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Our reference	PS 20080906.01
Date	21.01.2009

Drytech Italia SRL
Dr. Claudio Granatieri
Via Ravona, 1H

I-22020 San Fermo della Battaglia CO

Italy

Final Report

Dear Dr. Granatieri,

please find attached the final report for the test item:

Dryflex 1 (20080906.01).

Best regards

T. Wielpütz

Dr. Thomas Wielpütz

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FINAL REPORT

Dryflex 1

Batch No.: LQ13A1241

PARTITION COEFFICIENT

n – OCTANOL / WATER A.8. (OECD 107/117)

(shake flask method)

Study Director

Dr. T. Wielpütz

Study completed on

January 20, 2009

Laboratory Performing Analysis

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1. Objective

The objective of this study was the determination of the partition coefficient n-octanol/water of the test item according to the European Commission Regulation (EC) No. 440/2008,

Part A:	Methods for determination of physico-chemical properties. A.8. partition coefficient n-octanol/water
and	OECD test guidelines
	OECD 107, partition coefficient n-octanol/water OECD 117, HPLC-method

2. Presentation of the Test Item

Test item:	Dryflex 1
Molecular weight:	about 280 g/mol
Batch:	LQ13A1241
Physical state:	light brown fluid
Storage conditions:	0 – 30 °C, away from light or sunlight
Expiry date:	January 2009

3. General Remarks

Study Monitor:	Dr. Herbert Lebertz SGS Institut Fresenius GmbH Im Maisel 14 65232 Taunusstein, Germany
Sponsor:	Dr. Claudio Granatieri Drytech Italia S.r.l. Via Ravona, 1/H 22020 S. Fermo della Battaglia (CO) – Italy
Test facility:	Siemens AG Prozess-Sicherheit Industriepark Höchst, C 487 D-65926 Frankfurt am Main, Germany
Study director:	Dr. T. Wielpütz Siemens AG Prozess-Sicherheit Industriepark Höchst, C 487 D-65926 Frankfurt am Main, Germany
Quality assurance unit:	isomehr GmbH Dr. A. Roth Mainzer Straße 139/141 D-66121 Saarbrücken, Germany
Project-No.:	20080906.01
Experimental starting date:	October 30, 2008
Experimental completion date:	November 19, 2008

4. Performance of the Test

4.1. Procedure

4.1.1. Estimation from the Saturation Concentration

The n-octanol/water partition coefficient P_{OW} can be estimated by the following equation:

$$P_{OW} = c_s^{octanol} / c_s^{water}$$

where c_s are the saturation concentrations of the test item in n-octanol and water.

4.1.2. Preliminary Estimation of the Water Solubility

Amounts of the test item were stirred at room temperature in water, until the mixture appeared dissolved or the water solubility could be estimated to be below 10 mg/l.

4.1.3. Preliminary Estimation of the n-Octanol Solubility

At room temperature a defined volume of n-octanol was added to an amount of the test item. After the addition the mixture was stirred and visually checked for any undissolved parts.

4.1.4. Shake Flask Method

254 mg of the test item were dissolved in 100 ml n-octanol (saturated with with distilled water).
10 ml of this solution were added to each of six flasks (1A, 1B, 2A, 2B, 3A, 3B). To the test 1A and 1B 10 ml, to test 2A and 2B 20 ml, to test 3A and 3B 40 ml of n-octanol (saturated with water) were added. To each of the six solutions 10 ml water (saturated with n-octanol) were added. The six mixtures were shaken at ambient temperature (22 °C). After separation of the phases each phase was centrifuged (30 min at 20°C and 15000 rpm). The pH of the aqueous phases was measured. After sample preparation the concentration of the test item was determined by means of HPLC (for example chromatograms refer to chapter 6).

Sample preparation octanol phases:
The octanol phases of the experiments were diluted from 0.05 ml to 1 ml with the mobile phase and measured by means of HPLC.

Sample preparation of the aqueous phases:
The aqueous phases of the experiments were diluted from 0.1 ml to 1 ml with the mobile phase and measured by means of HPLC.

4.2. Reagents

- Distilled water, Roth
- 1-Octanol, Fluka
- Methanol Chromasolv, Riedel de Haen

4.3. Instruments

- Chromatographic apparatus refer to chapter 4.4
- Analytical balance, Sartorius, model R 160 P
- pH-meter, Mettler, model MP220
- Shaking apparatus for the solvents, GFL
- Variable and fixed pipettes, Brand and Eppendorf
- Centrifuge Kendro, model Biofuge stratos
- General laboratory glassware

4.4. Analytical Method (HPLC) for the octanol phases

HPLC equipment:	HPLC Series Agilent 1100: HPLC pump G1311A, autosampler G1313A, column oven G1316A, degaser G1322A and UV/VIS detector G1314A by Agilent
Column:	stationary phase: LiChrospher 100 RP 18 EC-5µ (8103-01) by Duratec Material: stainless steel, dimensions: 125 mm x 4.6 mm particle size: 5 µm, pore size: 100 Å column temperature: 20 °C
Mobile phase:	Methanol Chromasolv / distilled water (60 / 40 % (v/v))
Flow rate:	0.5 ml/min
Injection volume:	100 µl
Detection wavelength:	220 nm

The concentrations were quantified by comparing integrated peak areas with a calibration (external standard method). The solutions were determined by HPLC. The test item showed two peaks in the chromatogramms. Both peaks were integrated and employed for the quantification of the test item in the eluent. The integration was automatically carried out using the HPLC System Agilent 1100 series. The standards were prepared by dissolving the test item in the mobile phase. The detector linearity was checked (calibration at 7 concentration levels).

