

- Report -

BIOCEBO

Ready Biodegradability Modified Sturm Test

acc. to OECD 301 B Guideline / CO₂ Evolution Test
for Testing of Chemicals (1992)

Sponsor

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Study ID

acc. to GLP
190311BY / AST18675

Study completion date
2020-02-04

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Responsibilities

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Statement of GLP Compliance

| | |
|---------------|---|
| Title | BIOCEBO Ready Biodegradability, Modified Sturm Test |
| Guideline | OECD 301 B / CO ₂ Evolution Test (adopted July 17, 1992) |
| Test Item | BIOCEBO (batch number: 18/0004) |
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I declare that this study was conducted and reported in compliance with the present OECD, EC and German principles of Good Laboratory Practice.

2020-02-04

(Date)



(Dirk Scheerbaum, Study Director)

Statement of the Quality Assurance Unit

Title BIOCEBO
Ready Biodegradability, Modified Sturm Test

Guideline OECD 301 B / CO₂ Evolution Test (adopted July 17, 1992)

Test Item BIOCEBO
(Batch number: 18/0004)

Study director Dirk Scheerbaum

The study was verified and reported to the study director and test facility management as follows. The inspection(s) of the experimental phase of this study type is (are) part of a process-based inspection programme. The next date(s) with respect to the experimental phase of this study is (are) reported.

| Inspected study phase | | Inspection date | Date of report |
|-----------------------|--------------------------|-----------------|----------------|
| Study plan | | 2019-09-17 | 2019-09-17 |
| | | 2019-10-24 | 2019-10-24 |
| Experimental phase | Test item / Weighing out | 2019-11-21 | 2019-11-21 |
| | Disposal | 2019-12-20 | 2019-12-20 |
| Report | | 2020-01-15 | 2020-01-15 |
| | | 2020-01-20 | 2020-01-23 |
| | | 2020-01-23 | 2020-01-23 |
| | | 2020-02-04 | 2020-02-04 |

The reported results accurately and completely reflect the raw data of the study. Also methods, procedures, and observations are accurately and completely described in the report.

The accordance of the study with its study plan and the principles of Good Laboratory Practice is guaranteed.

2020-02-04
.....
(Date)


.....
(Dr. Ines Stanetzek)

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List of Abbreviations and Definitions

| | |
|--------------------|--|
| CFU | Colony forming unit |
| Date (notation) | YYYY-MM-DD (Year-Month-Day) |
| Degr. | Degradation |
| dw | Dry weight |
| HgCl ₂ | Mercury (II) chloride |
| mv | Mean value |
| QAU | Quality Assurance Unit |
| ThCO ₂ | Theoretical carbon dioxide (mg) is the quantity of carbon dioxide calculated to be produced from the known or measured carbon content of the test compound when fully mineralized; also expressed as mg carbon dioxide evolved per mg test compound. |
| TOC | Total organic carbon of a sample is the sum of the organic carbon in solution and in suspension; also expressed as mg carbon per mg test compound. |

1 Summary

The ready biodegradability of the test item BIOCEBO (batch no.: 18/0004) was determined with a non-adapted activated sludge over a test period of 28 days in the Modified Sturm Test. The study was conducted from 2019-10-24 to 2019-11-22, according to OECD 301 B at the test facility. The test item was tested at a concentration of 64 mg/L with 2 replicates corresponding to a carbon content (TOC) of 10.1 mg C/L in the test vessels. The test vessels were incubated at low light conditions and at a temperature of 19.0 - 22.5 °C.

The biodegradation of the test item was followed by titrimetric analysis of the quantity of CO₂ produced by the respiration of bacteria. The degradation was stopped on day 28 by acidification of the test solutions. The last titration was made on day 29 after residual CO₂ had been purged from the test solutions over a period of 24 hours. The percentage CO₂ production was calculated in relation to the theoretical CO₂ production (ThCO₂) of the test item. The biodegradation was calculated for each titration time.

To check the activity of the test system sodium benzoate was used as **functional control**. The percentage degradation of the functional control reached the pass level of 60 % within 8 days and a maximum biodegradation of 94 % on day 28.

