

Factory Production Control Manual

Basilisk Healing Agent – an admixture for concrete

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Revision history

Revision	Date	Description of amendments
0	07.01.2020	First edition
1	29.06.2020	Form no. BF1303 rev.0 – production instruction is added.
2	18.08.2020	Declared values and tolerances are added to table 5.
3	16.06.2021	Yearly review and updates
4	10-2-2022	New layouts and updates

General

This manual has been established in the process of obtaining a CE marking for Basilisk Healing Agent (HA), an additive for concrete mixtures. Basilisk HA is composed of a bio-based biodegradable granular additive which enables self-healing (sealing and waterproofing) of cracks with a crack width of up to 1 mm. Permanent sealing occurs due to formation of Calcium Carbonate (limestone), which is a common material within the concrete matrix.

Basilisk has tested its product based on the general and specific requirements mentioned in EN 934-1 and EN 934-2 plus the initial type testing and prepared a declaration of performance – BR2102.

There is no specific harmonized norm or standard for the primary function of HA which is its autonomously sealing and waterproofing of cracks. However, there is a harmonized norm, EN 934-2, for one of its secondary functions which is set retarding admixture.

Basilisk's engineers developed a test method, to control the quality of HA for its self-healing function which is in the verification phase.

The purpose of this manual is to assure that production of HA continues to meet the same requirements in accordance with the norms and standards.

Quality policy and objectives

The quality policy of Basilisk is to assure that its products including Basilisk HA meets their requirements including their expected quality, price, and delivery time.

To achieve its policy, a quality management system has been developed and maintained. The quality management system shall be executed not only by Basilisk personnel but also by all its production facilities.

All the relevant standards and regulations have been taken into account during developing of quality tests and procedures. In addition, a management review meeting will be held at least twice a year to ensure the effectiveness and adequacy of the quality management system.

The audit reports, customer feedback and complaints, objectives, nonconformity reports and corrective actions are among others the input to the management review meeting. Minutes of meetings including decision and actions shall be filed on the internal server.

Control of documents and records

QA engineer prepares manuals, procedures, forms, and reports within Basilisk company. An active documents master list - BR1102 provides, an overview of these documents. However, a document may be created by all individuals related to their tasks and functions. The requirement for creating a document is described in document no. BP1101. Other than that, a document would be created at the request of top management or in the process of obtaining a quality label or a quality certificate.

All the documents and data are stored digitally on Basilisk internal server. It is the responsibility of all personnel to assure that they are using an active form, report template, or other type of a document. The Basilisk contact person with other parties including laboratories, manufacturer, partners, and distributors is responsible for providing the other party with the latest Basilisk's documents.

All the record including the client orders, production, and test results will be retained digitally for at least 10 years on Basilisk's internal server.

Normative references

Applicable or used standards and regulations:

<i>ISO 9001</i>	<i>Quality Management System</i>
<i>EN 934-1</i>	Admixtures for concrete, mortar and grout - part 1: Common requirements
<i>EN 934-2</i>	Admixtures for concrete, mortar and grout - part 2: Concrete admixtures – definitions, requirements, conformity, marking and labelling
<i>EN 934-6</i>	<i>Admixtures for concrete, mortar and grout - part 6: Sampling, assessment and verification of the constancy of performance</i>
<i>EN 480-1</i>	<i>Admixture for concrete, mortar and grout test methods - part 1: Reference concrete and reference mortar for testing</i>
<i>EN 12620</i>	<i>Aggregate for concrete</i>
<i>EN 1015-2</i>	<i>Methods of test for mortar for masonry - part 2: Bulk sampling of mortars and preparation of test mortars</i>

Terms and definitions

For the purpose of this FPC, the terms and definitions given in ISO 9000 and EN 934 and the following apply.

Multifunction admixture

Admixture which effects several properties of fresh and/or hardened concrete by performing more than one of the main functions defined in 3.2.2 - 3.2.9 in EN 934-2.

Primary function

Single function of a multifunction admixture designed by the manufacturer.

Secondary function

Function of a multifunction admixture which is additional to the primary function.

Stiffing time

Time beyond which the workability of a hydraulic or polymer modified hydraulic cement repair concrete or mortar is lost.

Set retarding admixture

Admixture which extends the time to commencement of transition of the mix from the plastic to the rigid state.