In the HPLC-chromatogramms of the eluent, two additional peaks were observed. One of which is at a retention time of approximately 1.6 min, the other one at a retention time of about 6.3 min (see chapter 6). The first peak at 1.6 min superimposes, unfortunately, the first peak of the test item whose maximum is at about 1.8 min. Therefore, the mean peak area of the first peak at 1.6 min of two eluent measurements is substracted from the area of the first peak of the test-item for all standards.

Calibration (octanol phases): (see figure 5)	$y = mx + b$, x: Amount (mg/l), y: Area $m = 58928.3$ $b = 54.0$ correlation coefficient: 0.99987

Detection limit for measurement: 2.03 mg/l (lowest calibration standard)

Due to the sample preparation of the octanol phases the detection limit corresponds to a concentration of the test item in the octanol phases of 40.5 mg/l.

4.5. Analytical Method (HPLC) for the aqueous phases

HPLC equipment:	HPLC Series Agilent 1100: HPLC pump G1311A, autosampler G1313A, column oven G1316A, degaser G1322A and UV/VIS detector G1314A by Agilent
Column:	stationary phase: LiChrospher 100 RP 18 EC-5 µ (14708-07) by Duratec Material: stainless steel, dimensions: 125 mm x 4.6 mm particle size: 5 µm, pore size: 100 Å column temperature: 20 °C
Mobile phase:	Methanol Chromasolv / distilled water (60 / 40 % (v/v))
Flow rate:	0.5 ml/min
Injection volume:	10 µl
Detection wavelength:	220 nm

The concentrations were quantified by comparing integrated peak areas with a calibration (external standard method). The solutions were determined by HPLC. The test item showed two peaks in the chromatogramms. Both peaks were integrated and employed for the quantification of the test item in the eluent. The integration and calculation of the concentration were automatically carried out using the HPLC System Agilent 1100 series. The standards were prepared by dissolving and diluting the test item in the mobile phase. The detector linearity was checked (calibration at 7 concentration levels).

One can see in each of the calibration chromatogramms a peak at approximately 1.4 min. This peak arises from the eluent which can be seen rudimentarily in the chromatogramm of the eluent (see chapter 6). Fortunately, this peak can be separated from the two main peaks of the test-item in all chromatogramms. Therefore, no further actions were necessary.

Calibration (aqueous phases): $y = mx + b$, x: Amount (mg/l), y: Area
(see figure 1)
$m = 6657.5$
$b = -18.0$
correlation coefficient: 0.99950

Detection limit for measurement: 9.9 mg/l (lowest calibration standard)

Due to the sample preparation of the octanol phases the detection limit corresponds to a concentration of the test item in the octanol phases of 98.8 mg/l.

4.6. Individual Results

4.6.1. Preliminary Visual Estimation of the Water Solubility

Amounts of the test item and water were stirred at room temperature until the mixture appeared dissolved or the water solubility could be estimated to be below 10 mg/l.

Table 1: Appearance of the test mixtures

Amount of the test item in mg	**Total volume** in ml	**Appearance of mixture**
107.8	0.1	Undissolved*
	0.5	dissolved

*): determination difficult, the test item was supposed to be undissolved

The solubility of the test item in water is above 270 g/l and below 1078 g/l (without correction of the purity).

4.6.2. Preliminary Visual Estimation of the n-Octanol Solubility

An amount of the test item was stirred with n-octanol at room temperature.

Table 2: Appearance of the test mixtures

Amount of the test item (mg)	Total volume (ml)	Stirring time (min)	Appearance of mixture	Solubility (g/l)
546.6	3	35	undissolved	--
	8	30	undissolved	--
	18	30	undissolved	--
	28	30	undissolved	--
	53	50	undissolved	--
	103	45	dissolved	10.3

According to this preliminary test the solubility of the test item in n-octanol is above 5.31 g/l and below 10.3 g/l (without correction of the purity).

4.6.3. Calculation of the Partition Coefficient log P_{OW}

The partition coefficient P_{OW} may be estimated from the saturation concentrations in n-octanol and water by the following equation:

$$P_{OW} = c_S^{octanol} / c_S^{water}$$

S = saturation

With the data obtained from the experiments in chapter 4.6.1 and 4.6.2 the partition coefficient was calculated as log P_{OW} between -2.02 and -1.71. Due to this fact the partition coefficient n-octanol/water of the test item at ambient temperature could be determined by means of the shake flask method.

4.6.4. Shake Flask Method

Table 3: Concentration in the aqueous and n-octanol phases in the flasks:

Experiment	1A	1B	2A	2B	3A	3B
Volume of the test substance solution (ml)	10	10	10	10	10	10
Volume of n-octanol (ml)	10	10	20	20	40	40
Volume of distilled water (ml)	10	10	10	10	10	10
Total volume of the aqueous phase (ml)	20	20	20	20	20	20
Total volume of the n-octanol phase (ml)	10	10	20	20	40	40
Concentration found in n-octanol phase (g/l)	0.10	0.11	0.08	0.08	0.05	0.05
Concentration found in aqueous phase (g/l)	1.20	1.23	1.18	1.14	1.12	1.13
Mass balance (%)	98.1	100.6	98.6	96.1	95.7	96.4
pH aqueous phase (21°C)	6.8	6.8	6.4	6.2	6.9	6.8

The given values of the concentrations in the aqueous and the n-octanol phases are mean values, each of two measurements. The concentrations used for the calculation of the partition coefficient are not recovery corrected.

The concentration of the test-item in the aqueos phase was calculated with the two peaks of the test-item at about 1.9 min and at about 2.8 min which can be seen in the single runs 1A-3B (see chapter 6). There is a third peak which arises from the eluent at about 1.4 min. This peak could be seperated from the peaks of the test item and it is not further considered.

The concentration of the test-item in the n-octanol phase was calculated with the peak of the test-item at about 2.8 min. The first peak which is observed in the calibration was no more existent in the n-octanol phases 1A-3B. That is, the component causing the first peak is completely solved out in the aqueous phase.

