

30 September 2013

FINAL REPORT

(SUMMARY)

READY BIODEGRADABILITY
DOC DIE-AWAY TEST
OECD GUIDELINE: METHOD 301 A
TEST ITEM: NOVACLINE B2

SPONSOR

CHEMICALS NETWORK FRANCE
Port de Gennevilliers
1 Route du Bassin N° 5
92230 GENNEVILLIERS
FRANCE

TEST FACILITY

INERIS
Parc Technologique ALATA
BP 2
60550 VERNEUIL-EN-HALATTE
FRANCE

ACCEPTANCE OF THE FINAL REPORT

The Test Facility of INERIS and tests it carries out in domains 2, 4, 5 and 8 (toxicity studies ; environmental toxicity studies on aquatic and terrestrial organisms, and studies on behaviour in water, soil and air; bioaccumulation; analytical and clinical chemistry testing) are recognised by the "Groupe Interministériel des Produits Chimiques" (GIPC), in compliance with the principles relating to the OECD Good Laboratory Practice (GLP) included - "Article Annexe II à l'Article D523-8 du Code de l'Environnement du 16 octobre 2007 concernant les bonnes pratiques de laboratoire reprenant le décret n° 2006-1523 du 4 décembre 2006 qui modifiait le décret n° 81-278 du 25 mars 1981 portant création d'un groupe interministériel des produits chimiques".

We, the undersigned, certify that the results described in this report have been obtained by ourselves or under our responsibility; we also certify that this report is an accurate and reliable account of the ready biodegradability test obtained for the test item in respect of Good Laboratory Practices.

Study Director:

F. GONDELLE

Date: 30/09/2013



We, the undersigned, have reviewed this report and accept its contents.

Head of test facility:

E. THYBAUD

Date: 30/09/13



GLP CERTIFICATE OF THE TEST FACILITY



GRUPE INTERMINISTERIEL DES PRODUITS CHIMIQUES

CERTIFICAT DE CONFORMITE AUX BONNES PRATIQUES DE LABORATOIRE
SELON LES DIRECTIVES 2004/9/CE ET 2004/10/CE
CERTIFICATE OF COMPLIANCE WITH GOOD LABORATORY PRACTICES ACCORDING
TO DIRECTIVES 2004/9/CE AND 2004/10/CE

Certificat n°: 2013/32

Société ou organisme : INERIS - Parc technologique Alata – BP 2
Company : 60550 VERNEUIL EN HALATTE
Installation d'essais : INERIS - Parc technologique Alata – BP 2
Test facilities : 60550 VERNEUIL EN HALATTE

Vu les articles D.523-8 et suivants du code de l'environnement relatifs au groupe interministériel des produits chimiques,
Having regard to the articles D.523-8 and onwards relating to the interministerial group of chemical products (GIPC),

Vu les résultats de l'inspection périodique et d'extension réalisée par le Comité français d'accréditation (COFRAC) - Section Laboratoires – le : 22 au 24 janvier 2013
Having regard to the results of the periodic and extension inspection realised by the French Committee of accreditation (COFRAC) – Laboratory Section – on the : 22 an to 24 January 2013

Vu l'avis du GIPC en date du : 31 mai 2013
Having regard to the GIPC's opinion dated : 31 May 2013

La conformité aux principes des BPL de l'installation précitée est reconnue dans les domaines suivants :
Compliance with the principles of GLP is recognized for the facility above in the following areas:

- 2 - études de toxicité (*toxicity testing*)
- 4 - études écotoxicologiques sur les organismes aquatiques et terrestres (*environmental toxicity studies on aquatic and terrestrial organisms*)
- 5 - études portant sur le comportement dans l'eau, dans le sol et dans l'air ; bioaccumulation (*studies on behaviour in water, soil and air; bioaccumulation*)
- 8 - méthodes de chimie analytique et cliniques (y compris métabolisme) (*analytical and clinical chemistry testing*)

