), to be part of the current CE marking. Note: this blueprint does not cover yet CE marking as biostimulant, as this process (trials) are in development.

It is important to collaborate with Kaumera Cooperative UA, Kaumera sales & services (as a broker) and a third-party consultant to achieve a CE marking for new installations, as Kaumera is a patented process and product and there is a current Kaumera CE registration. The current CE marking is registered by Kaumera Cooperative UA as producer and seller, of which 4 Netherlands water authorities are a cooperative member.

2. Current Kaumera CE-status basis

(Annex: CE label and CE certificate)

Topic	Status/evidence to retain in technical file
Product identity	Acidic bio-based gel with peptides, polysaccharides and fatty acids; intended to improve physical soil properties and water-retention capacity.
PFC/CMC route	PFC 3(B) Inorganic soil improver; CMC 9 polymers other than nutrient polymers; CMC 1 sodium benzoate preservative.
Declared values	Dry matter 7.5% m/m and nitrogen 0.6% m/m; dossier bandwidths: dry matter 6.75-8.25%, nitrogen 0.48-0.72% m/m.
Assessment	EFCI Register, Notified Body 2832, Module B, full product assessment, PFC 3 soil improver, CMC 1 and CMC 9; certificate valid 23 Apr 2025-23 Apr 2030.
Tests/evidence	Seed germination, acute toxicity and analyses of nutrients, salts, pH, heavy metals, pathogens and relevant COA parameters.
Manufacturing	Thickened WWTP sludge; alkaline extraction at 80 degrees C for at least 120 minutes; separation; acid flocculation; second separation; preservation; acidic hydrogel approx. 7.5% dry matter.
REACH/CLP	Recovered substance after end-of-waste status; analysis supports polymer status under REACH; SDS states not classified under CLP and not regulated for transport.
TD.040	Manufacturer declarations cover representative sampling, phosphonates, risks, MRLs, chromium, ingredient-list completeness, nutrients/biuret where relevant, and impartial test reports.

3. Control gates for CE status

The blueprint uses control gates: A project should only proceed when the decision and minimum output of the previous gate are recorded.

Gate	Objective	Core actions	Minimum output
0	**Governance and dossier control**	Assign legal manufacturer, regulatory owner, QA/QC owner, process owner, consultant and notified-body contact; create document register and change control.	Dossier index, RACI, change log.
1	**Product definition and claims**	Fix product name, form, intended use, user group, application route, restrictions and conservative claims.	Product Definition Sheet, Claim Register.
2	**Legal route and end-of-waste**	Choose EU FPR CE route or national route; document source material, no-adverse-effects criterion and placing-on-market responsibility.	Regulatory Route Decision, End-of-Waste Note.
3	**PFC and CMC classification**	Classify by function; assign every ingredient to a CMC; check concentrations and restrictions.	PFC/CMC memo, ingredient table.
4	**Substance identity, REACH and CLP**	Justify identity/polymer status; check REACH; maintain SDS; run PFC 3(B) tests where required.	REACH/CLP/SDS pack, test set.
5	**Manufacturing and critical controls**	Describe feedstock to product; define temperature/time, pH, separation, additive dosing, preservation and change triggers.	Process description, control matrix.
6	**Function and claim evidence**	Link soil-improver/water-retention claims to evidence and label language.	Function memo, claim-evidence matrix.
7	**FPR safety, risk and declarations**	Complete TD.040-style declarations and resolve either/or choices visibly.	TD.040 statements, risk statements.
8	**Quality specification and batch release**	Set acceptance limits, sampling plan, test methods, COA, storage and shelf-life rules.	Specification, Sampling SOP, Batch Release SOP.
9	**Technical documentation dossier**	Assemble controlled evidence and trace each FPR requirement to a document.	Technical file, traceability matrix.
10	**Conformity assessment and NB**	Confirm module, submit dossier, answer findings and archive certificate scope/validity.	NB submission file, certificate.
11	**EU declaration and market release**	Approve final label and instructions, draw up EU DoC, affix CE mark and release product.	EU DoC, CE Release Approval.
12	**Post-market and replication**	Maintain records, complaints/CAPA, legal monitoring, renewal and site-equivalence checks.	Surveillance plan, replication pack.