In the **toxicity control** containing both test and reference item a biodegradation of 76 % was determined within 14 days, with 83 % after 28 days. The biodegradation of the reference item was not inhibited by the test item in the toxicity control.

In the **abiotic control** containing both test item and HgCl₂ the biodegradation was ≤ 1%.

The biodegradation of the **test item** is shown graphically in Figure 1 in comparison to the readily degradable functional control, the toxicity control and the abiotic control. The mean of replicates reached the 10 % level (beginning of biodegradation) within 4 days. Both test item replicates reached the 60 % pass level within 6 days. The mean biodegradation on day 28 was 83 %. The 10-day window was met.

Under the test conditions the test item is **readily biodegradable** within the 28 day period of the study.

Table 1: **Biodegradation of the Test Item BIOCEBO in Comparison to the Functional Control, Toxicity Control and Abiotic Control**

| | Biodegradation [%] | | | |
|--|--------------------|----|----|----|
| | Study Day [d] | | | |
| | 6 | 14 | 20 | 28 |
| Test Item, 1 st Replicate | 60 | 74 | 75 | 79 |
| Test Item, 2 nd Replicate | 63 | 79 | 79 | 87 |
| Functional Control | 58 | 82 | 86 | 94 |
| Toxicity Control test item + reference item | 42 | 76 | 78 | 83 |
| Abiotic Control | 0 | 0 | 0 | 1 |

2 Characterisation Data of the Test Item

2.1 Test Item Properties

| | |
|---------------------|---|
| Test item | BIOCEBO |
| Batch number | 18/0004 |
| Purity (certified) | 30.0% w/v (calculated) |
| Active ingredient | Hydrolysed protein |
| TOC* | 15.8 % |
| Appearance | Brown liquid |
| Expiry date | 2021-06-30 |
| Recommended storage | Store in the original container and protect from extreme humidity and temperatures. Store the containers between 5 and 35 °C, in a dry and well-ventilated place. |

The test item and the information concerning the test item were provided by the sponsor.

** The TOC was determined at the test facility.*

2.2 Test Facility Actions

| | |
|---------------------------|---|
| Receipt | 2019-06-17 |
| Identification parameters | Name, batch number, state and color |
| Retention sample | At least 1 g of the test item has been retained on 2019-06-28 and stored at 6 ± 2 °C. |
| Storage at test facility | 18 – 25 °C, dark, in the tightly closed original container. |

3 Method

| | |
|-------------------------------|---|
| Test guideline | OECD 301 B / CO ₂ Evolution Test (adopted July 17. 1992) |
| | The study was performed in compliance with GLP. For the respective guidelines, please refer to section 9. |
| Type and purpose of the study | Study of ready biodegradability over a period of at least 28 days with a non-adapted activated sludge in order to check the rate of biodegradation in % by determination of evolved CO ₂ . |

3.1 Test System and Pre-treatment

| | |
|--|---|
| Test system | Inoculum of the aqueous phase of non-adapted activated sludge |
| Reasons for the selection of the test system | Activated sludge from the sewage plant at Hildesheim is well suited as it receives predominantly municipal sewage and hardly any industrial chemical waste. |
| Source | Municipal sewage treatment plant, 31137 Hildesheim, Germany |
| Receipt | 2019-10-21 |
| Pre-treatment | The activated sludge was washed twice with chlorine free tap water. After the second washing the settled sludge was resuspended in mineral salts medium and was maintained in an aerobic condition by aeration with CO ₂ free air for two days before test start. Further treatment see section 'preparation of the test vessels'. 4.45 mL/L of this mixture were used to initiate inoculation (25.1 mg/L dw). |
| Colony forming units in the test vessel | Approx. 10 ⁷ - 10 ⁸ CFU/L |

3.2 Experimental Procedure

Functional control

| | |
|---------------------------------|-----------------------------|
| Reference item | Sodium benzoate |
| Test facility ID | 70025_1 |
| Batch number | BCBQ5652V |
| CAS No. | 532-32-1 |
| Purity | 99.6 % |
| Expiry date | 2021-11-15 |
| Replicates | Single |
| Test concentration | 20 mg/L |
| ThCO ₂ | 2.13 mg CO ₂ /mg |
| ThTOC | 0.58 mg C/mg |
| Carbon content in the vessel | 11.6 mg C/L |

