European Commission

Draft Assessment Report prepared according to the Commission Regulation (EU) N° 1107/2009

Pepino Mosaic Virus, EU strain, mild isolate Abp1
Pepino Mosaic Virus, CH2 strain, mild isolate Abp2
Product data: AbioProtect®

Volume 3 – Annex B.5 Analytical methods

Rapporteur Member State: Spain

July 2019

Version History

When	What
	Completeness check report of the dossier submitted by the notifier
March 2019	DAR submitted to the Notifier. Reception of comments
July 2019	DAR revised

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B.5. ANALYTICAL METHODS

B.5.1 Methods for the analysis of the preparation

The preparation AbioProtect® is formulated as a suspension concentrate of tomato plant extract infected with Pepino mosaic virus (PepMV), with a minimum content of at least $5x10^{11}$ genome copies (viral units)/L, that is a minimum content of at least $2.5x10^{11}$ genome copies (viral units) of PepMV, EU strain, mild isolate Abp1/L and a minimum content of at least $2.5x10^{11}$ genome copies (viral units) of PepMV, CH2 strain, mild isolate Abp2/L.

The details described in Agüero, 2017a above are considered confidential due to strategic commercial interests of the applicant. More information in confidential information, Volume 4, Annex C.

B.5.2 Methods to determine and quantify residues

PepMV, as other plant viruses, is not related to any animal or human pathogen. Plant viruses are harmless to humans and other animals because they only reproduce in plant living cells. They do not have a cellular structure and do not produce metabolites; they could be only produced in plant living cells. PepMV, EU strain, mild isolate Abp1 and PepMV, CH2 strain, mild isolate Abp2 are produced in tomato plants. Methods to determine and quantify residues are considered not relevant as:

- The virus is already naturally present on tomato plants in greenhouses today.

- The virus does not multiply outside its plant host. The virus only survives short periods outside the host cell since it is broken down by proteases, RNAses and UV light. However, some authors have reported that it can persist in dried plant sap 4 weeks at 5 ºC, 2 weeks at 15ºC and only 4 days at 25ºC (O'Neill et al., 2003). PepMV does not remain infectious in water at 20ºC more than 3 weeks (Mehle et al., 2014).

- The persistence in soil has been experimentally assayed in a GEP trial and found that PepMV is not persistent in the soil from plants treated with the formulation AbioProtect® (Prats, 2017b).

- Persistence in water has been assayed in a GEP trial and showed that Plant Protection Product AbioProtect® has no persistency in the leachate from tomato plants treated with AbioProtect®. Therefore, there is no risk of PepMV infection with this leachate (Prats, 2017a).

B.5.2.3 REFERENCES RELIED ON

The applicant has provided summaries and results of the scientific peer-review open literature, on the active substance and its relevant metabolites dealing with side-effects on health, the environment and non-target species and published within the last 10 years before the date of submission of the dossier. There is no information whether this literature search was performed in accordance to the provisions of the EFSA Guidance "Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) 1107/2009".

The literature search provided was conducted in accordance to the guidelines set up in document European Food Safety Authority; Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (OJ L 309, 24.11.2009, p.1-50), (EFSA Journal 2011; 9(2):2092. [49pp.]. doi:10.2903/j.efsa.2011.209)2. Full details and justification of how the literature search was performed could be found in Document K-MA 5.2.5 Hernando 2017.

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
B.5.1	Agüero J.	2017a	Method of production of the	N	N	Proprietary	Abiopep S.L.

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Microbial Pest Control Agent (MPCA) PepMV, EU strain, mild isolate Abp1 and PepMV, CH2 strain, mild isolate Abp2 and manufacturing of the Microbial Pest Control Product (MPCP). Abiopep S.L., Spain. No GLP Not published			information	
B.5.2	Mehle N., Gutiérrez-Aguirre I., Prezelj N., Delić D., Vidic U., Ravnikar M.	2014	Survival and transmission of Potato virus Y, Pepino mosaic virus, and Potato Spindle Tuber Viroid in Water. Applied and Environmental Microbiology 80:1455-1462. DOI: 10.1128/aem.03349-13. No GLP Published	N	N		LIT
B.5.2	O'Neil T., Spence N., Mumford R., Skelton A	2003	Final Report on project PC 181: Protected tomato: sources, survival and disinfection of Pepino mosaic virus (PepMV). ADAS/CSL, UK. No GLP Published	N	N		LIT
B.5.2	Prats C.	2017a	Field study to evaluate the crop safety and the efficacy of the Plant Protection Product (PPP) AbioProtect®, and its components or agents (PPA1 and PPA2), for the control of PepMV in tomato crop (Southern Spain, 2016). Agrocolor S.L., Spain. Report Number ACEX/1274/AB GEP Not published	N	Y	Proprietary information	Abiopep S.L.
B.5.2	Prats C.	2017b	Field study to evaluate the crop safety and the efficacy of the Plant Protection Product (PPP) AbioProtect®, and its components or agents (PPA1 and PPA2), for the control of PepMV in tomato crop (Southeast Spain, 2016). Agrocolor S.L., Spain. Report number: ACEX/1277/AB GEP Not published	N	Y	Proprietary information	Abiopep S.L.

*LIT: LITERATURE