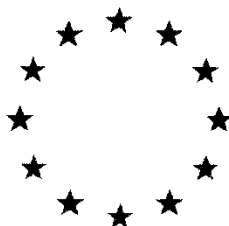


European Commission



**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.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 ON THE PLANT PROTECTION PRODUCT

B.4.1. PACKAGING AND COMPATIBILITY OF THE PREPARATION WITH PROPOSED PACKAGING MATERIALS

Materials	High density polyethylene (HDPE) white, construction by blow technology.
Specifications	UN 3H1/ X1.2/ 250/16 /E J304/ ENVAPLAST
Shape	Rectangular
Size	225 x 190x 166 mm
Capacity	5 L
Resistance	250 kPa Hydraulic test pressure
Type and size of openings	Round, diameter 63
Type of closures and seals	Round cap. Red HPDE. Thread, with sealing solutions: washer, induction and degassing valve
	ADR and UN standards approved.
	Suitable for the packaging of chemical products, pesticides, detergents, agrochemicals, chemical-organic. As well as for food and feed use.

B.4.2. PROCEDURES FOR CLEANING APPLICATION EQUIPMENT

The application equipment (tank, filters and nozzles) must be thoroughly washed with water immediately after use following the equipment manufacturer's procedure.

Exposed clothing must be washed with a standard laundry detergent in washing machine.

No study has been carried out to determine the effectiveness of laundry detergent to render PepMV harmless. Laundry detergent is considered suitable to render viruses harmless.

B.4.3. RE-ENTRY PERIODS, NECESSARY WAITING PERIODS OR OTHER PRECAUTIONS TO PROTECT MAN, LIVESTOCK AND THE ENVIRONMENT

There are no necessary harvest waiting periods, re-entry periods or withholding periods or other precautions required to protect man, livestock or the environment.

B.4.4. RECOMMENDED METHODS AND PRECAUTIONS CONCERNING: HANDLING, STORAGE, TRANSPORT OR FIRE

Handling and storage: The product has a shelf life of 9 months at $-18 \pm 2^{\circ}\text{C}$ 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 feeding stuff.

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

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

B.4.5. MEASURES IN THE CASE OF AN ACCIDENT

AbioProtect® contains PepMV, EU strain, mild isolate Abp1 and PepMV, CH2 strain, mild isolate Abp2, which 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 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.4.6. PROCEDURES FOR DESTRUCTION OR DECONTAMINATION OF THE PLANT PROTECTION PRODUCT AND ITS PACKAGING

AbioProtect® contains PepMV, EU strain, mild isolate Abp1 and PepMV, CH2 strain, mild isolate Abp2, which are harmless to non-target species, animals and humans.

B.4.6.1 Controlled incineration

There is no need for controlled incineration.

B.4.6.2 Others

The virus contained in AbioProtect® 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.4.7. 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	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

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B.4.5 B.4.6.2	Córdoba-Selles MC, García- Rández A, Alfaro- Fernández A, and Jordá- Fernández C	2007	Seed transmission of Pepino mosaic virus and efficacy of tomato seed disinfection treatments. Plant Disease 91:1250-1254 No GLP Published	N	N		LIT
B.4.5 B.4.6.2	Hull R.	2014	Plant virology. Chapter 16 pp 675-741 Academic press, San Diego, CA. No GLP. Published.	N	N		LIT
B.4.5 B.4.6.2	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.4.5 B.4.6.2	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.4.4 B.4.5 B.4.6	Anonymous	-	AbioProtect® Safety data sheet No GLP UnPublished	N	N		Abiopep S.L.

*LIT: LITERATURE