Test Item

| | |
|---------------------------------|---------------------------|
| Test Item | BIOCEBO |
| Replicates | Duplicates |
| Test concentration | 64 mg/L |
| TOC | 0.158 mg C/mg |
| ThCO ₂ | 0.580 CO ₂ /mg |
| Carbon content in the vessel | 10.1 mg C/L |
| Pretreatment | None |

Toxicity control

| | |
|------------|---|
| | Test item and reference item in test concentration. |
| Replicates | Single |

Inoculum control

| | |
|------------|---|
| | Test medium without test and/or reference item. |
| Replicates | Duplicates |

Abiotic control

| | |
|------------|--|
| | Test item in test concentration, without inoculum, poisoned with 10 mL/L HgCl ₂ solution (10 g/L) |
| Replicates | Single |

Test Method

| | |
|---------------------------|--|
| Duration | 28 days |
| Application | Once at test start |
| Test vessels | 5000 mL, brown glass |
| Volume of the test medium | 3000 mL |
| Test medium | Mineral salts medium acc. to OECD 301 B / CO ₂ Evolution Test |
| Test temperature | Nominal 22 ± 2 °C, actually measured 19.0 – 22.5 °C |
| Dispersion treatment | Continuous stirring |
| Aeration | 30 - 100 mL/min |
| Photoperiod | Low light conditions (brown glass bottles) |

Preparation of the test vessels

The concentration of the test item and the theoretical CO₂ production (ThCO₂) were calculated based on the carbon content.

The following incubation vessels were prepared:

- two for the inoculum control (C₁, C₂)
- one for the functional control (R₁)
- two for the test item concentration (P₁, P₂)
- one for the toxicity control (T₁)
- one for the abiotic control (A₁)

Supplemental replicates of the test item and the inoculum control were prepared for the measurement of ammonium and nitrate at test start.

The necessary amounts of ultrapure water, mineral salts medium and inoculum were placed in each incubation vessel. The vessels were aerated for 24 h with CO₂ free air. After 24 h the CO₂ adsorption vessels were connected to the air outlets of the incubation vessels via a series of 3 gas wash bottles, each containing 100 mL of a 0.0125 mol/L Ba(OH)₂ solution.

The test item and reference item were weighed out. The test item was weighed out into small beakers. A defined amount of ultrapure water was added to the test item. The test item dispersions and the reference item were transferred to the respective incubation vessels with ultrapure water. The vessels were made up to 3 L with ultrapure water and connected to the system for the production of CO₂ free air.

On day 28, 1 mL 37 % HCl was added to each of the vessels. Aeration was continued for further 24 h and the quantity of CO₂ released was determined.

3.3 Type and Frequency of Measurements

The room temperature was recorded continuously throughout the test.

Determination of ammonium and dissolved nitrate were determined at test start and at test end (test end after acidification).

Determination of CO₂ was carried out by titration subsequent to complete absorption of the released CO₂ in an alkaline solution (0.0125 mol/L Ba(OH)₂). For each titration the first gas wash bottle was removed and a new bottle was connected to the last one.

Back titration of the residual Ba(OH)₂ with 0.05 N HCl was carried out three times a week during the first ten days and thereafter twice weekly.

On day 28 the pH of all solutions was measured prior to acidification.

3.4 Equipment

DOC-Analysator Multi N/C 3100, ANALYTIK JENA
pH-Meter, Multi 350i, WTW
Thermohygrograph, LUFFT
Ultrasonic bath, SONOREX, BANDELIN
Analytical balance, SARTORIUS
Balance, KERN
Dispensette, BRAND
Digital Buret, continuous RS, VITLAB
Medo compressor, FA. REBIE
Magnetic stirrer Mono, VARIOMAG
Multipette X-Stream, EPPENDORF
Spectrophotometer NANOCOLOR®^{UV/VIS}, MACHEREY-NAGEL
Test Kits: AMMONIUM 50, AMMONIUM 3, NITRAT 50, all by MACHEREY-NAGEL
Various Pipettes

4 Evaluation

The theoretical production of carbon dioxide (ThCO₂) of the test item and functional control is calculated by the carbon content (1) and the molecular formula (2), respectively.