The following partition coefficients are calculated from the measured and unrounded concentration values and not from the rounded values given in table 3.

Table 4: Partition coefficients

Experiment	P_{OW}	log P_{OW}	Average log P_{OW}
1A	0.083	-1.081	-1.072
1B	0.087	-1.062	
2A	0.065	-1.190	-1.182
2B	0.067	-1.174	
3A	0.041	-1.389	-1.387
3B	0.041	-1.385	
mean values (experiment 1A to 3B)			-1.214
Relative standard deviation (%)			13,2

Table 5: Concentrations of standards for recheck

Standard	Measured concentration (mg/l)	% Recovery (mean value)
aqueous standard 3 (c = 123.5 mg/l)	124.73*	101.0
aqueous standard 2 (c = 145.4 mg/l)	147.4*	101.4
n-octanol standard 6 (c = 6.76 mg/l)	6.96*	103.0
n-octanol standard 6 (c = 10.14 mg/l)	10.41*	102.8

*) Mean of four measurements

The recoveries of the standards range from 101.0 % to 103.0 %, indicating a good accuracy of the analytical method.

5. Final Results

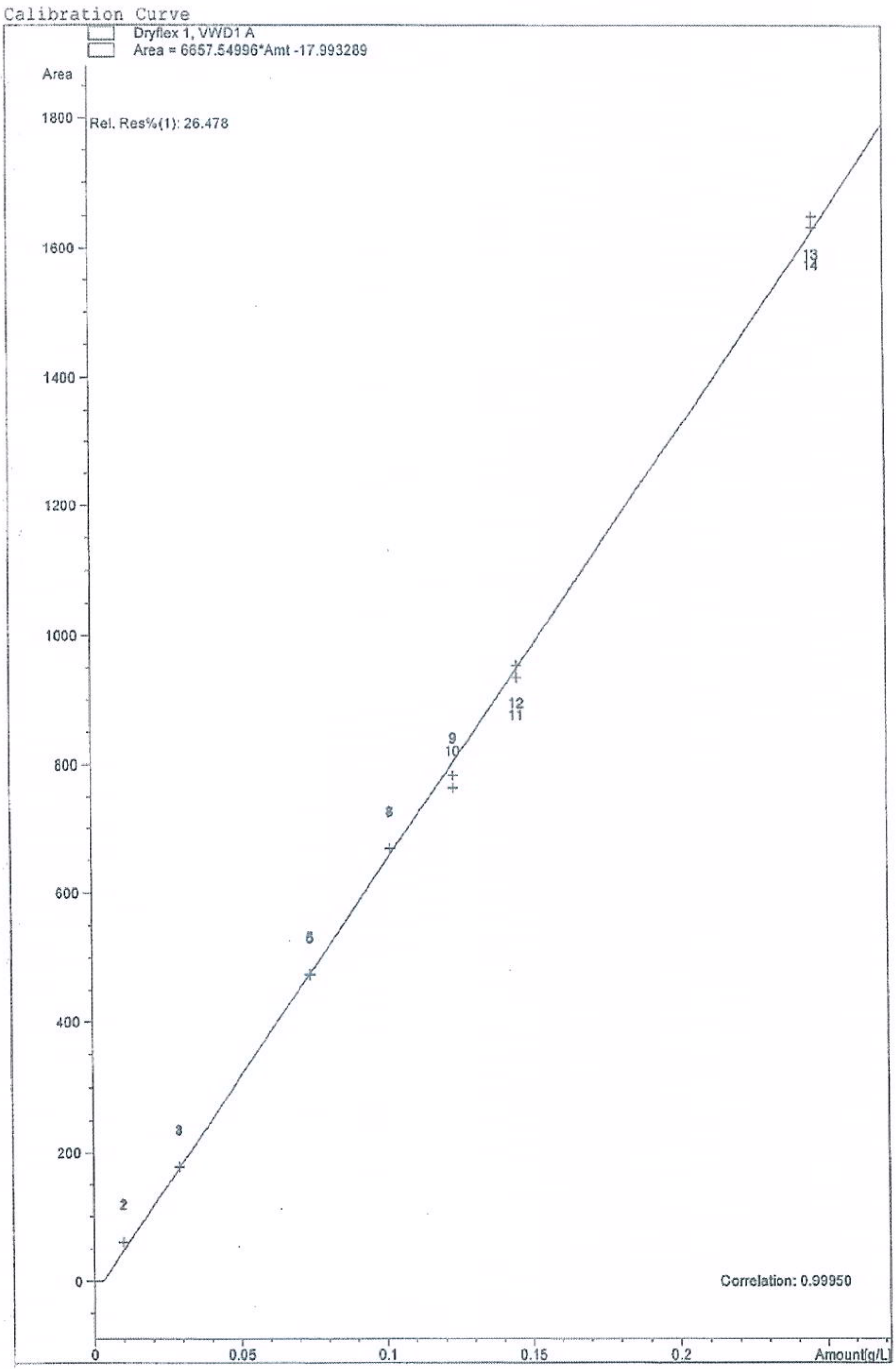
The partition coefficient n-octanol/water of the test item was determined according to the consolidated version of Guideline 67/548/EEC Annex V (Council Directive 92/69/EEC) to