Basilisk organization

Basilisk-Contracting BV (Basilisk), is 100 % owned by Green-Basilisk BV with a patented method that enables self-healing concrete technology. Basilisk is a young company with few employees who in addition to various activities present the following positions: managing director, product manager, project engineer, quality assurance (QA) engineer, R&D engineer, financial controller, account manager, and marketing manager. Basilisk also hires external expertise where necessary for example for implementation of projects on location. When needed, it can rely on scientific advice from TU Delft as well. The company structure including responsibilities and relationships is defined in the document number BP1701 – organisational structure & responsibilities.

The production of Basilisk HA is outsourced to a contract manufacturer in the Netherlands. It will be produced in other manufacturers too. The production in all the facilities shall be produced according to the process described in this manual.

The responsible personnel involved directly in the production are the Managing Director, Product Manager, and QA Engineer. The product manager is the contact person with the production facility in both inside and outside the Netherlands.

Figure 1- The production process shows the order of steps to be taken in the process of production from receiving an order till arranging the shipment to Basilisk's warehouse. Furthermore, it shows the steps that requires a decision and the possible options and following steps.

To clarify the responsibilities in each step, Table 1- Healing agent's production procedure is developed. It also provides the documents required for each step as an input and outcome. Besides the personnel responsible for each task, it defines the person who is accountable, who can support, who can consult, and who should be informed. The accountable person refers to a person who has to approve a task when it is finished while a responsible person is the one who should perform a task.

