Study N° 23025

Pourability / rinsability and persistent foaming of PMV-01

REPORT

10.2.e

Study Director : [redacted]
Project : DE CEUSTER / FO 23025 / Ch.5385 / 2012 / A
Study starting : September 11, 2012
Study completion : October 04, 2012

TEST FACILITY
Centre wallon de Recherches agronomiques
Département Agriculture et Milieu naturel
Unité Physico-chimie et Résidus des Produits Phytopharmaceutiques et des Biocides
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Centre wallon de Recherches agronomiques

Wallonie

10.2.e

Authenticity and confidentiality statement

Study plan number : 23025.

Project : DE CEUSTER / FO 23025 / Ch.5385 / 2012 / A.

Test item : PMV-01.

Study director : [redacted]

Study title : Pourability / rinsability and persistent foaming of PMV-01.

We, the undersigned, hereby declare that the work described in this report was performed under our supervision in accordance with the agreed study plan, and that the report provides a true and accurate record of the results obtained.

The information contained in this report is confidential and must not be discussed without the written consent of De Ceuster N.V.
The Plant Protection Products and Biocides Physico-chemistry and Residues Unit of CRA-W undertakes not to disclose any of the results, work practices or functions of De Ceuster N.V. conveyed to the Plant Protection Products and Biocides Physico-chemistry and Residues Unit of CRA-W during the course of this study.

5030 - GEMBLOUX, October 04, 2012.

[redacted]
Study director.

[redacted]
Scientific unit coordinator.

cra-w

10.2.e

Statement of GLP compliance

Study plan number : 23025.

Project : DE CEUSTER / FO 23025 / Ch.5385 / 2012 / A.

Test item : PMV-01.

Study director [redacted]

Study title : Pourability / rinsability and persistent foaming of PMV-01.

This study was performed in compliance with the OECD Principles of Good Laboratory Practice.
The Plant Protection Products and Biocides Physico-chemistry and Residues Unit of CRA-W has been certified for GLP compliance since October 1994.

Exempted from GLP are the following data and activities:
- Active substance content.

October 04, 2012.

[redacted]
Study director.

cra-w

10.2.e

Statement of Quality Assurance

Study plan number : 23025.

Project : DE CEUSTER / FO 23025 / Ch.5385 / 2012 / A.

Test item : PMV-01.

Quality assurance : [redacted]

Study title : Pourability / rinsability and persistent foaming of PMV-01.

The following inspections have been carried out in relation to this study :

Quality control	Date of inspection	Date reported to study director	Date reported to test facility manager
Study plan	September 11, 2012	September 11, 2012	September 11, 2012
Critical phases CIPAC MT 148	September 13, 2012	September 13, 2012	September 18, 2012
Raw data and draft report	September 17, 2012	September 17, 2012	September 18, 2012
Report	October 04, 2012	October 04, 2012	October 04, 2012

In addition the repetitive procedures and analytical methods are covered by process based inspections and were inspected within the framework of other similar GLP studies.

Similarly an inspection of the facility where this study was conducted was carried out on an annual basis.

I, Quality Assurance Inspector, hereby declare that the work described in this report is in accordance with the agreed study plan, and that the results in the report totally and accurately reflect the raw data.

October 04, 2012.

cra-w

[redacted]

Table of contents

Summary of results

10.1.c Wob juncto 63.2.d Vo 1107/2009

Test item : **PMV-01.**

Type of formulation : suspension concentrate (SC).

Active substance content (nominal concentration) : [redacted] Pepino mosaic virus, CH2 strain, isolate 1906.

Batch number : [redacted]

Manufacturing date : [redacted]

Expiry date : [redacted]

10.1.c Wob juncto 63.2.a Vo 1107/2009 juncto 39.2.a Vo 178/2002

Tests	Methods	Results
Pourability / rinsability	CIPAC MT 148	
Residue		**0.43 %**
Rinsed residue		**0.23 %**
Persistent foaming in CIPAC water D Temperature : 30°C ± 2°C Concentration : 5 % v/v	CIPAC MT 47.2	
after 10 seconds		**0 mL**
after 1 minute		**0 mL**
after 3 minutes		**0 mL**
after 12 minutes		**0 mL**

General information

Guidelines :
- EU legislation concerning pesticide technical and formulated products and more particularly :
  - Directive 91/414/EEC
  - Directive 2001/36/EC of May 16, 2001 amending the directive 91/414/EEC concerning the placing of plant protection products on the market
  - Directive 94/37/EC
  - Commission Regulation (EU) No. 545/2011 of June 10, 2011 implementing Regulation (EC) No. 1107/2009 of the European Parliament and of the Council as regards the data requirements for plant protection products
  - Draft working document concerning the data requirements for active substances of plant protection products made from plants or plant extracts – SANCO/10472/2003 rev.5 (July 06, 2004)
- Manual on the development and use of FAO and WHO specifications for pesticides, second revision of the first edition, 2010, Rome.
- CIPAC methods recommended by EU, FAO and WHO.
- Standard Operating Procedures and methods from the Plant Protection Products and Biocides Physico-chemistry and Residues Unit of the Walloon Agricultural Research Centre (CRA-W).

