

Renewal Assessment Report

***Bacillus thuringiensis ssp.
aizawai* strain ABTS-1857**

- XenTari® WG -

Volume 3 – B.3 Data on application and efficacy

Rapporteur Member State: The Netherlands

Co-Rapporteur Member State: Germany

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B.3 Data on application and efficacy

B.3.1 Field of use envisaged

Bacillus thuringiensis subsp. *Aizawai*, strain ABTS-1857 is used as an insecticide. The representative formulation for this active substance is Xentari WG.

For the representative uses please refer to the GAP in paragraph B.3.3 of this document.

B.3.2 Mode of action

Bacillus thuringiensis subsp. *Aizawai*, strain ABTS-1857 produces parasporal proteinaceous, crystal inclusion bodies. Upon ingestion, these are insecticidal to larvae of the order Lepidoptera. Once in the insect, the crystal proteins are solubilised under alkaline conditions and the insect gut proteases convert the original pro-toxin into a combination of active toxins (Cry IAa, Cry IAb, Cry IC and Cry ID). These hydrolysed toxins bind to the insect's midgut cells at high affinity, specific receptor binding sites where they interfere with the potassium-ion dependent, active amino acid symport mechanism. This disruption causes the formation of large cation-selective pores that increase the water permeability of the cell membrane. A large uptake of water causes cell swelling and eventual rupture, disintegrating the midgut lining. Affected insects stop feeding and die from the combined effects of starvation and tissue damage (Copping, 1998).

Bacillus thuringiensis subsp. *Aizawai*, strain ABTS-1857 is in Insecticide Resistance Action Committee group 11A.

B.3.3 Details of intended use

Representative uses supported in the EU for which data have been provided

The supported uses of the representative product XenTari® WG a Water Dispersible Granules (WG) formulation containing 540 g/kg *Bacillus thuringiensis* ssp. *aizawai* (strain ABTS 1857), are summarised in the following table.

Crop and/or situation (a)	Member State or EU region	Product code	F, G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc. of a.s.	Method (f-h)	Growth stage BBCH (j)	Number of applications (k)	Min. interval between applications (Days)	Kg a.s./hL	Water (L/ha)	Use rate Kg a.s./ha		
											min – max	min – max	min-max		
Outdoor fruit vegetables (pepper)	CEU / SEU	XenTari® WG (ABG-6314)	F	Lepidoptera larvae including but not limited to: HELIAR, HELISP, LAP-HEG, PY-RUNU, SPODLI, GNORAB, SPODSP.	WG (Water Dispersible Granules)	54% w/w Approx. 5×10^{13} cfu/kg	Spray	BBCH 09-92 (May-Oct) Start when larvae hatch (L1)	1 – 8, (1 - 3 per generation of pest)	6 - 10 Typically 7 days	0.027 – 0.054 kg a.s./hL (0.050 – 0.100 kg f.p./hL)	Typically 500-1000 L/ha	0.270–0.540 kg a.s./ha. (0.500-1.0 kg f.p./ha) Approx. 5×10^{13} cfu/ha	-	Increase dose rates at high pest pressure, and mixed populations with older larvae. Regarding water volume, typically 500-1,000 L/ha to ensure full coverage but not to the point of run off.
Indoor fruit vegetables	EU	XenTari® WG	G	Lepidoptera larvae including	WG (Water Dispersible	54% w/w	Spray	BBCH 09-	1 – 7, Typically	Typically 7 days	0.027 – 0.054	400–1000	0.270 – 0.540	-	Increase dose rates at high

Crop and/or situation (a)	Member State or EU region	Product code	F, G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc. of a.s.	Method (f-h)	Growth stage BBCH (j)	Number of applications (k)	Min. interval between applications (Days)	Kg a.s./hL	Water (L/ha)	Use rate Kg a.s./ha		
											min – max	min – max	min-max		
(pepper)		(ABG-6314)		but not limited to: 1NOC TF GNORAB HELIAR LAPHEG PLUSCH SPODLI SPODSP HELISP	Granules)	Approx. 5×10^{13} cfu/kg		BBCH 92 (Jan-Dec) Start when larvae hatch (L1)	(1 - 3 per generation of pest)		kg a.s./hL (0.050-0.100 kg f.p./hL)	Typically 1000 L/ha	kg a.s./ha. (0.500–1.0 kg f.p./ha) Approx. 5×10^{13} cfu/ha		pest pressure, and mixed populations with older larvae. Regarding water volume typically 1,000 L/ha to ensure full coverage but not to the point of run off.

