

Study Title

Water solubility of Niobium

DATA REQUIREMENT

REACH requirement EC/1907/2006

AUTHOR

Dr Andreas Königer

STUDY COMPLETION DATE:

2009-09-01

PERFORMING LABORATORY

CURRENTA GmbH & Co. OHG
Services Analytik
D-51368 Leverkusen
Federal Republic of Germany

SPONSOR

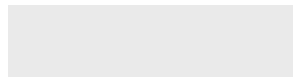
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LABORATORY PROJECT ID

Study No. 2009/0073/01



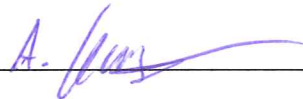
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1. **Statement of compliance with GLP (SOC) Claim**

This study was conducted in compliance with the OECD principles of Good Laboratory Practice (GLP, as revised in 1997) and with the Principles of Good Laboratory Practice according to Annex 1, German Chemical Law (Änderung des Anhangs 1 vom 8.Mai 2001).

STUDY DIRECTOR
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Services Analytik
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Dr Andreas Königler:



Date:

2009-09-01

FOR THE HEAD OF TEST FACILITY

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Federal Republic of Germany

Prof. Dr Caspers /
~~Dr Kreiss /~~
~~Dr Richter:~~



Date:

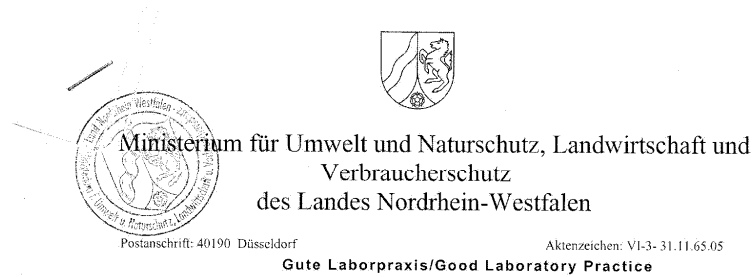
2009-09-02

2. **Archiving**

The original report, the study plan and all raw data pertaining to this study are stored in the "GLP Archiv, Services Analytik, Building Q 18, Currenta GmbH & Co. OHG, D-51368 Leverkusen". A sample of the test item is stored in "GLP-Probenlager, Services Analytik, Building DA 1, Currenta GmbH & Co. OHG, D-41538 Dormagen".

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3. GLP CERTIFICATE



Ministerium für Umwelt und Naturschutz, Landwirtschaft und
Verbraucherschutz
des Landes Nordrhein-Westfalen

Postanschrift: 40190 Düsseldorf

Aktenzeichen: VI-3- 31.11.65.05

Gute Laborpraxis/Good Laboratory Practice

GLP-Bescheinigung/Statement of GLP Compliance
(gemäß/according to § 19b Abs. 1 Chemikaliengesetz)

Eine GLP-Inspektion zur Überwachung der Einhaltung der GLP-Grundsätze gemäß Chemikaliengesetz bzw. Richtlinie 88/320/EG wurde durchgeführt in: Assessment of conformity with GLP according to Chemikaliengesetz and Directive 88/320/EEC at:

Prüfeinrichtung/Test facility Prüfstandort/Test site

Bayer Industry Services GmbH & Co OHG

Prüfeinrichtung BIS-SUA-Analytics

D-51368 Leverkusen

(unverwechselbare Bezeichnung und Adresse/Unequivocal name and address)

Prüfungen nach Kategorien

(gemäß ChemVwV-GLP Nr. 5.3/OECD guidance)

Kategorie 1

Prüfungen zur Bestimmung der physikalisch-chemischen Eigenschaften und Gehaltsbestimmungen

Kategorie 4

Ökotoxikologische Prüfungen zur Bestimmung der Auswirkungen auf aquatische und terrestrische Organismen

Kategorie 5

Prüfungen zum Verhalten im Boden, im Wasser und in der Luft; Prüfungen zur Bioakkumulation und zur Metabolisierung

Kategorie 8

Analytische Prüfungen an biologischen Materialien

Areas of Expertise

(according ChemVwV-GLP Nr. 5.3/OECD guidance)

category 1

physical-chemical testing

category 4

environmental toxicity studies on aquatic and terrestrial organisms

category 5

studies on behaviour in water, soil and air; bioaccumulation

category 8

analytical and clinical chemistry testing

Datum der Inspektion

(Tag, Monat, Jahr)

14. bis 16. September
und 26. bis 28. Oktober 2005

Die genannte Prüfeinrichtung befindet sich im nationalen GLP-Überwachungsverfahren und wird regelmäßig auf Einhaltung der GLP-Grundsätze überwacht.

Auf der Grundlage des Inspektionsberichtes wird hiermit bestätigt, dass in dieser Prüfeinrichtung die oben genannten Prüfungen unter Einhaltung der GLP-Grundsätze durchgeführt werden können.

Date of Inspection

(day, month, year)

on 14 until 16 September and on 26 until 28
October 2005

The above mentioned test facility is included in the national GLP Compliance Programme and is inspected on a regular basis.

Based on the inspection report it can be confirmed, that this test facility is able to conduct the aforementioned studies in compliance with the Principles of GLP.

Düsseldorf, den 11. Januar 2006
Im Auftrag

(Prof. Dr. David)



Dienstsiegel/official-seal

Please note: Effective January 1st, 2008, the company name Bayer Industry Services GmbH & Co. OHG was changed to CURRENTA GmbH & Co. OHG.

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4. Quality Assurance Statement

This report was audited by the Quality Assurance Unit Currenta, Services Analytik, Quality Management at Currenta GmbH & Co. OHG and this statement confirms that the final report reflects the raw data. The dates of Quality Assurance inspections and audits are given below.