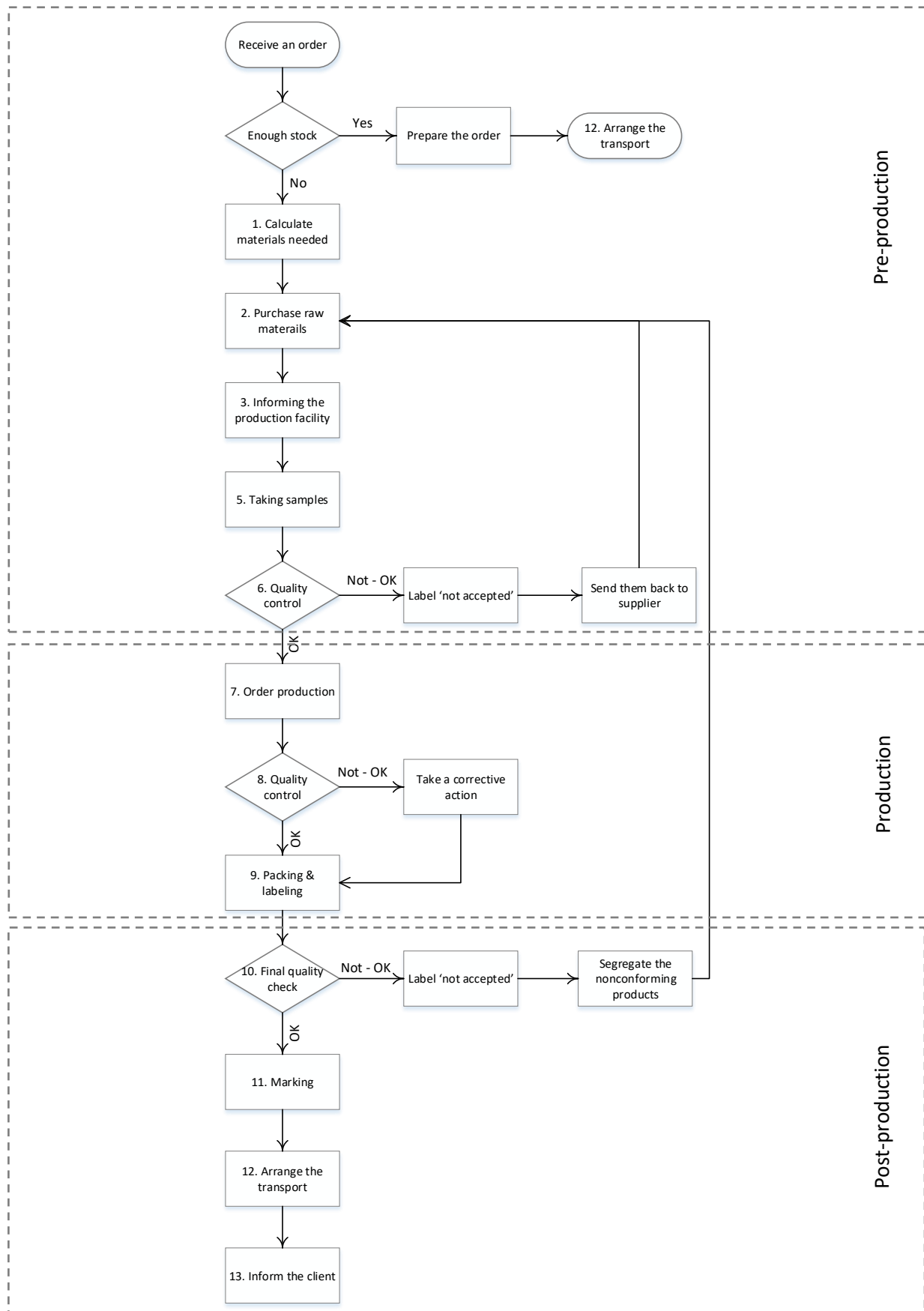


Figure 1- The production process

Table 1- Healing agent's production procedure

Key responsibilities:

R : responsible

A : accountable

S : supportive

C : consulted

I : informed

Input	Task	Output	Product Manager	QA engineer	Managing director	Production facility
Client order	1. Calculate materials needed	Production plan	R		A	I
Production plan	2. Purchasing raw materials	Purchase order	R	I	A	
Email, Packing list	3. Informing the manufacturer on the incoming goods	Email	R	I		I
Packing list	4. Receiving and storing of the raw materials	Email	I	R		R
Packing list, Email	5. Taking samples	Samples	S	R		S/ R*
Samples	6. Controlling the quality of raw materials	Test Report	R	I	I	I/ R*
MSDS Test report	7. Producing (mixing raw materials)	HA Form no. BF1302/ production report	C	S	I	R
Form no. BF1302	8. Production quality check	Form BF1302/ QC report	C	I/S		R
Basilisk labels	9. Packing and labelling	Form BF1302/ QC report Samples		S		R
Samples	10. Final quality check	Test report	I	R	A	I
Test report Client order	11. Marking	Marking label	S	S		R
MSDS Packing list	12. Arranging the shipment	Tracking number	R		A	I

*The manufacturer in the Netherlands has a laboratory and when needed they will carry out the quality control of raw materials and provide Basilisk with the report.

Raw materials

Basilisk HA consists of two raw materials presented in the Table 2. The suppliers provide their product with a Material safety data sheet (MSDS). A copy of MSDS is provided to the production facility and a copy is maintained on Basilisk internal server.

At this moment, there is only one supplier for both raw materials.

Table 2- Raw materials and their supplier and their ratio in the recipe.

Row	Name	Supplier	Ratio %
1.	Sentiall C10	Corbion - Purac Biochem	97.9
2.	Basilisk Base plus (B ²⁺)	Basilisk	2.1

Sentiall is purchased by Basilisk's Product Manager and will be delivered to the manufacturer warehouse few days before the production date. B²⁺ is a Basilisk's product and will be sent separately to the manufacturer via the Product Manager.

Sentiall shall be delivered in big bags of 500 kg and B²⁺ in a plastic bag of 5kg inside a plastic bucket. The raw materials shall be stored inside the manufacturer warehouse in a dry and cool condition (<30 °C).

Verification of raw materials' quality

There is no specific requirement for quality control of raw materials in EN 934-1, EN 934-2, and EN 934-6. However, for each raw material, there is some quality factors which has to be checked and pass its declared value.

For both raw materials, general appearance & colour has to be checked per batch. Table 4 shows the declared value.

Since particle size can have impact on the quality of HA, a granulometry test of dry component is required for Sentiall. Basilisk voluntary decided to perform the test in accordance with EN 12192-1. There is also an alternative when performing the test is not possible, use a sieve of 4 mm and let Sentiall be added to the mixer through the sieve. In this case, particles bigger than 4 mm shall be collected in a plastic bag or sample container. It shall be labelled with name, quantity, batch number, and date. It should be calculated if the quantity is conform what supplier agreed to deliver.

For the quality of B²⁺, there are two internal tests developed to check the ability of calcium carbonate formation and number of viable bacterial spores. These tests are performed at TU Delf laboratory and the test report is filed on the internal server.

Table 3- Test method and frequency - raw materials, presents a summary of quality controls for the raw materials.