Remarks:

- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
- (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
- (c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
- (d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
- (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
- (f) All abbreviations used must be explained
- (g) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench
- (h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated

- (i) g/kg or g/l
- (j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
- (k) The minimum and maximum number of application possible under practical conditions of use must be provided
- (l) PHI - minimum pre-harvest interval
- (m) Remarks may include: Extent of use/economic importance/restrictions

B.3.4 Application rate

Crop	Method of application	Rate of application per unit treated (as preparation)	Rate of application per unit treated (as active substance)
Outdoor fruit vegetables (pepper)	Spray	0.5 – 1.0 kg/ha	0.270 - 0.540 kg/ha Approx. 5×10^{13} cfu/ha
Indoor fruit vegetables (pepper)	Spray	0.5 – 1.0 kg/ha	0.270 - 0.540 kg/ha Approx. 5×10^{13} cfu/ha

B.3.5 Content of micro-organism in material used (e.g., in the diluted spray, baits or treated seed)

Crop	Method of application	Material used (e.g. diluted spray, baits, treated seed)	Content of microorganism in material used
Outdoor fruit vegetables (pepper)	Spray	0.05 – 0.10 kg/hL	Approx. 5×10^{12} cfu/hL
Indoor fruit vegetables (pepper)	Spray	0.05 – 0.10 kg/hL	Approx. 5×10^{12} cfu/hL

B.3.6 Method of application

Crop	Method of application	Type of equipment used	Type and volume of diluent per unit of area or volume
Outdoor fruit vegetables (pepper)	Spray	Spray equipment	500-1000 L water/ha
Indoor fruit vegetables (pepper)	Spray	Spray equipment	500-1000 L water/ha

B.3.7 Number and timing of applications

Please refer to the GAP in document B.3.3 of this document.

Foliar sprays are started at pest occurrence when larvae start to hatch (L1) and are repeated as necessary at an interval of 6-10 days. In practice, at 1-3 applications per generation of pests and 1-8 applications per crop cycle for control of larvae of *Lepidoptera*. The representative use is pepper, for this crop it has been assumed that there is only one crop cycle per year.

B.3.8 Necessary waiting periods or other precautions to avoid phytopathogenic effects on succeeding crops

It concerns an insecticide that has been on the market for some time. Effects on phytopathogenic effects on succeeding crops have been evaluated at product level when currently authorised products were evaluated in the different memberstates. No negative effects are known or expected.

B.3.8.1 Proposed instructions for use

Instructions are described on national level during product renewal or authorisation.

B.3.9 Efficacy data / Effectiveness

B.3.9.1 Preliminary tests

According to the latest guidance on the preparation of dossiers for the renewal of active substances, information on efficacy is not required (SANCO/10181/2013 – rev. 2.1, 13 May 2013). The representative products have all been authorised at Member State level for > 10 years and have therefore been assessed in line with Uniform Principles.

B.3.9.2 Testing effectiveness

According to the latest guidance on the preparation of dossiers for the renewal of active substances, information on efficacy is not required (SANCO/10181/2013 – rev. 2.1, 13 May 2013). The representative products have all been authorised at Member State level for > 10 years and have therefore been assessed in line with Uniform Principles.

Table B.9-2-1: Summary of existing uses of XenTari WG

Country	Status	Trade name	A.S. Content	Reg. Num-ber	Registered Uses
Austria	Registered	XenTari	540 g/kg	3431	Vegetables; cabbages; grapes; ornamentals; stone fruits; pome fruits; berries
Austria	Registered	Florbac	540 g/kg	3431-901	Vegetables; cabbages; grapes; ornamentals; stone fruits; pome fruits; berries
Belgium	Under evaluation	Xentari WG	540 g/kg	9067P/B	Indoor and outdoor vegetables; Outdoor Brassica; pome fruits; grapes; indoor /outdoor ornamentals; trees; sweet corn;
France	Registered	Xentari WG	540 g/kg	2020241	Indoor and outdoor vegetables; Outdoor Brassica; pome fruits; grapes; indoor /outdoor ornamentals; aromatic plants; grapes; general treatment; olives; rice
Germany	Registered	XenTari	540 g/kg	024426-00	Vegetables; cabbages; grapes; ornamentals; stone fruits; pome fruits; berries

