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**FINAL REPORT**

**ACTIVATED SLUDGE  
RESPIRATION INHIBITION TEST  
WITH  
ETHYLENE DIBROMIDE INDUSTRIAL  
(EDB)**

It's a true copy  
Hiteles Másolat

2010 AUG 3 0.

Signature  
Aláírás 

Date of Final Report: 30 August 2010

STUDY CODE: 10/112-027AS

## STATEMENT OF THE STUDY DIRECTOR

This study has been performed in accordance with the study plan agreed upon by Sponsor, the OECD Guidelines for Testing of Chemicals (No. 209, 04 April 1984), the Council Regulation (EC) No 440/2008, Part C, C.11, the Product Properties Test Guideline OPPTS 850.6800 of the United States Environment Protection Agency (EPA) and the Principles of Good Laboratory Practice Regulations as specified by national Hungarian GLP Regulations: 9/2001.(III.30.) EüM-FVM joint decree of the Minister of Health and the Minister of Agriculture and Regional Development which corresponds to the OECD GLP, ENV/MC/CHEM(98)17.

I the undersigned declare that this report constitutes a true record of the actions undertaken and the results obtained in the course of this study. By virtue of my dated signature I accept the responsibility for the validity of the data and the following conclusion drawn from them:

**“Based on measured inhibition rates the 3-hour EC<sub>50</sub> value were higher than 1000 mg/L.”**

Signature: \_\_\_\_\_

Krisztina Sipos, M.Sc.  
Study Director

Date: 30 August 2010

**STATEMENT OF THE MANAGEMENT**

According to the conditions of the research and development assignment between CHEMTURA CORPORATION (as Sponsor) and LAB Research Ltd. (as Testing Facility) "Activated Sludge Respiration Inhibition Test with Ethylene Dibromide Industrial (EDB)" has been performed insisting on the GLP requirement.

Signature:   
Christopher Banks, DABT  
Managing Director

Date: 30 August 2010

GENERAL INFO

## QUALITY ASSURANCE STATEMENT

Study Code: 10/112-027AS

Study Title: Activated Sludge Respiration Inhibition Test with Ethylene Dibromide Industrial (EDB)

Test Item: Ethylene Dibromide Industrial (EDB)

This study has been inspected, and this report audited by the Quality Assurance Unit in compliance with the Principles of Good Laboratory Practice. As far as it can be reasonably established the methods described and the results incorporated in this report accurately reflect the raw data produced during this study.

All inspections, data reviews and the report audit were reported in written form to the study director and to management. The dates of such inspections and of the report audit are given below:

Date of Inspection	Phase(s) Inspected/Audited	Date of report to	
		Management	Study Director
14 July 2010	Study Plan	14 July 2010	14 July 2010
03 August 2010	Oxygen and pH measurement	03 August 2010	03 August 2010
16 August 2010	Draft Report	17 August 2010	17 August 2010
30 August 2010	Final Report	30 August 2010	30 August 2010

Signature: Fabian Makovi-Eva  
 Éva Makovi-Fábián, B.Sc.  
 On behalf of QA

Date: 30 August 2010

## GENERAL INFORMATION:

STUDY TITLE : Activated Sludge Respiration Inhibition Test with Ethylene Dibromide Industrial (EDB)

TEST ITEM : Ethylene Dibromide Industrial (EDB)

MANUFACTURER : Chemtura Manufacturing UK Limited  
Address: Tenax Road, Trafford Park  
Manchester  
United Kingdom  
M17 1WT

SPONSOR : CHEMTURA CORPORATION  
Address: 199 Benson Road,  
Middlebury,  
Connecticut 06749  
USA

TEST FACILITY : LAB Research Ltd.  
Address H-8200 Veszprém, Szabadságpuszta  
Hungary  
Phone +36 88 545 300  
Fax +36 88 545 301

STUDY DIRECTOR : Krisztina Sipos, M.Sc.