log P_{OW} = -1.21
RSD = 13.2 %

6. Figures

Figure 1: Calibration for the aqueous phases

Print of window 66: Calibration Curve



Instrument 2 19.11.2008 10:19:51 D.Thomas

DP

Figure 2: HPLC-chromatogram of a blank (eluent) (measurement performed in the course of the calibration of the aqueos phase)

```
Data File C:\CHEM32\2\DATA\20080906\1811000027.D
Sample Name: Eluent

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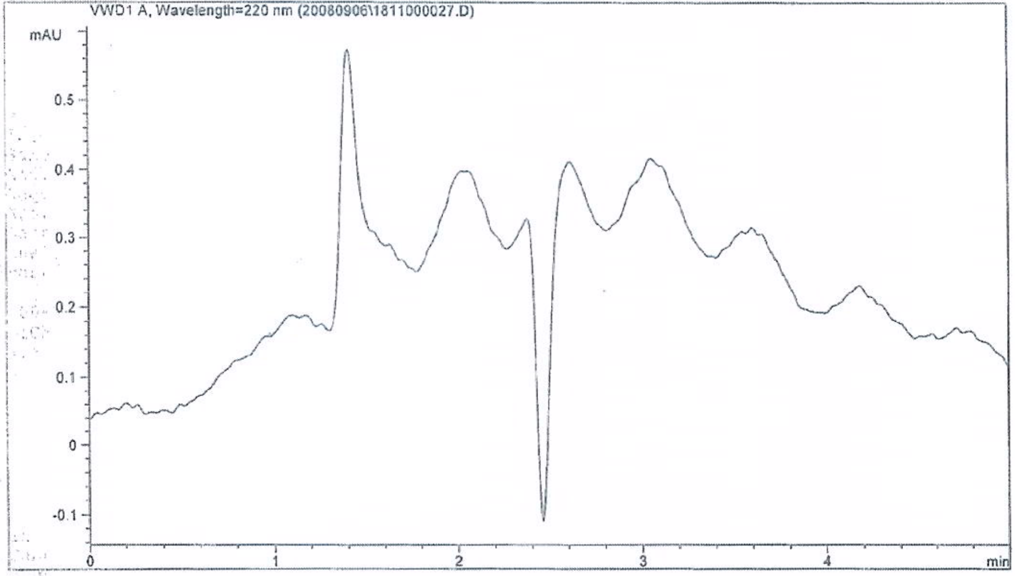
      Injection Date  : 18.11.2008 20:13:44            Seq. Line :  15
      Sample Name     : Eluent                          Location : Vial 15
      Acq. Operator   : D.Thomas                             Inj :   1
      Acq. Instrument : Instrument 2                  Inj Volume : 10 µl
      Acq. Method     : C:\CHEM32\2\METHODS-HAUS\20080906-W.M
      Last changed    : 18.11.2008 15:09:43  by D.Thomas
      Analysis Method : C:\CHEM32\2\METHODS-HAUS\20080906-O.M
      Last changed    : 17.12.2008 12:56:16  by D.Thomas
                        (modified after loading)
      20080906    A.8
      LiChrospher 100 RP18-5 EC
      4,6 x 125mm
      8103-01
      (für die Octanol-Phasen)
```



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                             Area Percent Report
      =====================================================================

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      Calib. Data Modified  :      17.12.2008 12:56:18
      Multiplier            :      1.0000
      Dilution              :      1.0000
      Use Multiplier & Dilution Factor with ISTDs


      Signal 1: VWD1 A, Wavelength=220 nm

      Peak RetTime  Type   Width     Area      Area    Name
        #   [min]          [min]   mAU   *s      %
      ----|-------|------|-------|----------|--------|---------------------
         1   0.000         0.0000    0.00000   0.0000 Dryflex 1

      Totals :                       0.00000

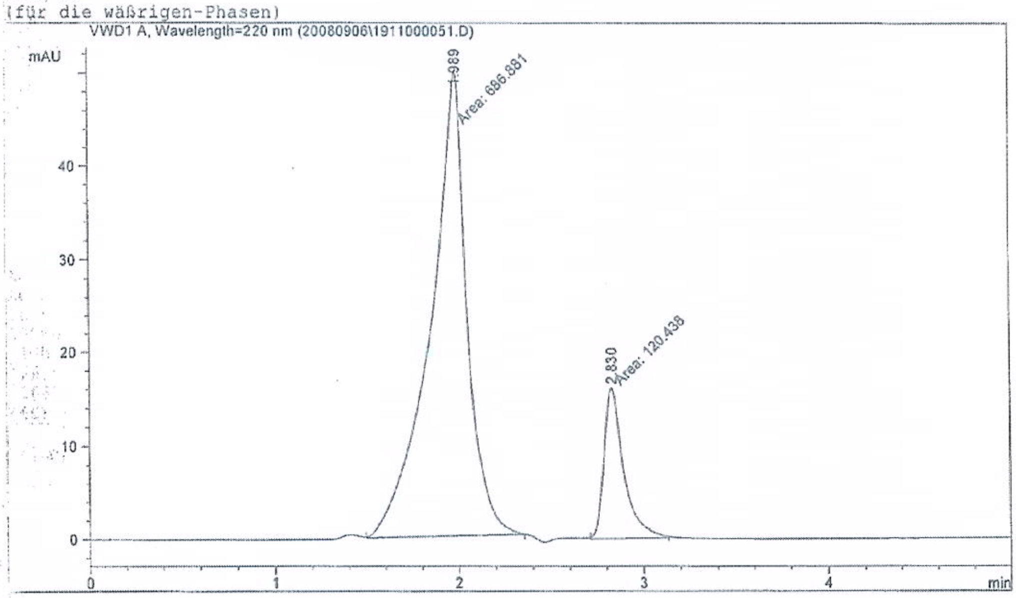

      1 Warnings or Errors :

      Warning : Calibrated compound(s) not found
      =====================================================================
                              *** End of Report ***
```

Figure 3: HPLC-chromatogram of standard 3 (c = 123.5 mg/l) (aqueous phase)

```
Data File C:\CHEM32\2\DATA\20080906\1911000051.D
Sample Name: Lösung 3 wäß-Ph.