Table 3- Test method and frequency - raw materials

Tests	Material name	Frequency	Test method	Declared value
General appearance & colour	Sentiall & B ²⁺	Each batch	Visual	See table 4
Granulometry of dry components	Sentiall	Each batch	EN 12192-1	TBA

Calcium Carbonate based mineral forming ability*	B ²⁺	Each batch	Basilisk internal method	<i>Positive</i>
Most probable number of viable bacterial spores*	B ²⁺	Each batch	Basilisk internal method	$10^7 < X < 10^9$ <i>X: spore</i>

*For these two tests, it is enough to request the reports of the manufacture and keep the documents.

It is possible to perform the Granulometry of dry components at both Basilisk laboratory and manufacturer laboratory in the Netherlands. A copy of test result shall be filed on the internal server.

Samples would be taken using a sampling scoop in accordance with EN 1015-2, minimum 150 grams from material below 10 cm the surface and from 3 different places to ensure a representative sample. Samples will be labelled with the following information:

- Product name
- Batch number
- Serial number
- Quantity/unit
- Manufacturer
- Production date
- Sampling date
- Sample quantity and unit
- Physical state
- Colour & appearance
- Name of sampler and signature

When a raw material is rejected because it does not meet its expected requirement, it shall be labelled as “not acceptable” and returned to its supplier. For rejections due to the transport or storage of raw materials, a root cause analysis will be carried out by the Basilisk production coordinator or QA engineer to prevent reoccurrence.

Table 4- Declared value - general appearance & color

Raw materials	Colour	Appearance
<i>Sentiall</i>	Yellowish	<u>Wax</u> like < 6 mm particles in 500 kg
<i>Basilisk Base plus</i>	Yellowish	Powder

Production process and quality control

The Production process of Basilisk HA consists of mixing the raw materials in a low-intensity mixer for about 10 minutes. The mixer used by the manufacturer has a capacity of 1500 liter per production. Basilisk’s Product Manager prepares a production instruction - form no. BF1303 and sends it to the manufacturer to be used for preparation of raw materials and during the production.

Furthermore, when Basilisk personnel can be present during the production, s/he will use form no. BF1302- production quality control form-HA. Otherwise, the manufacture shall provide Basilisk with a report or fill in the form number BF1302.

The product will be packed in a bag of 25 kg, will be stored on an euro pallet (EPAL – ISPM 15), 120*80 cm and will be sealed by a plastic wraps. It should be stored indoor in a dry place between 10 and 40°C. It is possible that the size of bags differ due to clients’ request.

The mixer is washed after each production and maintained once a year. The manufacture has a ISO 9001 certificate from KIWA (certificate no. KSC-K43803/06).

The material safety data sheets of raw materials will be sent to the manufacture to provide the appropriate protective equipment for the operator.

Final quality check and storage

The products will be stored on Basilisk's warehouse (indoor). One bag of Basilisk HA per batch in accordance with EN 934-6, will be sent to a laboratory for quality control. Besides that, one bag will be retained for at least the shelf life in the Basilisk warehouse for future reference.

Samples will be labelled with the following information:

- Product name
- Batch number
- Serial number
- Quantity/unit
- Manufacturer
- Production date
- Sampling date
- Sample quantity and unit
- Physical state
- Colour & appearance
- Name of sampler and signature

A list of required quality checks conform EN 934-2 plus the test frequency, and acceptance criteria are presented in Table 5. As not all these tests will be done for each batch production, in the form no. BF1302 will be registered which tests have been performed. A copy of tests result will be kept for at least 10 years on Basilisk's server.

For production facilities outside the Netherlands, it is the responsibility of the manufacturer to test the quality of final product and share the test results with Basilisk.

Table 5- Test method and frequency – final product

Tests	Frequency	Test method	Requirement***
<i>Homogeneity</i>	Per batch	Visual	Homogeneous when used. To prevent segregation, use a whole HA bag which is 25 kg or pre-mix a bag and then use partially.
<i>colour</i>	Per batch	Visual	Yellowish; Uniform and similar to the description declared by the manufacturer.
<i>Conventional dry material content</i>	Per batch	EN 480-8	Declared value: 98% by mass. Tolerance: $\pm 5\%$
<i>Chloride content**</i>	4 times a year*	EN 480-10	Declared value: $\leq 0.10\%$ by mass. Tolerance: NA.
<i>Alkali content</i>	Twice a year*	EN 480-12	Declared value: $\leq 1\%$ Tolerance: NA.
<i>Setting time</i>	3 times a year*	EN 480-2	Initial: test mix $\geq$ control mix + 90 min Final: test mix $\leq$ control mix + 360 min