QUALITY ASSURANCE : Szabolcs Gáty, M.Sc.  
Head of QAU

START OF EXPERIMENT : 03 August 2010  
END OF EXPERIMENT : 03 August 2010  
DRAFT REPORT : 17 August 2010

BASIS OF STUDY : OECD Guidelines for Testing of Chemicals, No.: 209  
Council Regulation (EC) No 440/2008, Part C, C.11  
Product Properties Test Guideline OPPTS 850.6800 of  
the United States Environment Protection Agency (EPA)

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## 1. SUMMARY

A laboratory test was carried out with Ethylene Dibromide Industrial (EDB) to evaluate the effect of the test item on microorganisms by measuring the respiration rate. The test concentrations (10, 31, 100, 313 and 1000 mg/L) were chosen to permit the determination of the EC<sub>50</sub>.

In comparison to the inoculum controls the respiration rate of the activated sludge was inhibited between 17.4 % and 32.1 % in the examined nominal test concentration range (10 - 1000 mg/L). Concentrations exceeding 1000 mg/L nominal were not tested.

In parallel to the study with the test item, the reference item 3,5-Dichlorophenol was tested (the nominal test concentrations of 5, 16 and 32 mg/L) under otherwise identical test conditions.

The 3-hour EC<sub>50</sub> of 3,5-Dichlorophenol was calculated to be 7.91 mg/L with 95 % confidence limits of 5.85 to 10.69 mg/L.

### **Based on measured inhibition rates it can be stated that :**

The 3-hour EC<sub>20</sub> was determined to be in the range of 10 to 100 mg/L, it was calculated to be 68.18 mg/L with 95 % confidence limits of 15.90 to 292.34 mg/L.

**The 3-hour EC<sub>50</sub> were higher than 1000 mg/L**

The 3-hour EC<sub>80</sub> were higher than 1000 mg/L.

## 2. INTRODUCTION

The purpose of the 3-hour toxicity test was to evaluate the influence of the test item on the activity of activated sludge by measuring the respiration rate under defined conditions. The respiration rate (oxygen consumption) of an aerobic activated sludge fed with a standard amount of synthetic sewage was measured in the presence of various concentrations of the test item after an incubation period of 3 hours. The inhibitory effect of the test item at the particular concentrations was expressed as percentage of the mean respiration rate of two controls.

The test method of application and the test system was conducted to comply with all relevant test guidelines.

## 3. MATERIALS AND METHODS

### 3.1. TEST ITEM

Name:	Ethylene Dibromide Industrial (EDB)
Chemical name:	1,2-Dibromoethane
Batch No.:	510100003
Active component:	>99.94 % 1,2-Dibromoethane (CAS 106-93-4)
Description:	clear to amber liquid
Manufacture date:	February 2010
Expiry date:	February 2011
Storage:	room temperature; 15-25°C (humidity 50 % ± 20)
Safety Precautions:	see Safety Data Sheet

### 3.2. REFERENCE ITEM

Reference item:	3,5-Dichlorophenol
Supplier:	SIGMA-ALDRICH
Batch No.:	15809KI
Expiry Date:	30 August 2012
Storage:	In original container, at room temperature

The test item of a suitable chemical purity was provided by the Sponsor. All precautions required in the handling and disposal of the test item were outlined by the Sponsor.

Identification of the test item was performed on the basis of its batch number, name, appearance and colour included in the analytical certificate and TIDS.

### 3.3. FORMULATION

Defined amounts of test item were directly weighed into the designated test flasks to reach the planned nominal concentrations. The nominal test item concentrations were prepared by mechanical dispersion. These test solutions were freshly prepared at the beginning of the experiment, in the testing laboratory.

### 3.4. CONTROLS

#### 3.4.1. Untreated Control (C1 and C2)

Two controls (deionised water, synthetic sewage and inoculum, but without addition of the test item) were tested in parallel.

#### 3.4.2. Reference Control (R1 – R3)

In parallel to the study with the test item, the reference item 3,5-Dichlorophenol was tested (the nominal test concentrations of 5, 16 and 32 mg/L) under otherwise identical test conditions.