    =====================================================================
    Injection Date  : 19.11.2008 18:21:16            Seq. Line :  28
    Sample Name     : Lösung 3 wäß-Ph.                Location : Vial 16
    Acq. Operator   : D.Thomas                             Inj :   1
    Acq. Instrument : Instrument 2                  Inj Volume : 10 µl
    Method          : C:\CHEM32\2\METHODS-HAUS\20080906-W.M
    Last changed    : 19.11.2008 10:19:27  by D.Thomas
    20080906   A.8
    LiChrospher 100 RP18-5 EC
    4,6 x 125mm
    8103-01
    (für die wäßrigen-Phasen)
```



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                           Area Percent Report
    =====================================================================

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    Calib. Data Modified :        Wednesday, 19. November 2008 10:17:50
    Multiplier           :        1.0000
    Dilution             :        1.0000
    Use Multiplier & Dilution Factor with ISTDs

    Signal 1: VWD1 A, Wavelength=220 nm

    Peak RetTime  Type   Width     Area      Area    Name
      #   [min]          [min]   mAU   *s     %
    ----|-------|------|-------|----------|--------|---------------------
       1   0.000          0.0000    0.00000   0.0000 Dryflex 1
       2   1.989 MM       0.2299  686.88098  85.0818 ?
       3   2.830 MM       0.1247  120.43781  14.9182 ?

    Totals :                      807.31879

    2 Warnings or Errors :

    Warning : Calibration warnings (see calibration table listing)
    Warning : Calibrated compound(s) not found

    =====================================================================
                            *** End of Report ***

Instrument 2 25.11.2008 08:10:22  D.Thomas                       Page    1 of 1
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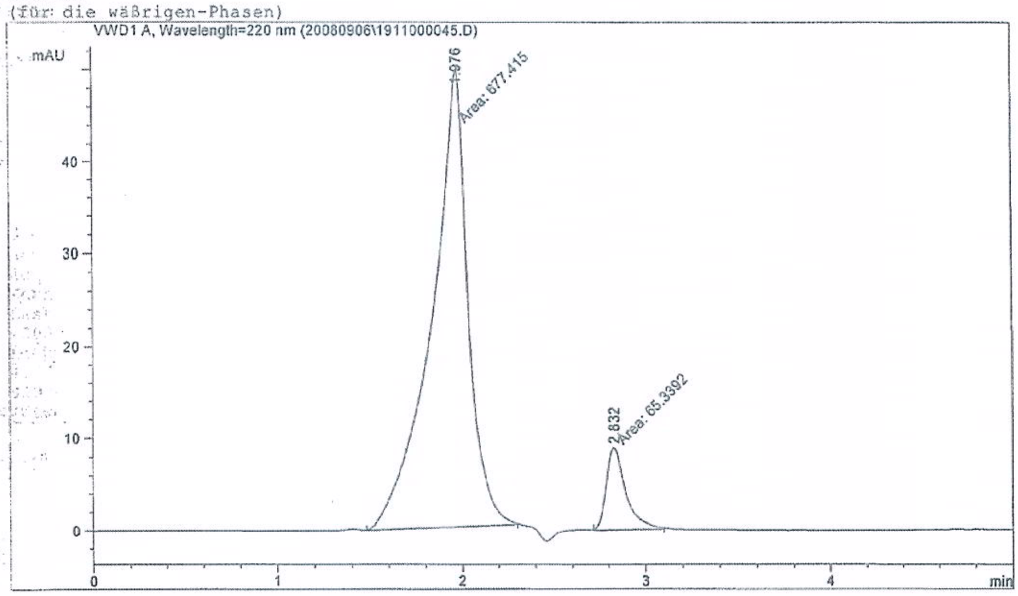
DP

Figure 4: HPLC-chromatogram of experiment 2B (aqueous phase)

```
Data File C:\CHEM32\2\DATA\20080906\1911000045.D
Sample Name: Ansatz 2B-wäßrig

    =====================================================================
    Injection Date   : 19.11.2008 17:14:48            Seq. Line :  25
    Sample Name      : Ansatz 2B-wäßrig                Location : Vial 23
    Acq. Operator    : D.Thomas                             Inj :   1
    Acq. Instrument  : Instrument 2                  Inj Volume : 10 µl
    Method           : C:\CHEM32\2\METHODS-HAUS\20080906-W.M
    Last changed     : 19.11.2008 10:19:27  by D.Thomas
    20080906   A.8
    LiChrospher 100 RP18-5 EC
    4,6 x 125mm
    8103-01
    (für die wäßrigen-Phasen)
```



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    =====================================================================
                          Area Percent Report
    =====================================================================

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    Multiplier            :      1.0000
    Dilution              :      1.0000
    Use Multiplier & Dilution Factor with ISTDs

    Signal 1: VWD1 A, Wavelength=220 nm

    Peak RetTime  Type  Width     Area      Area    Name
      #   [min]         [min]  mAU   *s      %
    ----|-------|------|-------|----------|--------|---------------------
      1   0.000         0.0000    0.00000   0.0000 Dryflex 1
      2   1.976 MM      0.2281  677.41541  91.2031 ?
      3   2.832 MM      0.1223   65.33919   8.7969 ?

    Totals :                    742.75459

    2 Warnings or Errors :

    Warning : Calibration warnings (see calibration table listing)
    Warning : Calibrated compound(s) not found
    =====================================================================
                             *** End of Report ***

Instrument 2 20.11.2008 13:29:14   D.Thomas                        Page   1 of 1
```