4. Kaumera-specific action emphasis per gate

Gate group	Kaumera-specific actions
G0-G2: ownership and legal route	Use Kaumera Cooperative UA as legal manufacturer for the current Kaumera dossier. Consult Kaumera Cooperative early for products using Kaumera brand/IP or Haskoning patents. Prepare a no-adverse-effects/end-of-waste safety dossier based on representative lab, pilot and full-scale measurements.
G3-G4: classification and substance safety	Keep PFC 3(B), CMC 9 EPS polymer and CMC 1 preservative aligned with the ingredient list. Maintain REACH polymer rationale and SDS. Conduct or retain seed germination, acute toxicity and analyses of nutrients, salts, pH, heavy metals, pathogens and other PFC 3(B) criteria.
G5-G6: process and function evidence	Record the extraction process, alkaline extraction at 80 degrees C for at least 120 minutes, separation, acid flocculation, preservation and critical parameters. Keep soil-improver and water-retention claims within the certified label scope.
G7-G8: declarations and batch release	Treat TD.040 as a mandatory manufacturer-declaration statement. Translate label/SDS values into operational lower/upper limits, representative sampling and a COA procedure. Do not release a batch without production record, sample record, current specification, current label and QA release decision.
G9-G12: dossier, CE release and replication	The file should contain CE label, type certificate, SDS, process description, REACH memo, function note, ingredient list, TD.040 and test/COA evidence. Confirm EU Declaration of Conformity and production-conformity records. For new WWTPs/sites, re-check feedstock, process equivalence, quality variation and certificate scope with the notified body.

5. TD.040 declaration statement

The TD.040 general compliance statement should be treated as a formal declaration statement within the FPR technical file. It connects product testing, safety and quality control to the notified-body submission.

TD.040 topic	Required action/record
Representative sampling	Approved sampling SOP; sample log with batch, date, location, method, preservation, chain of custody and link to envisaged production.
Phosphonates	Declaration whether intentionally added; if not, basis that unintentional presence is not expected or remains below 0.5% by mass.
Risk assessment and MRLs	SDS cross-check plus specific review of acidity, storage temperature, biological decomposition/pressure build-up, use, transport, exposure and environmental risks; MRL evidence retained.
Chromium/contaminants	Chromium declaration (< or > 200 mg/kg dry matter), test frequency and source explanation if above threshold; include relevant heavy metals/pathogens.
Ingredient list, nutrients, biuret	Controlled ingredient list with exact percentages or bands; align N/P declarations with label; mark nutrient/biuret items applicable or not applicable.
Test-report integrity	Use competent/accredited laboratories where possible; retain impartiality declaration, sample IDs, reports and chain-of-custody records.

6. Quality and batch-release plan

Control area	What to control
Incoming material	Feedstock identity, origin, acceptance criteria, unusual wastewater/process events, contamination risk.
Critical process parameters	Extraction temperature/time, pH adjustment, separation steps, additive dosing and preservative addition.
Product characteristics	Appearance, dry matter, pH, density, nitrogen, preservative range, specific heavy metals, pathogens and any final-dossier parameters; use current Kaumera COA procedure.
FPR contaminants/declarations	Chromium, MRL-relevant substances, phosphonates where relevant and other FPR-specific checks.
Safety, storage and documentation	Storage temperature, closed packaging, ventilation, pressure relief, shelf-life/stability, batch record, sample record, COA, label version and release decision.

7. Conclusion for LIFE deliverable T.3.3b

The Kaumera case shows that CE marking of a recovered WWTP material is feasible when the project output is converted into a controlled EU fertilising product. The main replication lessons are to define the product function early, map every component to the FPR, build a controlled technical file, use representative production sampling under a COA procedure with lower and upper limits, add signed manufacturer declarations such as TD.040, translate certification into batch-release controls, and maintain CE status through surveillance, change control and legal monitoring. Involve both a specialist consultant and Kaumera Cooperative UA early to de-risk submission to the notified body.

kaumera Sales & Services

www.kaumera.com

kaumera soil improver

General Information

Kaumera® soil improver is an acidic bio-based gel containing peptides (amino acids), polysaccharides and fatty acids. Kaumera® soil improver is designed to maintain and improve the physical properties and increases the water retention capacity of EU fertilising products when applied to soil. Kaumera® soil improver can also be used in nutrient mixes as a functional ingredient.