A stock solution of 3,5-Dichlorophenol was prepared according to the OECD Guideline No. 209: 0.25 g of 3,5-Dichlorophenol was dissolved in 5 mL 1 mol/L NaOH and diluted to about 15 mL with deionised water. Excess of NaOH was neutralised with approximately 4 mL of 0.5 mol/L H<sub>2</sub>SO<sub>4</sub> to the point of incipient precipitation. Thereafter, the mixture was made up to 0.5 litre with deionised water. The final pH was measured to be 7.60 and the final concentration amounted 500 mg/L.

### 3.5. TEST SYSTEM AND TEST CONDITIONS

Species:	Activated sludge, microorganisms from a domestic waste water treatment plant.
Source:	The activated sludge was supplied from the sewage plant for domestic sewage in Veszprém, Hungary
Conditioning:	The activated sludge used for this study was washed and centrifuged and the supernatant liquid phase was decanted. The solid material was re-suspended in isotonic saline solution and again centrifuged. This procedure was repeated twice.

An aliquot of the final sludge suspension was weighed, dried and the ratio of wet sludge to dry weight determined.

Based on this ratio, calculated amounts of wet sludge were suspended in isotonic saline solution to yield a concentration equivalent to 4 g per litre (on dry weight basis). The pH of the activated sludge inoculum was determined to be pH 7.60. The activated sludge was used directly after conditioning.

### 3.5.1 Test units

Type and size: Erlenmeyer bottles of approximately 350 mL volume, and BOD bottles with special neck of 300 mL volume.

Identification: Each test flask was uniquely identified with at least study code, treatment and replicate codes (in case of controls).

### 3.5.2 Test conditions

Surrounding type: Climate chamber (during the incubation) and controlled environment room (during the formulation and oxygen measuring)

Temperature: 19.5 – 20.7 °C (during the incubation) and 20.0 – 21.1 °C (during oxygen measurement)

Aeration: With compressed air (1 litre per minute)

Recording: Test conditions were measured with suitable instruments and documented in the raw data.

## 3.6. ADMINISTRATION OF THE TEST ITEM

### 3.6.1. Concentrations

Before the start of the test defined amounts of the test item were directly weighed into the test flasks and mechanically dispersed.

The test concentrations (10, 31, 100, 313 and 1000 mg/L) were chosen to permit the determination of the EC<sub>50</sub>. Concentrations in excess of nominal 1000 mg test item/L were not tested.

## 3.7. PERFORMANCE OF THE TEST

## 3.7.1. Preparations of the test flasks

One test solution with a final volume of 330 mL was tested per treatment in a glass flask. 10.56 mL synthetic sewage and an adequate amount of the test item or an adequate volume of the stock solution of the reference item was filled up with deionised water to 198 mL before the start of the test. At the start of the test 132 mL activated sludge inoculum with a sludge concentration of 4 g/L (dry weight) was added, first to first control (C1), then in time intervals of 15 minutes (an arbitrary but convenient interval) to the test solutions of the reference item and the test item and finally to a second control (C2). Time interval between the last test solution flask and the second control was more than 15 minutes.

## 3.7.2. Composition of Test Media (For 330 mL)

Table 1.: Composition of test media (For 330 mL):

Flask No.	Identification	Test group	Synthetic waste-water (mL)	Amount of test item (mg)*	Aliquot of stock solution (mL)**	Activated sludge (mL)	Deionised water (mL)	Final concentration (mg/L)
1	C1	Control	10.56	---	---	132	187.44	---
2	R1	Ref. item	10.56	---	3.30	132	184.14	5
3	R2	Ref. item	10.56	---	10.56	132	176.88	16
4	R3	Ref. item	10.56	---	21.12	132	166.32	32
5	T1	Test item	10.56	3.3	---	132	187.44	10
6	T2	Test item	10.56	10.2	---	132	187.44	31
7	T3	Test item	10.56	33.0	---	132	187.44	100
8	T4	Test item	10.56	103.3	---	132	187.44	313
9	T5	Test item	10.56	330.0	---	132	187.44	1000
15	C2	Control	10.56	---	---	132	187.44	---

\* The test item was weighed directly into the designated test flasks

\*\* Stock solution of 3,5-dichlorophenol (3,5-DCP, 500 mg/L)