Sponsor : **De Ceuster N.V.**
Fortsesteenweg 30
2860 Sint-Katelijne-Waver
BELGIUM

Study monitor : [redacted]
DCM - De Ceuster Meststoffen n.v.
Bannerlaan 79
2280 Grobbendonk
BELGIUM
Phone : [redacted]
Fax : [redacted]
E-mail [redacted]@dcm-info.com

Study director : [redacted]
Walloon Agricultural Research Centre (CRA-W)
Agriculture and Natural Environment Department (D3)
Plant Protection Products and Biocides
Physico-chemistry and Residues Unit (U10)
Carson Building
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Quality Assurance : [redacted]
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Agriculture and Natural Environment Department (D3)
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Phone [redacted]
Fax : [redacted]
E-mail [redacted]@cra.wallonie.be

Technical personnel [redacted]

Secretariat : [redacted]

Archivist : [redacted]

Time schedule : Study plan
- signed by the study director on September 11, 2012.
- signed by the study monitor on September 14, 2012.

Analysis on the test item as received
- from September 12 until September 13, 2012.

Archives : All the documentation relating to this study will be kept under the test item number in the archives of the Plant Protection Products and Biocides Physico-chemistry and Residues Unit of the Walloon Agricultural Research Centre (CRA-W), presently located at 11, rue du Bordia, B - 5030 - GEMBLOUX, BELGIUM, for a period of at least 10 years starting on the study completion date, unless instructions to the contrary are received from the sponsor.

Archived documents include as minimum :

- study plan
- all correspondence
- protocols
- raw data
- report
- Quality Assurance Inspection reports.

An aliquot of the remaining original test item after analysis will be stored by the test facility at room temperature in the original container under shelter from direct sunlight for a period of at least 5 years starting on the study completion date. After this period, it will be destroyed unless instructions to the contrary are received from the sponsor.

REPORT

10.1.c Wob juncto 63.2.d Vo 1107/2009

1. Study objective

The purpose of this study is to determine the pourability / rinsability and the persistent foaming of the formulated product **PMV-01**, a formulation suspension concentrate (SC) [redacted] Pepino mosaic virus, CH2 strain, isolate 1906.

All the tests have been carried out by the Plant Protection Products and Biocides Physico-chemistry and Residues Unit of the Walloon Agricultural Research Centre (CRA-W).

This report deals with all the results obtained after analysis.

2. Materials

2.1 Test item

10.1.c Wob juncto 63.2.d Vo 1107/2009

Code* : **PMV-01**.

Type of formulation* : suspension concentrate (SC).

Active substance content (nominal concentration)* : [redacted] Pepino mosaic virus, CH2 strain, isolate 1906.

Supplier : De Ceuster N.V., Fortsesteenweg 30, 2860 Sint-Katelijne-Waver, Belgium.

Containers : 2 commercial PET bottles of 1 litre.

10.1.c Wob juncto 63.2.a Vo 1107/2009 juncto 39.2.a Vo 178/2002

Batch number* : [redacted]

Manufacturing date* : [redacted]

Expiry date* : [redacted]

[see certificate of analysis of [redacted] on page 13].

Receipt date at the test facility : September 04, 2012.

Registration number at the test facility : Ch.5385.

Storage : before the analysis : at 4°C ± 3°C in the original container under shelter from direct sunlight, during the analysis : a sub-sample was kept at room temperature.

* : information supplied by the sponsor.

The GLP Principles require that the sponsor provides to the study director the active substance content, the batch number, the estimated expiry date and the stability and homogeneity of the active substance of test item in the vehicle (when applicable) unless

the determination of these items is planned in the study. The shipment of the test item until the receipt at the test facility is under the responsibility of the sponsor.

2.2 Analytical standard

Not relevant for this study.

3. Analytical methods

3.1 Pourability / rinsability

CIPAC method MT 148, CIPAC Handbook F - pg. 348.
- Conditions of applying : in a 500 mL stoppered measuring glass cylinder.
- Temperature : 20°C ± 2°C.
- Time : 24 hours.

Determination of residue R and rinsed residue R'.

3.2 Persistent foaming

CIPAC method MT 47.2, CIPAC Handbook F - pg. 152.
- Concentration : at the highest concentration of use :
  5 % v/v corresponding to 8 L / 160 L water.
- Water : CIPAC water D,
  CIPAC method MT 18.1.4, CIPAC Handbook F - pg. 62.
- Temperature : 30°C ± 2°C.

Determination of the volume of foam after 10 seconds ± 1 second, 1 minute, 3 minutes and 12 minutes ± 10 seconds.

4. Results

Dates of analysis : from September 12 until September 13, 2012.

4.1 Pourability / rinsability

Dates of analysis : from September 12 until September 13, 2012.

Determination	Residue (%)	Rinsed residue (%)
1	0.43	0.23
2	0.42	0.22
Mean	**0.43**	**0.23**

4.2 Persistent foaming

Date of analysis : September 12, 2012.