$$\text{ThCO}_2 [\text{mgCO}_2/\text{mg}] = 3.67 \cdot \text{TOC} [\text{mgC}/\text{mg test item}] \quad (1)$$

$$\text{ThCO}_2 [\text{mgCO}_2/\text{mg}] = \frac{\text{C - Atoms} \cdot \text{molecular weight of CO}_2}{\text{molecular weight of reference item}} \quad (2)$$

The produced CO₂ is calculated by (3):

$$1 \text{ mL HCl } (c = 0.05 \text{ mol/L}) = 1.1 \text{ mg CO}_2 \quad (3)$$

The net amount of CO₂ produced is calculated by correcting the results of the test item and functional control for endogenous CO₂ production of the inoculum controls.

The biodegradation is calculated from the ratio theoretical CO₂ production to net CO₂ production in the following equation (4):

$$\text{Degradation } [\%] = \frac{\text{netCO}_2 \cdot 100}{\text{ThCO}_2 [\text{mgCO}_2/3\text{L}]} \quad (4)$$

Software

Excel, MICROSOFT CORPORATION
 SigmaPlot (Windows), SPSS CORPORATION

All data were computer generated and rounded for presentation from the fully derived data. Consequently, if calculated manually based on the given data minor variations may occur from these figures.

5 GLP

Chronological test description

- Pre-treatment of the non-adapted activated sludge
- Preparation of the test solutions and aeration for 24 h with CO₂ free air
- Weighing out of the test item (experimental starting) and weighing out of the reference item
- Application
- Incubation
- Determination of ammonium and nitrate at test start
- Determination of CO₂ by titration
- Determination of the pH-values on day 28 and acidification
- Last titration on day 29
- Determination of ammonium and nitrate after last titration
- Evaluation of the data

Dates

| | |
|-------------------------|------------------------|
| Study initiation | 2019-10-24 |
| Study plan amendment | None |
| Experimental starting | 2019-10-24 |
| Experimental completion | 2019-11-22 |
| Study completion | Please refer to page 1 |

Deviations from the guideline

None

Deviations from the Studyplan

The temperature dropped down to 19°C three times overnight.
One replicate for the functional control was prepared (erroneously stated two).

These deviations are considered to have no impact on the quality and integrity of the study.

Archiving

The following will be retained in the archive of the test facility for at least 15 years:

- all raw data
- study plan
- final report
- all records performed by the quality assurance programme including master schedules
- samples of test and reference items

The test facility may use a GLP contract archive.

6 Results

6.1 Carbon Content of the Test Item

Based on the carbon content a ThCO₂ of 0.580 mg CO₂/mg test item was calculated. A test concentration of 64 mg/L, corresponding to a carbon content of 10.1 mg C/L in the test vessels was selected.

6.2 Colony Forming Units of the Inoculum

Colony forming units (CFU) of the inoculum for the Modified Sturm Test were determined prior to test start by standard dilution plate count: approx. 1.50×10^9 CFU/L, corresponding to approx. 0.67×10^7 CFU/L in the test vessel.

6.3 CO₂-Production and Biodegradation

The total amount of CO₂ produced in 28 days was analysed by titration in 12 measurements.

The 28 d-values are shown in comparison to the readily degradable functional control in summarized form in Table 2.

The results of the net CO₂-production and biodegradation rate of each measurement are given in Table 3 to Table 4.

Table 2: CO₂-Production and Biodegradation after 28 Days for Test Item

| CO ₂ -Production | Functional Control | Test Item | | Toxicity Control Test Item + Reference Item | Abiotic Control |
|-----------------------------|--------------------|-----------|------|---|-----------------|
| | | 1 | 2 | | |
| Net [mg/3 L] | 120.4 | 88.3 | 97.2 | 197.6 | 1.0 |
| | 40.1 | 29.4 | 32.4 | 65.9 | 0.3 |
| Theor. [mg/3 L] | 127.8 | 111.4 | | 239.2 | 111.4 |
| | 42.6 | 37.1 | | 79.7 | 37.1 |
| Degradation [%] | 94 | 79 | 87 | 83 | 1 |

The adaptation phase of the **functional control** changed within 4 days into the degradation phase (degradation $\geq 10\%$). The course of the degradation was rapid and the functional control reached the pass level of 60 % within 8 days and a maximum biodegradation of 94 % on day 28. The validity criterion degradation $\geq 60\%$ after 14 days is fulfilled.