Greece	Under evaluation	Xentari WG	540 g/kg	1798	Indoor and outdoor vegetables; Outdoor Brassica; pome fruits; stone fruits; olives; grapes; indoor /outdoor ornamentals; rice
Italy	Under evaluation	Xentari WG	540 g/kg	011793	Indoor and outdoor vegetables; Outdoor Brassica; pome fruits; stone fruits; grapes; indoor /outdoor ornamentals; olives; rice
Netherlands	Registered	Xentari WG	540 g/kg	12437N	Indoor and outdoor vegetables; Outdoor Brassica; pome fruits; grapes; indoor /outdoor ornamentals; strawberry; berries; tree nursery
Netherlands	Registered	Florbac	540 g/kg	15033N	Indoor and outdoor vegetables; Outdoor Brassica; pome fruits; grapes; indoor /outdoor ornamentals; strawberry; berries; tree nursery

Spain	Under evaluation	Xentari GD	540 g/kg	19692	Indoor and outdoor vegetables; pome fruits; grapes; ornamentals; grapes; pome fruits; rice
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B.3.10 Information on the development of resistance

Bacillus thuringiensis subsp. *aizawai* Strain ABTS-1857 is a microbial disruptor of insect midgut membranes. As with any insecticide, too frequent use of one type of *Bt* strain or one type of *Bt* delta-endotoxin can result in resistance of the insect to the active ingredient. *Bacillus thuringiensis* is a biological non-persistent insecticide thus reducing the chances of resistance build up. No cross-resistance has been reported between chemical insecticides and *Bt* products (Sarnthoy *et al.*, 1997; Smirle *et al.*, 2003). Certain insect species have developed a resistance to particular *Bt* products caused by prolonged use resulting in a reduction in binding of specific Cry toxins to the gut membrane binding site. However, indications are that certain pest species are susceptible to more than one Cry toxin produced by different *Bt* subspecies. Therefore, resistance management strategy of altering applications of *Bt* products can prove effective.

In conclusion, *Bt* products like any other insecticide should be used in IRM (Insecticide Resistance Management) or IPM (Integrated Pest Management) programs and not used over and over as the only insecticide of choice. IRM and IPM cultural practices are commonly in place already.

While resistance to *Bacillus thuringiensis* does occur, it can be concluded that the proposed gap for the representative uses is still realistic. Resistance management will have to be evaluated by member states during product renewal or authorisation, as it can depend on local resistant populations, agricultural practices and other variables.

B.3.11 Adverse effects on treated crops

B.3.11.1 Effects on the yield of plants or plant products in terms of quantity and/or quality

The representative products have all been authorised at Member State level for > 10 years this data requirement has already been assessed in line with Uniform Principles.

B.3.11.2 Effects on the quality of plants or plant products

The representative products have all been authorised at Member State level for > 10 years this data requirement has already been assessed in line with Uniform Principles.

B.3.11.3 Effects on the transformation process

The representative products have all been authorised at Member State level for > 10 years this data requirement has already been assessed in line with Uniform Principles.

B.3.11.4 Effects on the yield of treated plants or plant products

The representative products have all been authorised at Member State level for > 10 years and have therefore been assessed in line with Uniform Principles.

B.3.11.5 Phytotoxicity to target plants (including different cultivars), or to target plant products

The representative products have all been authorised at Member State level for > 10 years this data requirement has already been assessed in line with Uniform Principles.

B.3.12 Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms, on succeeding crops, other plants or plants used for propagating purposes (e.g. seeds, cuttings, runners)

B.3.12.1 Impact on succeeding crops

Please refer to paragraph B.3.8. in this document.

B.3.12.2 Impact on other plants, including adjacent crops

The representative products have all been authorised at Member State level for > 10 years and have therefore been assessed in line with Uniform Principles.

B.3.12.3 Impact on treated plants or plant products to be used for propagation

The representative products have all been authorised at Member State level for > 10 years and have therefore been assessed in line with Uniform Principles.

B.3.12.4 Effects on beneficial and other non-target organisms

Please refer to Volume 3 – B.9 Effects on non-target organisms.

B.3.13 Other/special studies

No data submitted.

B.3.14 Summary and evaluation of efficacy data (3.2)

According to the latest guidance on the preparation of dossiers for the renewal of active substances, information on efficacy is not required (SANCO/10181/2013 – rev. 2.1, 13 May 2013). The representative products have all been authorised at Member State level for > 10 years and have therefore been assessed in line with Uniform Principles.

B.3.15 References relied on

No references were used.