Concentration : 5 % v/v corresponding to 8 L / 160 L water.
Temperature : 30°C ± 2°C.
Water : CIPAC water D.

	mL of foam after :			
Determination	**10 seconds**	**1 minute**	**3 minutes**	**12 minutes**
1	0	0	0	0
2	0	0	0	0
Mean	**0**	**0**	**0**	**0**

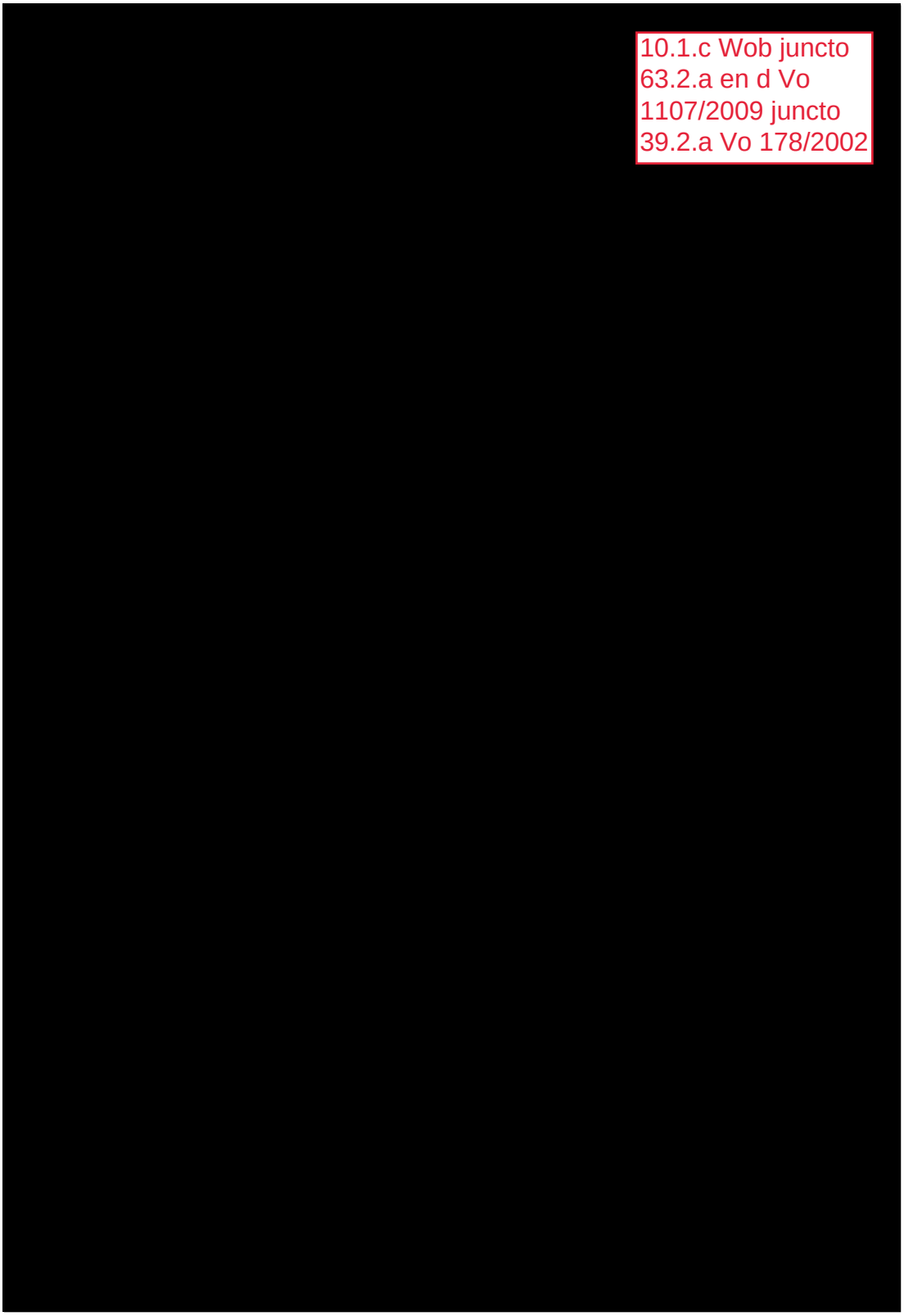
5. Amendment to the study plan

No amendment was issued for this study.

6. Deviation to the study plan

No deviation was issued for this study.

Appendices



10.1.c Wob juncto 63.2.a en d Vo 1107/2009 juncto 39.2.a Vo 178/2002

STATEMENT OF GLP COMPLIANCE

Assessment of conformity with GLP according to the directive 2004/9/EC.
Date of inspection : 24→27 October 2011

According to the criteria specified in the article 5, § 8 of the Royal Decree of March 6, 2002 the General Director of the Scientific Institute of Public Health, endorses on the advice of the GLP Monitorate, that the Test Facility,

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Registration No : C04

carries out physico-chemical, stability, residues, analytical chemistry and field studies with respect to the OECD and the EU principles of Good Laboratory Practices.

The Test Facility is regularly inspected within a cycle of 2 to 3 years.

[redacted]

Brussels,
18.01.2012

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GLP certificate