### 3.7.3. Synthetic Sewage Feed (ratio of composition of culture media referring to 1000 mL)

Peptone	16.0	g
Meat extract	11.0	g
Urea	3.0	g
NaCl	0.7	g
CaCl <sub>2</sub> x 2H <sub>2</sub> O	0.4	g
MgSO <sub>4</sub> x 7H <sub>2</sub> O	0.2	g
K <sub>2</sub> HPO <sub>4</sub>	2.8	g
Deionised water	add 1000.0	mL

### 3.7.4. Measurement of Respiration Rate

For the measurement of the respiration rate a well-mixed sample of each treatment was poured into a BOD flask after exactly 3 hours incubation time, and was not further aerated. The oxygen concentration was measured with a stirring O<sub>2</sub> electrode and was recorded for about ten minutes. The oxygen consumption (in mg O<sub>2</sub> L<sup>-1</sup> minute<sup>-1</sup>) was determined from the most linear part of the respiration curve.

### 3.7.5. Measurement of pH, Dissolved Oxygen and Water Temperature

The pH and the oxygen concentrations were determined at the start and at the end of the incubation period in all treatments. The temperature was measured in the climate chamber with a min/max thermometer during the incubation period. The water temperature was recorded during the oxygen measurement in all BOD bottles.

## 3.8. RESULT EVALUATION

### 3.8.1. Definitions

**Respiration Rate:** The oxygen consumption of waste-water microorganisms in aerobic activated sludge, expressed as mg O<sub>2</sub> per litre per minute.

**EC<sub>50</sub>:** The calculated concentration of test item which results in a 50 % inhibition of the respiration rate.

### 3.8.2. Determination of the Inhibitory Effects

The inhibitory effect of the test item respectively of the reference item at a particular concentration on the respiration rate were expressed as percentage of the mean value of the respiration rates of the two controls according to:

$$\left[ 1 - \frac{2R_s}{R_{c1} + R_{c2}} \right] * 100 = \% \text{ inhibition}$$

where:

$R_s$  = oxygen consumption rate at tested concentration of test item

$R_{c1}$  = oxygen consumption rate of control 1

$R_{c2}$  = oxygen consumption rate of control 2

The 3-hour  $EC_{20}$  of the test item and the 3-hour  $EC_{50}$  of the reference item with 95 %-confidence limits were calculated by Probit analysis using TOXSTAT software.

The 3-hour  $EC_{50}$  and  $EC_{80}$  of the test item could not be calculated.

### 3.9. VALIDITY CRITERIA

- The respiration rates of the two controls did not differ by more than 15 % (1.85 %).
- The 3-hour  $EC_{50}$  of the reference item 3,5-Dichlorophenol for the used activated sludge batch was determined to be in the range of 5 to 30 mg/L.
- The concentration of dissolved oxygen did not drop below 2.5 mg  $O_2$ /L during the incubation period, and just before the measurements of the respiration rates the oxygen concentrations were at least 7.4 mg  $O_2$ /L.

### 3.10. ARCHIVES

The study documents:

- study plan,
- all raw data,
- sample of the test item,
- study report and any amendments,
- correspondence

are stored in the archives of LAB Research Ltd., 8200 Veszprém, Szabadságpuszta, Hungary according to the Hungarian GLP and to our SOPs.

## 3.11 DISTRIBUTION OF THE FINAL REPORT

Sponsor:           1 x pdf  
                      1 x copy, bound  
                      1 x copy, unbound

Archive:           1 x original, bound

## 3.12. REFERENCES

1. Council Regulation (EC) No 440/2008, Part C, C.11. "Activated Sludge Respiration Inhibition Test", Official Journal of the European Union L 142 of 31 May 2008.
2. Organization for Economic Co-operation and Development (OECD), Guidelines for Testing of Chemicals, Guideline No.: 209, "Activated Sludge, Respiration Inhibition Test", adopted April 04, 1984.
3. Hungarian Good Laboratory Practice Regulations: 9/2001. (III. 30) EüM-FVM joint decree of the Minister of Health and the Minister of Agriculture and Regional Development which corresponds to the OECD GLP ENV/MC/CHEM (98) 17
4. Product Properties Test Guideline OPPTS 850.6800 of the United States Environment Protection Agency (EPA), "Modified Activated Sludge, Respiration Inhibition Test for Sparingly Soluble Chemicals", April 1996
5. OECD Principles of Good Laboratory Practice, adopted by Council on 26th November 1997; Environment Directorate, Organisation for Economic Co-operation and Development, Paris 1998
6. Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (codified version)