Product specific labelling requirements

Dry matter	7.5	% m/m
Nitrogen (N)	0.6	% m/m

Ingredients

Extracellular polymer — CMC 9: Polymers other than nutrient polymers

Intended use

Applied to soil to maintain and improve the physical properties and the biological activity of the soil.

Application rates, timing and frequency

- **Irrigation (spraying)**

Dose 20 to 200 litres product/hectare through the irrigation spraying system with an interval of at least 3 months. The product can be diluted in tap water for field applications and optionally solubilised if needed. Avoid spraying on edible crops within 5 weeks prior to harvest.

- **Pouring into the soil**

Use the product with an interval of at least 3 months, applying between 1000 and 5000 litres of product/hectare in the soil. The product can be diluted in tap water for field applications and optionally solubilised if needed.

- **Creating a soluble formulation (optional)**

When the product (pH 2.2) is diluted in water it forms a gel suspension that will settle without agitation (e.g. mixing or shaking). In case a soluble liquid formulation is needed, the product can be neutralised. Instructions can be found on the product website.

- **General recommendation**

When mixing with other products, compatibility has to be tested by a jar test prior to mixing. No adverse effects are known when the acidic product is diluted and comes in contact with the soil, root, plant or leaves.

Functionality period

Re-application during the functionality period of 3 months is not allowed.

Storage recommendations

Store in tightly closed original packaging. Store in a well-ventilated place. An overpressure relieve opening is recommendable for bulk storage. Keep away from direct sunlight, frost or extreme temperatures. Store preferably cold.

Health & safety

To our knowledge this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice. Pressure buildup can be caused by organic decomposition (risk of over pressure). Persistence and degradability: readily biodegradable.

Please wear recommended personal protective equipment. Ventilate spillage area. Do not breathe vapors. Avoid contact with skin, eyes and clothing. Do not eat, drink or smoke when using this product. Always wash hands after handling the product. Keep out of reach of children. Read label before use.

First-aid measures:

- general: no hazards which require special first aid measures.
- after inhalation: remove person to fresh air and keep comfortable for breathing.
- after skin contact: take off contaminated clothing. Wash hands with water and soap.
- after eye contact: rinse eyes with water as a precaution.
- after ingestion: call a poison center or a doctor if you feel unwell.

Warranty

Registrant warrants that this product conforms to its description and is reasonably fit for the purpose stated on the label when used in accordance with the stated directions under normal conditions of use. Buyer assumes the risk of any use contrary to such directions.

Product function category

PFC 3 (B) Inorganic soil improver

Manufacturer

Cooperative Kaumera | Liemersweg 2 | 7006 GG |
PO Box 148 | 7000 AC Doetinchem The Netherlands |+31314 369 369
Website: www.kaumera.com e-mail: info@kaumera.com

Quantity

Production date

Batch Number

CE

Waterschap Rijn en IJssel | Liemersweg 2 | 7006 GG | Postbus 148 | 7000 AC Doetinchem
SWIFTadres NWABNL2G | IBAN NL68NWAB063675331 | BTW NL 805432759B01 | KvK 0921548

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EU type examination certificate

STICHTING EFCI Register, appointed Notified Body FPR 2019/1009, registered under NANDO number 2832, registered with the Dutch Chamber of Commerce under number 72629665, statutory address Kruisplein 328, 3012CC, Rotterdam, Netherlands, herewith declares:

-- The following product has been assessed according to the FPR 2019/1009 using the relevant FPR guidelines and the applicable (harmonised) standards and meets all applicable essential safety requirements as documented in the FPR 2019/1009. Assessment was done in accordance with Annex 1 of this certificate. --

Product	Kaumera
Manufacturer	Coöperatie Samenwerking Kaumera
Manufacturer address	Liemersweg 2, 7006 GC, Doetichem, Netherlands
Certification module	B
Examination scope	Full product I Assessment of the adequacy of technical design fertilisers
PFC	3. Soil improver (Inorganic soil improver)

Contained materials: CMC's: CMC 1, CMC 9

Purpose: Polymer soil improver

Specifications: Polymer soil improver

Certificate number & Issue date:	EFCI Register - FPR 2019/1009 - B-Kaumera-23/04/2025-23/04/2030-DE.2412	23/04/2025
Certificate expires on:	23/04/2030	

On behalf of stichting EFCI Register:	G.M.C. Tettelaar, Chairman	mrs M.L. Lagemaat, secretary
Signature:	Giel Tettelaar	Marlot Lagemaat