In the **toxicity control** containing both test item and reference item a biodegradation of 76 % was determined within 14 days, with 83 % after 28 days. The biodegradation of the reference item was not inhibited by the test item in the toxicity control.

In the **abiotic control** containing both test item and HgCl_2 the biodegradation was $\leq 1\%$.

The biodegradation of the **test item** is shown graphically in Figure 1 in comparison to the readily degradable functional control, the toxicity control and the abiotic control. The mean of replicates reached the 10 % level (beginning of biodegradation) within 4 days. Both test item replicates reached the 60 % pass level within 6 days. The mean biodegradation on day 28 was 83 %. The 10-day window was met.

Table 3: **CO₂-Production and Biodegradation in the Inoculum Control, the Functional Control and the Toxicity Control**

| Study Day | Date | Inoculum Control [mg CO ₂ /3 L] mv | Functional Control | | | Toxicity Control | | |
|-----------|------------|---|---------------------------|---------|--------------|---------------------------|---------|--------------|
| | | | [mg CO ₂ /3 L] | | Degr. [%] | [mg CO ₂ /3 L] | | Degr. [%] |
| | | | Gross | Net Sum | | Gross | Net Sum | |
| 1 | 2019-10-25 | 4.5 | 16.2 | 11.7 | 9 | 28.5 | 24.0 | 10 |
| 4 | 2019-10-28 | 16.1 | 53.6 | 49.2 | 38 | 53.6 | 61.5 | 26 |
| 6 | 2019-10-30 | 14.0 | 39.5 | 74.7 | 58 | 53.6 | 101.1 | 42 |
| 8 | 2019-11-01 | 13.0 | 27.8 | 89.5 | 70 | 53.1 | 141.2 | 59 |
| 11 | 2019-11-04 | 10.6 | 17.2 | 96.1 | 75 | 40.4 | 171.0 | 71 |
| 14 | 2019-11-07 | 13.2 | 22.3 | 105.2 | 82 | 23.0 | 180.8 | 76 |
| 18 | 2019-11-11 | 10.9 | 14.5 | 108.8 | 85 | 17.5 | 187.4 | 78 |
| 20 | 2019-11-13 | 6.2 | 7.9 | 110.5 | 86 | 5.2 | 187.4 | 78 |
| 25 | 2019-11-18 | 11.8 | 13.6 | 112.3 | 88 | 15.6 | 191.2 | 80 |
| 28 | 2019-11-21 | 5.6 | 8.4 | 115.1 | 90 | 7.7 | 193.3 | 81 |
| 29* | 2019-11-22 | 1.4 | 6.7 | 120.4 | 94 | 5.7 | 197.6 | 83 |

Degr. = degradation

mv = mean value

*) results of last two gas wash bottles

In the **inoculum** control the total CO₂ production was 35.8 mg CO₂/L after 28 days.

Table 4: **CO₂-Production and Biodegradation in the Inoculum Control, the Test Item Samples and the Abiotic Control**

