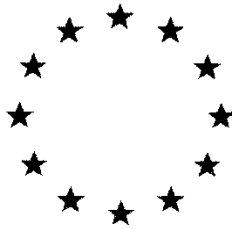


European Commission



**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
Active organism data
Volume 3 – Annex B.4 Further information**

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.4. FURTHER INFORMATION

B.4.1. RECOMMENDED METHODS AND PRECAUTIONS CONCERNING HANDLING, STORAGE, TRANSPORT OR FIRE

Storage: The MPCAs have a shelf life of 9 months at <-18°C following production. The product must be stored in a dry area, in the original packaging and out of the reach of children. Keep it also away from food, drink and animal feed stuff.

Transport: is not regulated. Not considered a hazard product according to national and international transport regulations.

Fire: since the product is a water base plant extract, it is not flammable and the risk of fire is extremely low.

B.4.2. PROCEDURES FOR DESTRUCTION OR DECONTAMINATION

PepMV, EU strain, mild isolate Abp1 and PepMV, CH2 strain, mild isolate Abp2 are harmless to non-target species, animals and humans. Therefore, there is no need to render the microorganism harmless in case of contamination.

Nonetheless, viruses could be inactivated by treatment with 0.1 N hydrochloric acid, sodium orthophosphate, or sodium hypochlorite (Hull, 2014). Other methods for inactivation of PepMV are heat (>60 °C, for 3 min, O'Neil et al., 2003), NaOCl (1- 5%, Ling et al., 2010), trisodium phosphate (3h Córdoba-Sellés et al, 2007) or commercial disinfectants (O'Neil et al, 2003).

B.4.3. MEASURES IN CASE OF AN ACCIDENT

PepMV, EU strain, mild isolate Abp1 and PepMV, CH2 strain, mild isolate Abp2 are harmless to non-target species, animals and humans. Therefore, there is no need to render the microorganism harmless in case of an accident. Nonetheless, viruses could be inactivated by 0.1 N hydrochloric acid, sodium orthophosphate, or sodium hypochlorite (0.2 M) (Hull, 2014). Other methods for inactivation of PepMV are heat (>60 °C, for 3 min), NaOCl (1-5%), trisodium phosphate or commercial disinfectants (O'Neil et al., 2003, Ling et al., 2010, Córdoba-Sellés et al., 2007).

B.4.4. POSSIBLE OCCURRENCE OF PESTICIDE DEGRADATES FROM DRINKING WATER TREATMENTS

PepMV, EU strain mild isolate Abp1 and PepMV, CH2 strain, mild isolate Abp2 are plant viruses already naturally present on tomato plants in greenhouse today. The virus does not multiply outside its plant host, it only survives short periods outside the host cell since it is broken down by proteases, RNases and UV light. Persistence in water has been evaluated in a GEP trial and found that PepMV was not persistent in the leachate from the tomato plants treated, concluding that there is no risk of infection from this leachate (see Document K-MP 6.2/04, Prats, 2017a). Furthermore, as viruses have no metabolism of their own are not able to produce secondary metabolites. Thus, the risk to consumers is negligible and impact of water treatment processes on the active substance and its metabolites in water abstracted for drinking water is not foreseen.

B.4.5. 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 Doc. No., (prev. used Doc. No.), (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.4.2 B.4.3	Córdoba-Selles MC, García-Rández A, Alfaro-Fernández A, and Jordá-Fernández C	2007	Seed transmission of <i>Pepino mosaic virus</i> and efficacy of tomato seed disinfection treatments. Plant Disease 91:1250-1254 No GLP Published	N	N	-	LIT
B.4.2 B.4.3	Hull R.	2014	Plant virology. Chapter 16 pp 675-741 Academic press, San Diego, CA. No GLP Published	N	N	-	LIT
B.4.2 B.4.3	Ling KS	2010	Effectiveness of chemo- and thermotherapeutic treatments on Pepino mosaic virus in tomato seed. Plant Dis. 94:325-328. No GLP Published	N	N	-	LIT
B.4.2 B.4.3	O'Neil T, Spence N, Mumford R, Skelton A,	2003	Final Report on project PC 181: Protected tomato: sources, survival and disinfection of <i>Pepino mosaic virus</i> (PepMV) ADAS/CSL, UK No GLP Published	N	N	-	LIT
B.4.1	Anonymous	-	AbioProtect® Safety data sheet No GLP UnPublished	N	N		Abiopep S.L.

* LIT: LITERATURE