## 3.13. DEVIATION FROM THE STUDY PLAN

Concerning:	Preparations of the test flasks
According to the Study Plan:	At the start of the test 132 mL activated sludge inoculum with a sludge concentration of 2-4 g/L (dry weight) will be added, first to first control (C1), then in time intervals of approximately 15 minutes (an arbitrary but convenient interval) to the test solutions of the reference item and the test item and finally to a second control (C2).
Deviation:	At the start of the test 132 mL activated sludge inoculum with a sludge concentration of 4 g/L (dry weight) was added, first to first control (C1), then in time intervals of 15 minutes (an arbitrary but convenient interval) to the test solutions of the reference item and the test item and finally to a second control (C2). Time interval between the last test solution flask and the second control was more than 15 minutes.
Reason for this change:	Technical
Presumed Effect on the Study:	None

## 4. RESULTS

### 4.1. INHIBITION OF THE RESPIRATION RATE

For the measurement of the respiration rate a well-mixed sample of each treatment was poured into a BOD flask after exactly 3 hours incubation time, and was not further aerated. The oxygen concentration was measured with a stirring O<sub>2</sub> electrode and was recorded for about ten minutes. The oxygen consumption (in mg O<sub>2</sub> L<sup>-1</sup> minute<sup>-1</sup>) was determined from the most linear part of the respiration curve.

#### 4.1.1. Test item

In comparison to the inoculum controls the respiration rate of the activated sludge was inhibited between 17.4 % and 32.1 % in the examined nominal test concentration range (10 - 1000 mg/L). Concentrations exceeding 1000 mg/L nominal were not tested.

The influence of Ethylene Dibromide Industrial (EDB) on the respiration rate of activated sludge in Table 2 and in Figure 1.

Table 2. Influence of test item on oxygen consumption of activated sludge

Flask No.	ID	Test group	Concentration (mg/L)	Oxygen consumption (mg O <sub>2</sub> /L/min)	Inhibition (%)	pH-values		Oxygen concentration (mg O <sub>2</sub> /L)	
						start *	end *	start *	end *
1	C1	Control	–	0.550	–	7.28	7.35	8.2	7.9
15	C2	Control	–	0.540	–	7.32	7.32	8.4	7.7
		Mean	–	0.545	–	–	–	–	–
		Deviation (%)	–	1.85	–	–	–	–	–
5	T1	Test item	10	0.450	17.4	7.20	7.82	8.1	7.9
6	T2	Test item	31	0.440	19.3	7.23	8.01	8.1	7.7
7	T3	Test item	100	0.440	19.3	7.24	8.06	8.1	7.7
8	T4	Test item	313	0.440	19.3	7.20	8.09	8.4	7.9
9	T5	Test item	1000	0.370	32.1	7.24	8.11	8.2	7.4

\* start and end of 3-hour aeration

ID: Code of each group

**Based on measured inhibition rates it can be stated that :**

The 3-hour EC<sub>20</sub> was determined to be in the range of 10 to 100 mg/L, it was calculated to be 68.18 mg/L with 95 % confidence limits of 15.90 to 292.34 mg/L.

**The 3-hour EC<sub>50</sub> were higher than 1000 mg/L**

The 3-hour EC<sub>80</sub> were higher than 1000 mg/L.

## 4.1.2. Reference item

The following nominal concentrations of the positive reference control 3,5-Dichlorophenol were tested on the same activated sludge and under identical conditions as the test item: 5, 16 and 32 mg/L. In comparison to the controls the respiration rate of the activated sludge was inhibited by 39.4 % at the lowest nominal concentration of 5 mg/L.

At the nominal concentrations of 16 and 32 mg/L, the respiration rate was inhibited by 67.0 % and 79.8 %, respectively. The results are summarised in Table 3 and in Figure 1-2.