| Study Day | Date | Inoculum Control [mg CO ₂ /3 mv | Test Item | | | | | | Abiotic Control | | |
|-----------|------------|--|---------------------------|------|-----------|---------------------------|------|-----------|---------------------------|-----|----------|
| | | | Replicate 1 | | | Replicate 2 | | | Replicate 1 | | |
| | | | [mg CO ₂ /3 L] | | Degr. | [mg CO ₂ /3 L] | | Degr. | [mg CO ₂ /3 L] | | Degr. |
| | | | Gross | Net | [%] | Gross | Net | [%] | Gross | Net | |
| 1 | 2019-10-25 | 4.5 | 10.9 | 6.4 | 6 | 12.0 | 7.5 | 7 | 3.2 | 0.0 | 0 |
| 4 | 2019-10-28 | 16.1 | 52.9 | 43.2 | 39 | 53.0 | 44.4 | 40 | 6.3 | 0.0 | 0 |
| 6 | 2019-10-30 | 14.0 | 37.2 | 66.4 | 60 | 39.7 | 70.1 | 63 | 4.6 | 0.0 | 0 |
| 8 | 2019-11-01 | 13.0 | 19.6 | 73.0 | 66 | 21.9 | 79.0 | 71 | 4.6 | 0.0 | 0 |
| 11 | 2019-11-04 | 10.6 | 16.6 | 79.0 | 71 | 17.8 | 86.2 | 77 | 4.2 | 0.0 | 0 |
| 14 | 2019-11-07 | 13.2 | 16.4 | 82.2 | 74 | 14.9 | 87.9 | 79 | 6.1 | 0.0 | 0 |
| 18 | 2019-11-11 | 10.9 | 12.0 | 83.3 | 75 | 9.8 | 87.9 | 79 | 3.6 | 0.0 | 0 |
| 20 | 2019-11-13 | 6.2 | 7.0 | 84.1 | 75 | 6.8 | 88.5 | 79 | 4.4 | 0.0 | 0 |
| 25 | 2019-11-18 | 11.8 | 11.1 | 84.1 | 75 | 13.6 | 90.3 | 81 | 7.7 | 0.0 | 0 |
| 28 | 2019-11-21 | 5.6 | 6.8 | 85.3 | 77 | 8.5 | 93.2 | 84 | 4.0 | 0.0 | 0 |
| 29* | 2019-11-22 | 1.4 | 4.1 | 88.3 | 79 | 5.4 | 97.2 | 87 | 1.9 | 1.0 | 1 |

Degr. = degradation

mv = mean value

*) results of last two gas wash bottles

6.4 Water Parameters

On day 28 (2019-11-21) the pH-value of all solutions was measured prior to acidification. The results are given in Table 5.

Table 5: **pH-Values on Day 28**

| Inoculum Control | | Functional Control | Test Item | | Toxicity Control | Abiotic Control |
|------------------|-------|--------------------|-----------|-------|------------------|-----------------|
| No. 1 | No. 2 | No.1 | No. 1 | No. 2 | No. 1 | No. 1 |
| 7.68 | 7.65 | 7.72 | 7.55 | 7.57 | 7.64 | 7.42 |

Determination of ammonium and dissolved nitrate was determined on 2019-10-24 (test start) and 2019-11-22 (test end). The results are given in Table 6.

Table 6: **Ammonium and Dissolved Nitrate at Test Start and Test End for the Test Item and Inoculum Control**

| Replicate | No. | Ammonium [mg/L] | | Dissolved Nitrate [mg/L] | |
|------------------|-----|-----------------|----------|--------------------------|----------|
| | | Test Start | Test End | Test Start | Test End |
| Test Item | 1 | 1.07 | < 1 | 0 | 19.0 |
| | 2 | - | < 1 | - | 19.2 |
| Inoculum Control | 1 | 0 | < 1 | 0 | 8.18 |
| | 2 | - | < 1 | - | 8.76 |

- = not determined

7 Validity Criteria

The study was performed according to guideline OECD 301 B and GLP principles.

The validity criteria were fulfilled according to the guideline:

Table 7: **Validity Criteria**

| Validity Criterion | Required | This study |
|--|------------------|----------------|
| Percentage degradation of the functional control | ≥ 60 % by day 14 | 82 % on day 14 |
| Total CO ₂ evolution in the inoculum control at the end | < 40 mg/L | 35.8 mg/L |
| Differences of extremes of replicate values of removal of the test item at the end of the test, at the plateau or at the end of the 10-d-window as appropriate | < 20 % | 8 % |
| Percentage degradation of the toxicity control | ≥ 25 % by day 14 | 76 % on day 14 |

8 Conclusion

Under the test conditions the test item is readily biodegradable within the 28 day period of the study and fulfilling the 10-day-window.