DP

Figure 5: Calibration for the octanol phases

Print of window 66: Calibration Curve

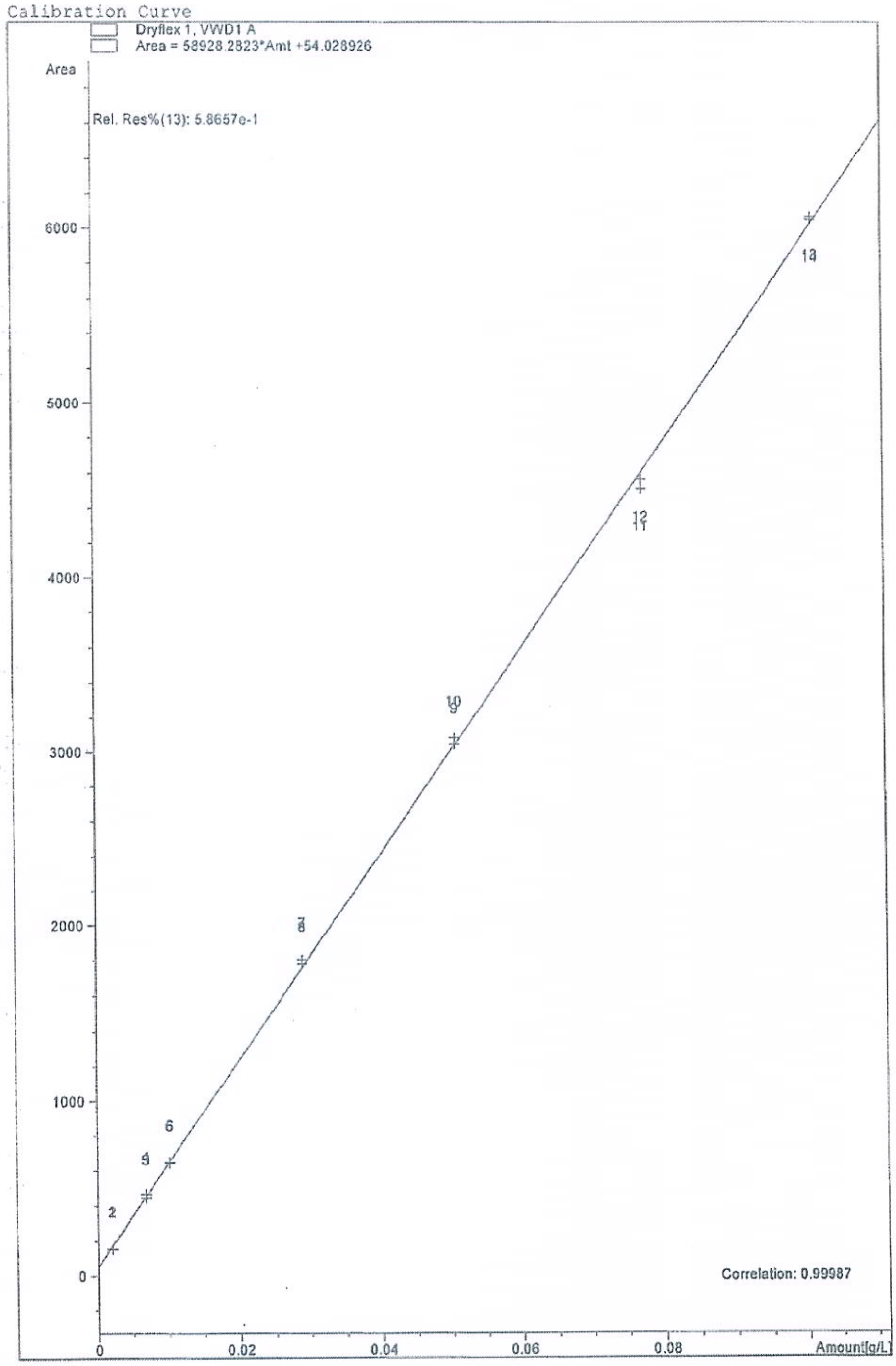
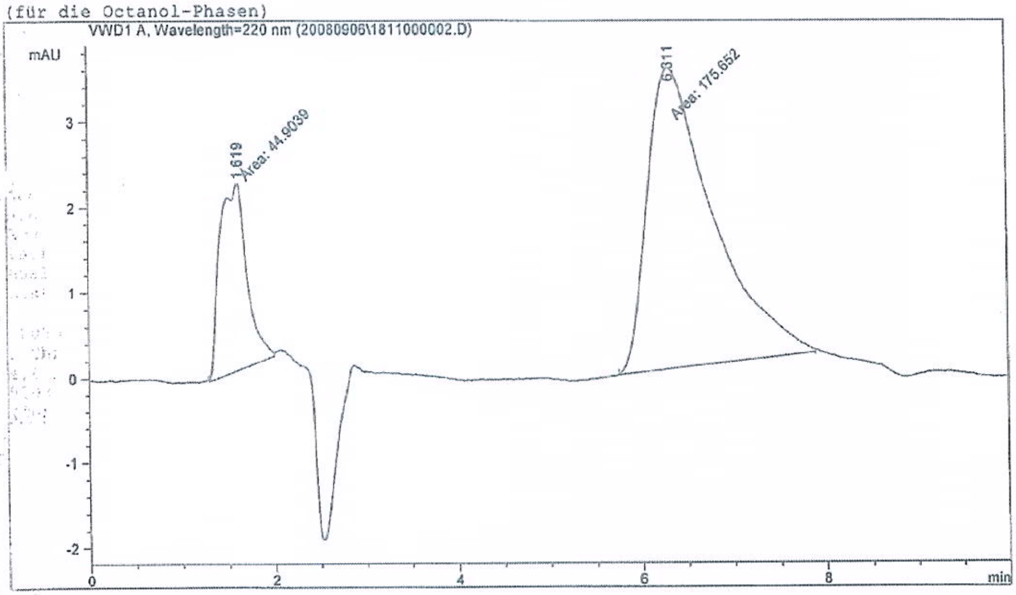