The 3-hour  $EC_{50}$  of 3,5-Dichlorophenol was calculated to be 7.91 mg/L with 95 % confidence limits of 5.85 to 10.69 mg/L.

The influence of the reference item on the respiration rate of activated sludge in Table 3 and in Figure 1-2.

Table 3. Influence of reference item on oxygen consumption of activated sludge

Flask No.	ID	Test group	Concentration (mg/L)	Oxygen consumption (mg O <sub>2</sub> /L/min)	Inhibition (%)	pH-values		Oxygen concentration (mg O <sub>2</sub> /L)	
						start *	end *	start *	end *
1	C1	Control	–	0.550	–	7.28	7.35	8.2	7.9
15	C2	Control	–	0.540	–	7.32	7.32	8.4	7.7
		Mean	–	0.450	–	–	–	–	–
		Deviation (%)	–	1.85	–	–	–	–	–
2	R1	Ref. item	5	0.330	39.4	7.23	7.30	8.2	8.1
3	R2	Ref. item	16	0.180	67.0	7.29	7.29	8.4	8.2
4	R3	Ref. item	32	0.110	79.8	7.28	7.36	8.3	8.3

\* start and end of 3-hour aeration

ID: Code of each group

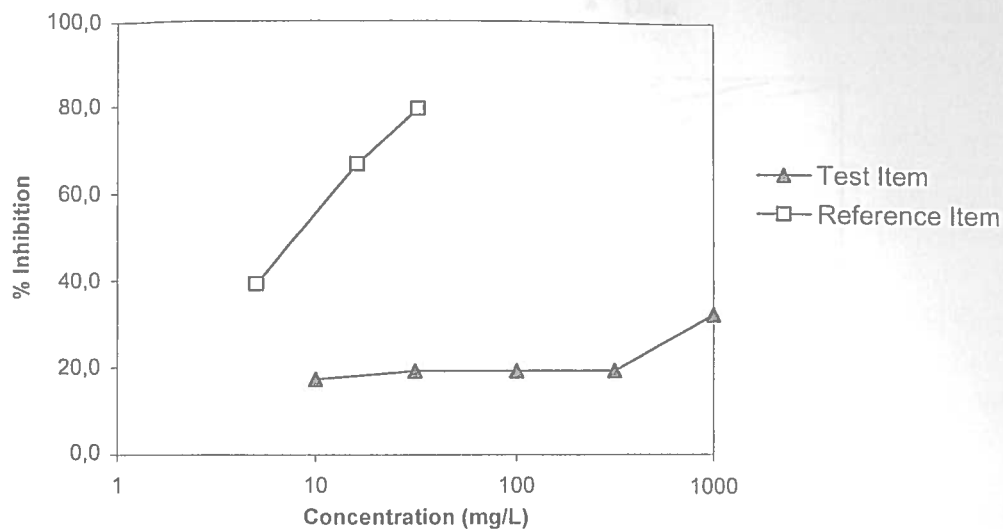


Figure 1. Influence of Test and Reference Items on the Respiration rate of Aerobic Wastewater Microorganisms after 3 Hours of Exposure

Table 4. Influence of reference item on oxygen consumption of activated sludge

Concentration [mg/L]	Number subject	Number observed	Observed proportion	Predicted proportion
5	100	39	0.3900	0.3933
16	100	67	0.6700	0.6612
32	100	79	0.7900	0.7952