Audits	Dates of QAU Inspections	Dates of Reports
Study plan inspection	2009-07-23	2009-07-23
Inspection of experimental phase	2009-04-20*	2009-04-20*
Report inspection	2009-09-02	2009-09-02

* Process based inspection

FOR THE HEAD OF QUALITY ASSURANCE

Ms D.I. Senic /
~~Dr Doerzbach-Lange /~~
~~Dr Neupert:~~

A. Senic

Date:

2009-09-02

5. Study Time Table

Study initiation date:	2009-07-23
Study completion date:	2009-09-01
Start of Experimental Tests:	2009-07-27
End of Experimental Tests:	2009-08-14

6. Summary

Report: Dr Andreas Königer: Water solubility of Niobium; Currenta, report no.: 2009/0073/01

Guidelines: The test was performed according to OECD Guidelines for Testing of Chemicals, Section 1 – Physical-Chemical Properties OECD TG 105 (1995)

Deviation from Guidelines: No

GLP: Yes (certified laboratory)

Time of experimental tests: 2009-07-31 - 2009-08-14

Materials and Determinations: With Niobium, batch no.: AD/4202, purity >98.5 %, the water solubility was determined for niobium.

Due to the expected insolubility of the test item (niobium metal) in water no preliminary test was performed. Three tests with each approx. 1 g of the sample in 1 l deionized water (Millipore water) and a blank test were performed. The content of niobium was determined by ICP-MS.

Results:

The solubility of the test item in water at 20 °C is below the limit of quantification (LOQ) which is 0.5 µg/l water. The pH-value was 6.0.

Blank values	Determination 1	Determination 2	Mean value
Niobium content	< 0.5 µg/l	< 0.5 µg/l	< 0.5 µg/l
pH-value	6.02	--	6.0

Water solubility at 20 °C	Flask 1	Flask 2	Flask 3	Mean value
Niobium content (Determination 1 Determination 2)	< 0.5 µg/l < 0.5 µg/l	< 0.5 µg/l < 0.5 µg/l	< 0.5 µg/l < 0.5 µg/l	< 0.5 µg/l
pH-value	5.94	5.95	5.96	6.0

The limit of quantification (LOQ) for this determination is 0.5 µg/l.

7. **Methods and Documents**

The determination of the water solubility was based on the following guidelines:

Currenta-internal SOP 00190 Version 1, covering OECD TG 105 (1995).

Currenta-internal SOP 00178 Version 2 for the determination of the pH-value.

Currenta-internal method 2011-0366401-92D: Determination of niobium by ICP-MS technique.

8. **Sample description**

Product name:	Niobium	Chemical name:	Niobium
Empirical formula:	Nb	Molecular mass:	92.9 g/mol
CAS-No:	7440-03-1	Batch No.:	AD/4202
Content:	> 98.5 %	Expiry date:	2010-01-21
Arrival at test site:	2009-07-21	Sample no./year:	997/2009

9. **Test Methods**

9.1 The determination of the water solubility by the flask method.

9.1.1 Preparation of the test solutions

SOP: 00190 Version 1 (water solubility)
This procedure corresponds to test method OECD 105 for the determination of the water solubility.

Supervisor: Dr Königer

Procedure:

Due to the expected insolubility of the test item (niobium metal) in water no preliminary test was performed. Three tests with each approx. 1 g of the sample in 1 l deionized water (Millipore water) and a blank test were performed. The content of niobium was determined by ICP-MS.

Approx. 1 g of the test item granules were weight each into stoppered glass bottles and agitated on a magnetic stirrer for 24h, 48h and 72h, respectively, at 30 °C in a thermostatted water bath. Following this procedure, the temperature is reduced to 20 °C and the bottles were kept in the thermostatted water bath for another 24h. After phase separation by filtering through a membrane filter (0.45 µm) the concentration of niobium was determined by ICP-MS.

A blank test with water was also performed.

Agitating time for the test at 20 °C: Flask 1 : 72 hours at 30 °C and 24 hours at 20 °C
Flask 2 : 48 hours at 30 °C and 24 hours at 20 °C
Flask 3 : 24 hours at 30 °C and 24 hours at 20 °C

Test concentrations

	Flask 1	Flask 2	Flask 3
Initial weight [g]	1.01	1.02	1.01
Volume of water [ml]	1000	1000	1000

9.1.2 Analysis of the test solutions

9.1.2.1 Test: pH measurement

SOP: SOP 00178 Version 2

Supervisor: Dr. Königer

Description of the method: After phase separation of the test mixtures the determination of the pH-value was performed with a pH-meter with single-rod glass electrode after previous calibration.

9.1.2.2 Test: Content of niobium by ICP-MS

Method no.: 2011-0366401-92D

Supervisor: Dr Schweer

Procedure: ICP-MS

The aqueous solutions were acidified with hydrofluoric acid and determined by ICP-MS using rhodium as internal standard.

9.1.3 Results

Blank values	Determination 1	Determination 2	Mean value
Niobium content	< 0.5 µg/l	< 0.5 µg/l	< 0.5 µg/l
pH-value	6.02	--	6.0

Water solubility at 20 °C	Flask 1	Flask 2	Flask 3	Mean value
Niobium content (Determination 1 Determination 2)	< 0.5 µg/l < 0.5 µg/l	< 0.5 µg/l < 0.5 µg/l	< 0.5 µg/l < 0.5 µg/l	< 0.5 µg/l
pH-value	5.94	5.95	5.96	6.0

The limit of quantification (LOQ) for this determination is 0.5 µg/l.