Figure 6: HPLC-chromatogram of a blank (eluent) (measurement performed in the course of the calibration of the octanol phase)

```
Data File C:\CHEM32\2\DATA\20080906\1811000002.D
Sample Name: Eluent

    Methanol/dest.H2O 60/40% (V/V)

    =====================================================================
    Injection Date  : 18.11.2008 15:23:18            Seq. Line :    1
    Sample Name     : Eluent                          Location : Vial 1
    Acq. Operator   : D.Thomas                             Inj :    2
    Acq. Instrument : Instrument 2                  Inj Volume : 100 µl
    Acq. Method     : C:\CHEM32\2\METHODS-HAUS\20080906-O.M
    Last changed    : 18.11.2008 15:06:27  by D.Thomas
    Analysis Method : C:\CHEM32\2\METHODS-HAUS\20080906-O.M
    Last changed    : 19.11.2008 09:31:33  by D.Thomas
                      (modified after loading)
    20080906    A.8
    LiChrospher 100 RP18-5 EC
    4,6 x 125mm
    8103-01
    (für die Octanol-Phasen)
```



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    =====================================================================

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    Multiplier             :      1.0000
    Dilution               :      1.0000
    Use Multiplier & Dilution Factor with ISTDs


    Signal 1: VWD1 A, Wavelength=220 nm

    Peak RetTime Type  Width     Area      Area    Name
      #   [min]        [min]  mAU   *s      %
    ----|-------|------|-------|----------|--------|---------------------
       1   1.619 MM     0.3422   44.90394  20.3594 ?
       2   1.900        0.0000    0.00000   0.0000 Dryflex 1
       3   6.311 MM     0.8297  175.65219  79.6406 ?

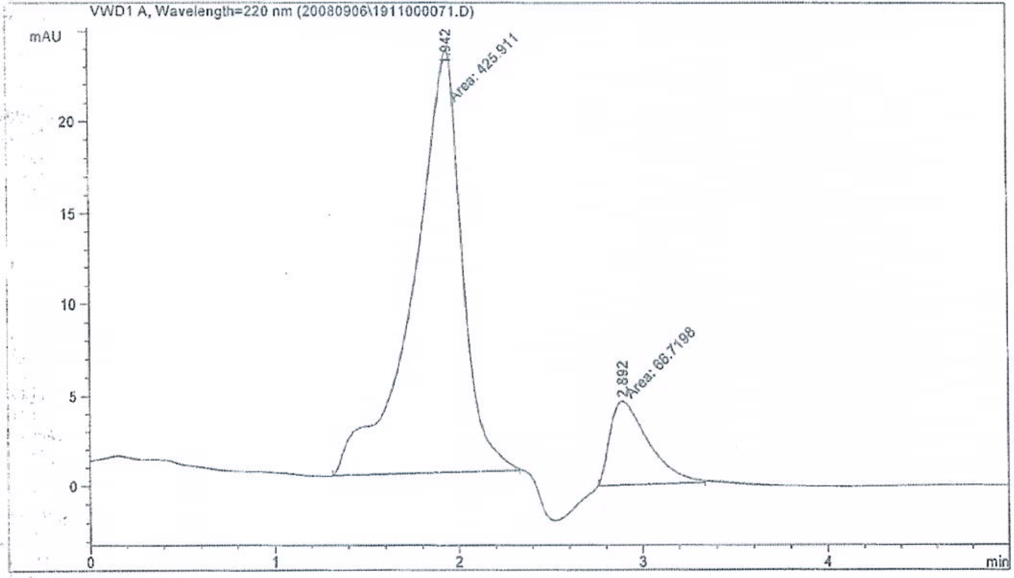
    Totals :                    220.55613

    1 Warnings or Errors :
```

Figure 7: HPLC-chromatogram of standard 6 (c = 6.76 mg/l) (octanol phase)

```
Data File C:\CHEM32\2\DATA\20080906\1911000071.D
Sample Name: Lösung 6 Oct-Ph.