9 Literature

- (1) OECD 301 B Guideline / CO₂ Evolution Test for Testing of Chemicals (adopted 17/7/1992)
- (2) OECD Principles on Good Laboratory Practice (as revised in 1997). ENV/MC/Chem (98)17, Environment Directorate, OECD, Paris, 1999
- (3) Directive 2004/10/EC, The OECD Principles of Good Laboratory Practice (GLP)
- (4) Principles of Good Laboratory Practice – German Chemical Law (ChemG), Annex 1

10 Graph

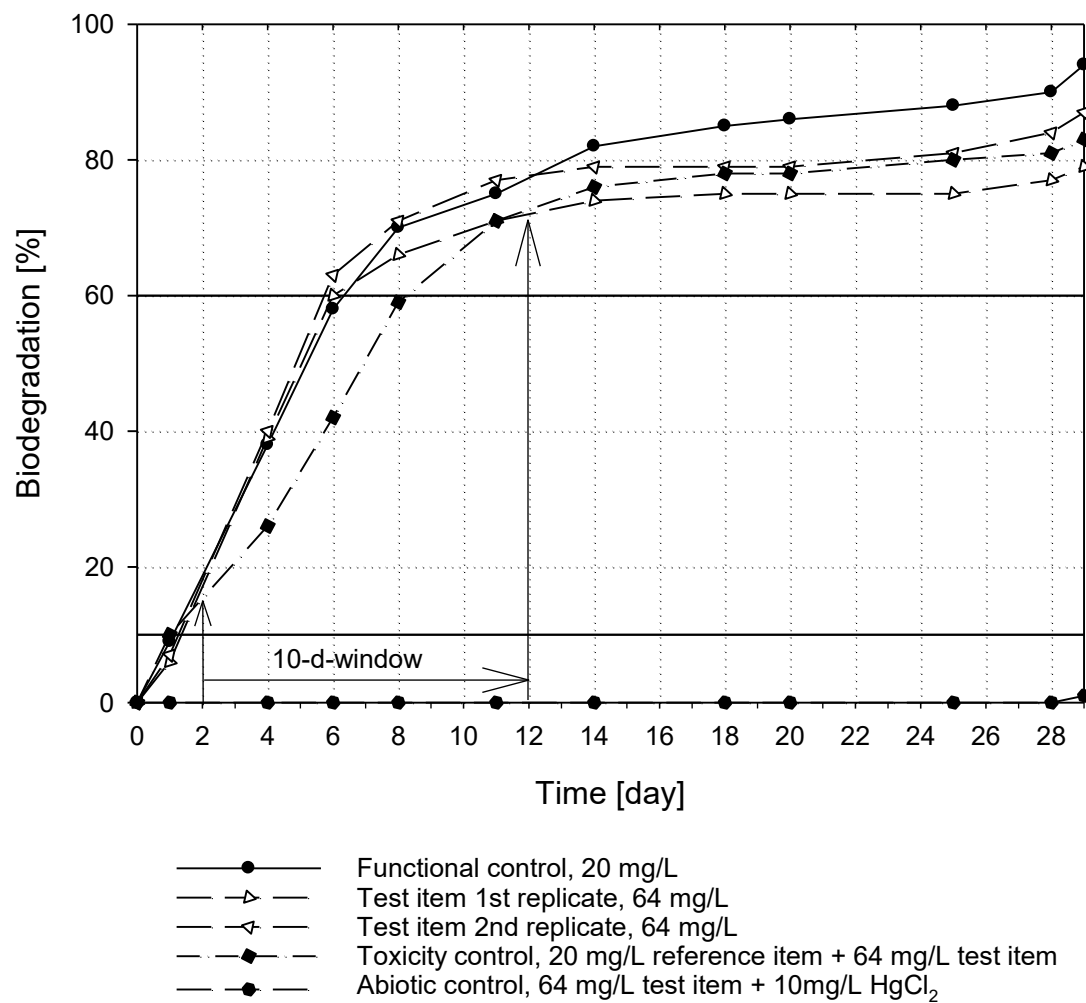


Figure 1: **Biodegradation Curve**

Report

190311BY / AST18675

BIOCEBO

Ready Biodegradability

Modified Sturm Test acc. to OECD 301 B

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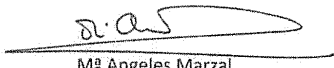
11 Certificate of Analysis



