# **REPORT AMENDMENT NUMBER 1**

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

## Study Title

# ASSESSMENT OF ACUTE INHALATION TOXICITY WITH PEPINO

# MOSAIC VIRUS, CH2 STRAIN, ISOLATE 1906 IN THE RAT

<u>Author</u>

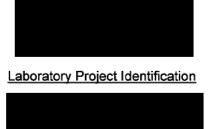
Sponsor

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

10.2.e

Test Facility



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

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.

17 July 2012

Section Head Toxicology

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

Type of Inspection Inspection Gate

Start End
Inspection Inspection Gate

Study Report Amendment 01 12-jul-12 12-jul-12

17-Jul-2012.

Head of Quality Assurance

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