    =====================================================================
    Injection Date   : 19.11.2008 22:17:11          Seq. Line :   38
    Sample Name      : Lösung 6 Oct-Ph.              Location : Vial 3
    Acq. Operator    : D.Thomas                          Inj :    1
    Acq. Instrument  : Instrument 2                 Inj Volume : 100 µl
    Method           : C:\CHEM32\2\METHODS-HAUS\20080906-O.M
    Last changed     : 19.11.2008 10:24:47  by D.Thomas
    20080906   A.8
    LiChrospher 100 RP18-5 EC
    4,6 x 125mm
    8103-01
    (für die Octanol-Phasen)
```



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                          Area Percent Report
    =====================================================================

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    Multiplier               :      1.0000
    Dilution                 :      1.0000
    Use Multiplier & Dilution Factor with ISTDs


    Signal 1: VWD1 A, Wavelength=220 nm

    Peak RetTime  Type   Width     Area      Area    Name
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    ----|-------|------|-------|----------|--------|---------------------
       1   0.000         0.0000    0.00000   0.0000 Dryflex 1
       2   1.942 MM      0.3064  425.91077  86.4564 ?
       3   2.892 MM      0.2398   66.71983  13.5436 ?

    Totals :                     492.63059

    2 Warnings or Errors :

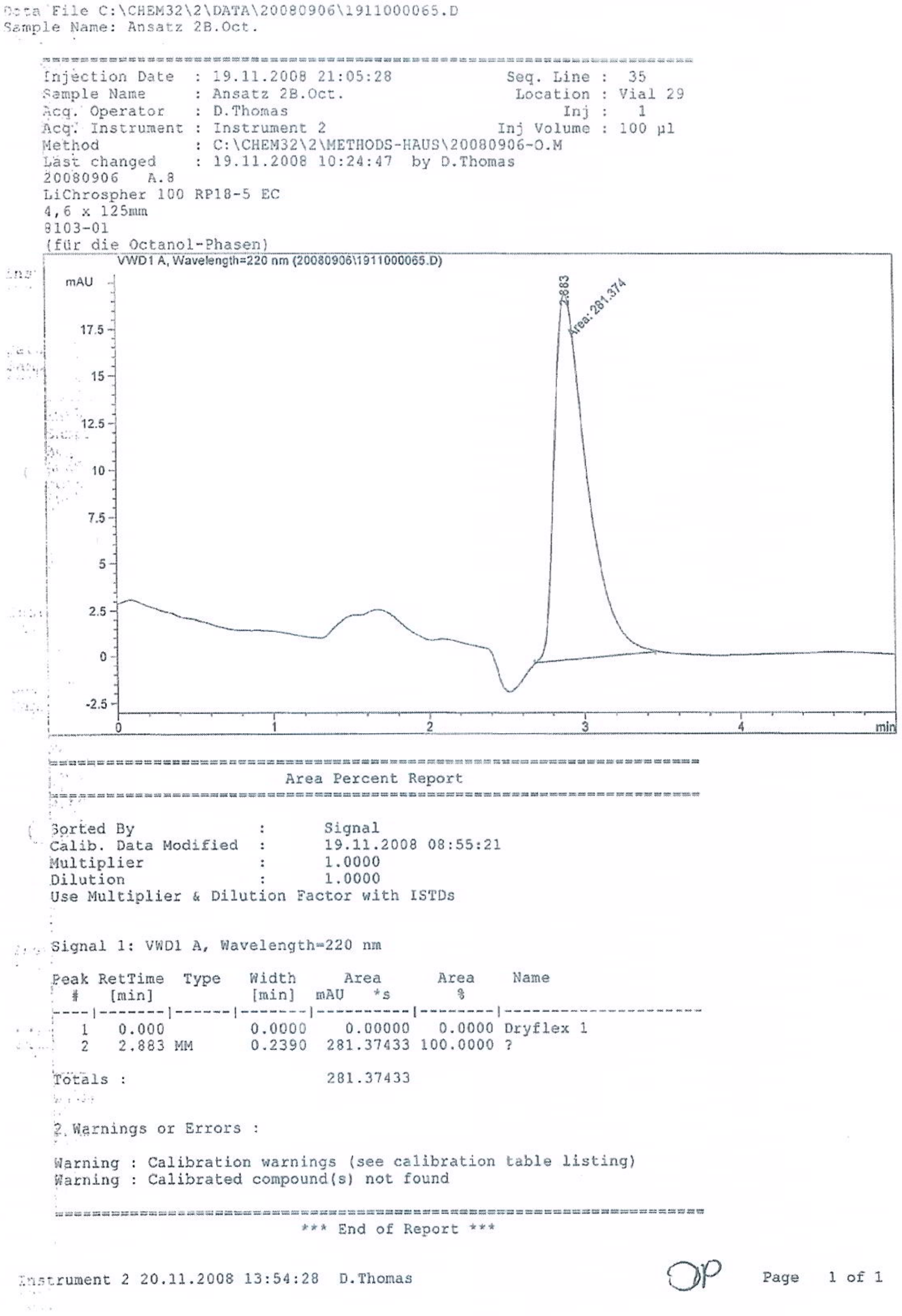
    Warning : Calibration warnings (see calibration table listing)
    Warning : Calibrated compound(s) not found

    =====================================================================
                          *** End of Report ***

Instrument 2 25.11.2008 09:32:12  D.Thomas                          Page   1 of 1
```

DP

Figure 8: HPLC-chromatogram of experiment 2B (octanol phase)



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Data File C:\CHEM32\2\DATA\20080906\1911000065.D
Sample Name: Ansatz 2B.Oct.

     =====================================================================
     Injection Date   : 19.11.2008 21:05:28            Seq. Line :  35
     Sample Name      : Ansatz 2B.Oct.                  Location : Vial 29
     Acq. Operator    : D.Thomas                             Inj :   1
     Acq. Instrument  : Instrument 2                  Inj Volume : 100 µl
     Method           : C:\CHEM32\2\METHODS-HAUS\20080906-O.M
     Last changed     : 19.11.2008 10:24:47  by D.Thomas
     20080906   A.8
     LiChrospher 100 RP18-5 EC
     4,6 x 125mm
     8103-01
     (für die Octanol-Phasen)
```

```
     =====================================================================
                          Area Percent Report
     =====================================================================

     Sorted By             :      Signal
     Calib. Data Modified  :      19.11.2008 08:55:21
     Multiplier            :      1.0000
     Dilution              :      1.0000
     Use Multiplier & Dilution Factor with ISTDs

     Signal 1: VWD1 A, Wavelength=220 nm

     Peak RetTime Type  Width     Area      Area    Name
       #   [min]        [min]  mAU   *s      %
     ----|-------|------|-------|----------|--------|---------------------
        1   0.000        0.0000    0.00000   0.0000 Dryflex 1
        2   2.883 MM     0.2390  281.37433 100.0000 ?

     Totals :                    281.37433

     2 Warnings or Errors :

     Warning : Calibration warnings (see calibration table listing)
     Warning : Calibrated compound(s) not found

     =====================================================================
                           *** End of Report ***

Instrument 2 20.11.2008 13:54:28   D.Thomas                        Page   1 of 1
```

OP

7. Appendix

Personnel involved in the study: Mrs. D. Thomas

Signatures:

Date: 20.01.2009

Signature of the study director: T. Wielpütz

(Dr. T. Wielpütz)

Date: 20.01.2009

Signature of the head of the test facility:

(Dr. J. Franke)