Chi<sup>2</sup> lack of fit = 0.0561

Likelihood lack of fit = 0.0562

Table Chi<sup>2</sup> = 3.8415, alpha = 0.05, df = 1

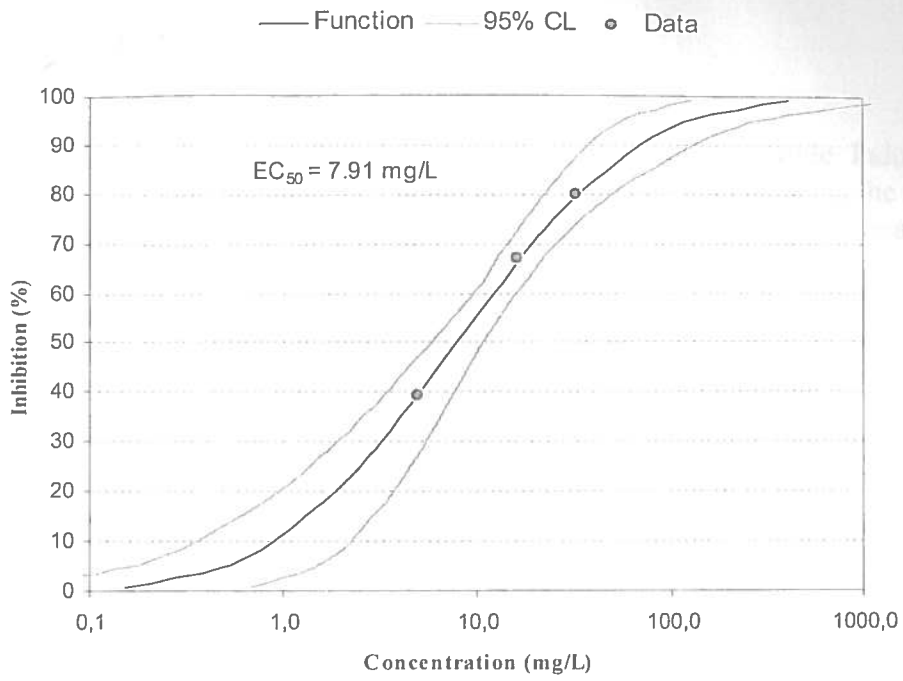


Figure 2. Probit Curve of the Reference Item

## 5. CONCLUSION

A laboratory test was carried out with Ethylene Dibromide Industrial (EDB) to evaluate the effect of the test item on microorganisms by measuring the respiration rate. The test concentrations (10, 31, 100, 313 and 1000 mg/L) were chosen to permit the determination of the  $EC_{50}$ .

In comparison to the inoculum controls the respiration rate of the activated sludge was inhibited between 17.4 % and 32.1 % in the examined nominal test concentration range (10 - 1000 mg/L). Concentrations exceeding 1000 mg/L nominal were not tested.

In parallel to the study with the test item, the reference item 3,5-Dichlorophenol was tested (the nominal test concentrations of 5, 16 and 32 mg/L) under otherwise identical test conditions.

The 3-hour  $EC_{50}$  of 3,5-Dichlorophenol was calculated to be 7.91 mg/L with 95 % confidence limits of 5.85 to 10.69 mg/L.

**Based on measured inhibition rates it can be stated that :**

The 3-hour  $EC_{20}$  was determined to be in the range of 10 to 100 mg/L, it was calculated to be 68.18 mg/L with 95 % confidence limits of 15.90 to 292.34 mg/L.

**The 3-hour  $EC_{50}$  were higher than 1000 mg/L**

The 3-hour  $EC_{80}$  were higher than 1000 mg/L.

## APPENDIX

## COPY OF THE GLP CERTIFICATE



ORSZÁGOS GYÓGYSZERÉSZETI INTÉZET  
National Institute of Pharmacy

H-851 Budapest, Zrínyi u. 9.

Mail: 1372 P.O. Box 450.

Phone: +36 1 8869-300

Fax: +36 1 8869-460

E-mail: ugyintegyi.hu

Budapest, 20<sup>th</sup> December 2008

No: 38625/48/2007

Our ref.: Szilvia Karsai

Subject: GLP Certificate

GOOD LABORATORY PRACTICE (GLP)  
CERTIFICATE


Based on the Inspection report and the discussion of follow up activities it is hereby certified that the test facility

LAB Research Ltd.  
H-8201 Veszprém, Szabadságpuszta, Hungary

is able to carry out Physical-chemical testing, Toxicity studies, Mutagenicity studies, Environmental toxicity studies on aquatic and terrestrial organisms, Studies on behaviour in water, soil and air, bioaccumulation, Bioanalytical, Analytical and clinical chemistry testing compliance with the Principles of GLP (Good Laboratory Practice).

Date of the inspection: 13-22 October 2008.

This GLP Certificate is valid for 2 years.

  
Zsuzsanna Szepezdi, Ph. D.  
Director-General