

REPORT AMENDMENT NUMBER 1

Study Title

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

ASSESSMENT OF ACUTE INHALATION TOXICITY WITH
[REDACTED] PEPINO
MOSAIC VIRUS, CH2 STRAIN, ISOLATE 1906
IN THE RAT

Author

10.2.e

Sponsor

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Test Facility

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

Laboratory Project Identification

[REDACTED] Pepino Mosaic Virus,
CH2 strain, isolate 1906

AMENDMENT DESCRIPTION

CONCERNING

Page 7, Paragraph 5.2., Aims of study.

NEW TEXT:

The following text has to be added:

For the design of the acute inhalation study in rats after single exposure to the 'Tomato watery leaf extract containing Pepino mosaic virus, CH2 strain, isolate 1906', all available information was evaluated prior to study start to decide if any supplementary observations were necessary on pathogenicity/infectivity of the test substance.

In general, plant viruses do not infect humans or animals since they do not possess receptors that bind to human or animal cells. Thus the pathogenicity of this virus for humans and animals was considered as irrelevant as this virus is not able to infect humans and animals. In addition, this virus is commonly present in tomato plant in greenhouse and consequently, humans are exposed to this virus. Diseases or adverse effects caused by this virus were never reported, which confirms the lack of pathogenicity/infectivity of this virus. Finally, this plant virus is not listed as possible human or animal pathogenic virus (EU Directive 2000/54/EC).

Based on this information is concluded that there was no indication for tissue collection and investigation of the pathogenicity/infectivity in this study.

REASON FOR AMENDMENT

This statement has to be added based on response of the authorities with respect to the reason for not including investigation of the pathogenicity/infectivity in this study.

APPROVAL

Due to the absence of the Study Director this report amendment was signed by Management.

[REDACTED]

Section Head Toxicology

17 July 2012
Date:

10.2.e

This report amendment has been audited by the Quality Assurance Unit.

Type of Inspections Study	Phase/Process	Start Inspection date	End Inspection date	Reporting date
	Report Amendment 01	12-jul-12	12-jul-12	12-jul-12

[REDACTED]

Head of Quality Assurance

17-Jul-2012
Date:

10.2.e