Fait à Ivry, le 19 JUIN 2013
Le Président,


Jean-Marc GROGNET

Secrétariat général du GIPC - DGCIS- SI – 67, rue Barbès – 94201 Ivry-sur-Seine CEDEX
Téléphone : 01 79 84 96 10 –
Adresse mail : gipc.dgcis@finances.gouv.fr


MINISTÈRE DU REDRESSEMENT
PRODUCTIF

QUALITY ASSURANCE STATEMENT (QAS) Study N° 13-010-139060

The Quality Assurance Programme of INERIS is defined as follows :


The Inspections of the Test Facility (II) are classed as Internal Inspections and are performed by Quality Assurance Inspectors between two Inspections of the National GLP Monitoring Authority. These Internal Inspections are carried out according to the schedule drawn up by the Quality Metrology Unit approved by INERIS Management. The maximum duration between two Internal Inspections does not exceed 24 months.

The audit of the studies (SA) in progress are scheduled by the Quality Assurance personnel in charge of the study designated by the Test Facility Management (TFM) with regards to the subject of the study, the Quality Assurance personnel inspects the deciding phases of the study or refers to the audit of a similar study previously performed.

The Quality Assurance personnel attests, by this Q A S, that the results reported in the Final Report (FR) accurately reflect the raw data of the study.

In the following table, the Quality Assurance personnel confirms that the inspections were carried out on the dates noted (Inspection) and the dates that any findings were reported to the Study Director (SD) and to the Test Facility Management (TFM) are those noted.

Object	Inspection	SD	TFM
II	August 31 th , 2012	-	December 6 th , 2012
SA	June 4 th , 2013	June 6 th , 2013	June 10 th , 2013
FR	September 2 nd , 2013	September 2 nd , 2013	September 3 rd , 2013

Verneuil en Halatte: 30/09/2013
Quality Assurance personnel: Pucheux Nicolas
Signature: 

TEST PURPOSE

This test aims at assessing the "ultimate" biodegradability of an organic compound in an aqueous mineral under aerobic conditions, by analysis of dissolved organic carbon removed, according to the test procedure described in the OECD Guideline for testing of chemicals 301 A, in conformity with the clauses recommended in the study plan of 22 May 2013, signed on 24 May 2013.

TEST PURPOSE

This test aims at assessing the "ultimate" biodegradability of the test item: **NOVACLINE B2** in an aqueous mineral under aerobic conditions, by analysis of dissolved organic carbon removed.

The biodegradation process was followed normally over 28 days incubation time by determination of DOC. The ratio eliminated DOC was expressed as the degradation at each sampling time.

TEST METHOD

OECD Guideline for testing of chemicals 301 A: "DOC Die-away Test" (17 July 1992)

TEST ITEM

NOVACLINE B2

TEST CONCENTRATION

25 mg/L as dissolved organic carbon (DOC)

REFERENCE ITEM

Aniline (25 mg/L DOC)

INOCULUM

Prepared from activated sludge from a sewage treatment works (Domestic sewage).

DURATION

28 days

RESULTS

- % degradation (Dt (DOC)):

Incubation time	NOVA CLINE B2		Aniline
	FE 1 25 mg C/L	FE 2 25 mg C/L	25 mg C/L
7 days	72.6	71.8	94.5
14 days	75.0	77.3	94.3
28 days	91.3%	86.8%	95.9%
	Mean: 89.1%		

The biodegradation of the test item has begun very quickly (adaptation phase less than 1 day) and has been reached 72.2% after only 7 days of incubation.

The pass level for ready biodegradability, 70% removal of DOC, has therefore been reached in a 10-d window within the 14-d period of test and others criteria for good evidence of “ready biodegradability” were also reached in test conditions.

So, the test item NOVA CLINE B2 can be considered as readily biodegradable, according to the OECD Guideline 301 for the testing of chemicals.