CERTIFICATE OF ANALYSIS

Ver nº: 2



| | |
|--------------------|--------------|
| Product | BIOCEBO |
| Code | F0187 |
| Batch number | 18/0004 |
| Parameter | Result |
| Description | Brown liquid |
| pH | 4.9 |
| Density | 1.14 g/mL |
| Hydrolyzed protein | 30.0 % w/v |
| Manufacturing date | June 2018 |
| Expiry date | June 2021 |


Mª Angeles Marzal
Head of Laboratory
Palafolls, June 19, 2019

Two additional numbers at the end of the code identify selected packaging and labeling

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12 GLP-Certificate

| | | |
|---|--|--|
|  <p>Gewerbeaufsicht in Niedersachsen</p> |  <p>Staatliches Gewerbeaufsichtsamt Hildesheim</p> | |
| <p>Gute Laborpraxis / Good Laboratory Practice GLP-Bescheinigung / Statement of GLP Compliance <small>(gemäß / according to § 19 b Abs.1 Chemikaliengesetz)</small></p> | | |
| <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>Eine GLP-Inspektion zur Überwachung der Einhaltung der GLP-Grundsätze gemäß Chemikaliengesetz bzw. Richtlinie 2004/9/EG wurde durchgeführt in:</p> <p style="text-align: center;"><input checked="" type="checkbox"/> Prüfeinrichtung / Test facility</p> </div> <div style="width: 45%;"> <p>Assessment of conformity with GLP according to Chemikaliengesetz and Directive 2004/9/EC at:</p> <p style="text-align: center;"><input type="checkbox"/> Prüfstandort / Test site</p> </div> </div> | | |
| <p>Noack Laboratorien GmbH Käthe-Paulus-Str. 1 31157 Sarstedt DEUTSCHLAND</p> | <p>Noack Laboratorien GmbH Käthe-Paulus-Str. 1 31157 Sarstedt GERMANY</p> | |
| <p>Prüfungen nach Kategorien / Areas of Expertise (gemäß / according ChemVwV-GLP Nr. 5.3/OECD guidance)</p> | | |
| <p>1 - Prüfungen zur Bestimmung der physikalisch-chemischen Eigenschaften und Gehaltsbestimmungen</p> <p>4 - Ökotoxikologische Prüfungen zu Bestimmung der Auswirkungen auf aquatische und terrestrische Organismen</p> <p>5 - Prüfungen zum Verhalten im Boden, im Wasser und in der Luft, Prüfungen zur Bioakkumulation und zur Metabolisierung</p> <p>6 - Prüfungen zur Bestimmung von Rückständen</p> | <p>1 - physical-chemical testing</p> <p>4 - environmental toxicity studies on aquatic and terrestrial organisms</p> <p>5 - studies on behaviour in water, soil and air; bioaccumulation</p> <p>6 - residue studies</p> | |
| <div style="display: flex; justify-content: space-between;"> <div style="width: 30%;"> <p>Ort / Place</p> <p>Sarstedt Sarstedt</p> </div> <div style="width: 65%;"> <p>Datum der Inspektion / Date of Inspection <small>(Tag, Monat, Jahr / month, day, year)</small></p> <p>07. – 10. Juni 2016 & 13. Juli 2016 / Jun 07th – Jun 10th, 2016 & Jul 13th, 2016</p> </div> </div> | | |
| <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>Die/Der genannte Prüfeinrichtung/Prüfstandort befindet sich im nationalen GLP-Überwachungsverfahren und wird regelmäßig auf Einhaltung der GLP-Grundsätze überwacht.</p> <p>Auf der Grundlage des Inspektionsberichtes wird hiermit bestätigt, dass in dieser Prüfeinrichtung/diesem Prüfstandort die oben genannten Prüfungen unter Einhaltung der GLP-Grundsätze durchgeführt werden können.</p> </div> <div style="width: 45%;"> <p>The above mentioned test facility/test site is included in the national GLP Compliance Programme and is inspected on a regular basis.</p> <p>Based on the inspection report it can be confirmed, that this test facility/test site is able to conduct the aforementioned studies in compliance with the Principles of GLP.</p> </div> </div> | | |

Hildesheim, 03.01.2017

Staatliches Gewerbeaufsichtsamt Hildesheim
 Im Auftrage

Jahn
 Bahn