<i>Air content in fresh concrete</i>	<i>Once a year*</i>	<i>EN 12350-7</i>	Declared value: <i>Test mix $\leq$ (Control mix + 2%)</i> Tolerance: NA.
<i>Compressive strength</i>	<i>Once a year*</i>	<i>EN 12390-3</i>	After 7 days: <i>Test mix $\geq$ 80% control mix</i> After 28 days: <i>Test mix $\geq$ 90% of control mix</i>

** When the production is less frequent, every batch has to be tested.*

***Total chlorine also has to be tested if it is significantly different from the chloride content.*

****Test mix HA dosage is set at 3% ratio of cement content (w/w).*

When test results confirm the expected quality of the product, Basilisk product manager will arrange transport of the final product to a client in accordance with the contract requirements and regulations. A shipping label (Marking) shall be attached to the pallets which includes among other information, supplier name and address, purchase order, delivery address, weight and dimensions of pallet, and packing list number.

Traceability and marking

To be able trace the product, Basilisk uses a batch number. The batch number consists of 8 characters HAYYMMXX where

HA refers to the name of the product- healing agent,

YY shows the year of the production,

MM refers to the month;

XX refers to the number of production in a month.

The batch number is printed on the Basilisk's label. Two labels in accordance with EN 934-2 will be added to the package. They provide the application instruction, product characteristics, and hazardous warnings.

Note: At the moment, Basilisk is working on a solution to use also a serial number for the traceability at the production facility in the Netherlands. When the product is produced in another manufacturer, it is required to have both batch and serial number.

In addition to that a material safety data sheet and an application instruction is provided to the client where among other information includes the storage and handling of the product.

For each batch number of Basilisk HA, form no. BF1302 (production quality control form) is filled in, where detailed information of used raw materials is registered. This form will be retained digitally on the Basilisk's server, which enables the traceability of the product.

Laboratory instruments and equipment

At this time, the 'granulometry of dry components' test for raw materials of Basilisk HA is performed at Basilisk's laboratory. Other required tests are performed by an external test laboratory.

For this test, a test sieve machine and a scale are used (laboratory instruments and equipment inventory - BF1802 on folder 'Laboratory'.

The sieve machine is cleaned regularly according to the instruction provided by its manufacturer and when necessary in accordance with required regulations. Generally, the lab personnel will clean an equipment before and after use.

Measuring equipment will be calibrated periodically and the certificates plus and an overview of calibrations (Calibration database – BR1801) are maintained under folder 'laboratory'.

For the production facility, an initial inspection is performed by Basilisk QA engineer to control the maintenance & cleaning plan and the calibration certificate of the instruments used during the production of Basilisk HA. Basilisk shall randomly control the calibration certificates and records of maintenance and cleaning.

Basilisk uses an accredited laboratory for QC of final product. Their accreditation is checked on the website of Dutch accreditation council www.rva.nl.

Nonconformity and corrective action

A nonconformity or a possible nonconformity can be identified during:

- Quality control of raw materials
- During production
- Final quality control
- During a project
- As an outcome of an audit (internal or external)
- Management review
- Client complaint
- Or others.

In this case a nonconformity report (NCR) - BR1101 shall be completed. The notifier shall appoint an investigation committee and inform the QA engineer when s/he is not in the committee.

The result of investigation will be registered in the NCR and when applicable a (corrective) action will be performed to minimize the effect of nonconformity and/or a preventive action to eliminate the reoccurrence of it.

When there is nonconformity regarding one of Basilisk's products, the frequency of tests (before, during, and after production) will be increased. The nonconforming products shall be labelled with 'not accepted' and segregated from other products.

The NCR will be maintained on Basilisk internal server (SharePoint). Depending on the nature of a nonconformity, it will be retained for at least 10 years.

List of attachments

BF1102 – Sample label for the laboratory

BF1104 – Sample label to be retained

BF1105 – Document request form

BF1201 – Client complain form

BF1203 – Complaint log

BF1302 – Production quality control form

BF1802 – Instrument & equipment inventory – Basilisk laboratory

BP1101 – Procedure for control of documented information

BP1201 – Client complaint procedure

BP1701 – organisational structure & responsibilities

BR1101 – Nonconformance report

BR1103 – Active documents master list

BR1202 – Declaration of performance – Basilisk Healing Agent

BR1801 – Calibration database – Basilisk laboratory

BR2102 – Declaration of Performance – Basilisk Healing Agent