Renewal
Assessment Report

Bacillus thuringiensis ssp. aizawai strain ABTS-1857

- XenTari® WG -

Volume 3 – B.2 Physical and chemical properties

Rapporteur Member State: The Netherlands

Co-Rapporteur Member State: Germany

Version history

When	What
September 2018	

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B Summary, evaluation and assessment of the data and information

B.2 Physical and chemical properties of the plant protection product XenTari® WG

The product data was evaluated in the original DAR (2008). In the column 'reference' it is indicated in what section of the original DAR the study can be found. No new studies have been provided and all data evaluated in the DAR is still considered acceptable, except for the density (bulk density) as the pour density the tap density should also be provided by the applicant.

XenTari WG is a water dispersible granule (WG-formulation). It is sprayed at 0.27 – 0.54 kg a.s./ha, corresponding to 0.5 – 1.0 kg product/ha, with 400 – 1000L water/ha. The in-use concentrations therefore range from 0.05 – 0.25%.

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.1 Appearance						
Physical state and colour B.2.1/01	In-house method, comparison with Munsell colour system	XenTari WG Lot no. 77-805-PG *Bacillus thuringiensis* mean potency – 15,000 IU per mg	Munsell colour code 10YR 6/6 light brown Musty odour Fine granules No change after 24 months storage at 25°C	Acceptable	Y	Comb (2004) ZAB018/042800 (originally submitted for DAR(2008), B.2.2.1 (IIIM 2.1/01))
B.2.2 Explosive and oxidising properties						
Explosive properties B.2.2/01	92/69/EC Test A14	XenTari WG Lot no. 30-297-BJ DBM mean potency – 35,000 Diamondback Moth Units per mg	Not explosive Mechanical sensitivity (shock and friction): There was no observable or audible reaction with either of these two tests. Thermal sensitivity (effect of flame):	Acceptable	Y	Young (1997) ABT 372/973849 (originally submitted for DAR(2008), B.2.2.3 (IIIM

			There was no explosion or deformation with any of the tubes, although the test substance did ignite.			2.3/01))
Oxidising properties B.2.2/02	n.a.	XenTari WG Lot no. 30-297-BJ DBM mean potency – 35,000 Diamondback Moth Units per mg	Not oxidising	Acceptable Although no study have been provided for the oxidising properties (within the study by Young 1997, ABT 372/973849) originally submitted for DAR (2008, B.2.2.3 (IIIM 2.3/01)), it is assumed based on the composition that the formulation does not poses any oxidising properties.	Y	n.a.
B.2.3 Flammability and auto-flammability						
Flash point of the liquids formulations B.2.3/01			Not applciable			
Flammability of solid formulations B.2.3/02	92/69/EC Test A10 Flammability	XenTari WG Lot no. 30-297-BJ DBM mean potency – 35,000 Diamondback Moth Units per mg	Not highly flammable The test flame burnt the surface of the pile black. The flame did not propagate along the test pile. Further testing was not required under the terms of the directive as the test substance did not burn the full 200mm.	Acceptable	Y	Young (1997) ABT 372/973849 (originally submitted for DAR(2008), B.2.2.3 (IIIM 2.3/01))
Self-heating of formulations B.2.3/03	92/69/EC Test A16 Self ignition	XenTari WG Lot no. 30-297-BJ DBM mean potency – 35,000 Diamondback	Self ignites at 225^{o}C	Acceptable	Y	Young (1997) ABT 372/973849 (originally submitted for DAR(2008),

		Moth Units per mg				B.2.2.3 (IIIM 2.3/01))
B.2.4 Acidity/alkalinity and pH value						
pH of the neat aqueous formulation B.2.4/01			Not applicable			
pH of a 1 % dilution of the solid or non aqueous formulation B.2.4/02	CIPAC MT 75.2	XenTari WG Lot no. 77-805-PG *Bacillus thurin-giensis* mean potency – 15,000 IU per mg	Initial: pH 4.7 After 12 months, 25°C: pH 4.8 After 24 months, 25°C: pH 4.8	Acceptable	Y	Comb (2004) ZAB018/042800 (originally submitted for DAR(2008), B.2.2.1 (IIIM 2.1/01))
Acidity / Alkalinity B.2.4/03			Not applicable based on pH			
B.2.5 Viscosity and surface tension						
Viscosity of the liquid formulation B.2.5/01			Not relevant as product is a solid and forms a suspension in water.			
Surface tension of the formulation B.2.5/02			Not relevant as product is a solid and forms a suspension in water.			
B.2.6 Relative density and bulk density						
Relative density of the liquid formulation B.2.6/01			Not applicable			
Bulk density (pour and tap) of powder or granules	151A-16	Y	Bulk density 0.383 g/ml at 23°C	Not acceptable		Yuan, 1990 originally

B.2.6/02				The study was accepted in the original DAR, but the pour and tap density are not reported and are required according 284/2013 and should therefore be provided.		submitted in DAR(2008), B.2.2.7.8 (IIIM 2.5/01)
B.2.7 Storage stability and shelf-life: effects of temperature on technical characteristics of the plant protection product						
Stability after accelerated storage (54°C during 14 days, 8 weeks at 40°C, 12 weeks at 35°C or 18 weeks at 30°C) B.2.7/01		XenTari WG Lot nos. 69-510-PG, 76-577-PG, 77-805-PG *Bacillus thuringiensis* mean potency – 15,000 IU per mg	Accelerated storage: 14 days at 54 °C Not appropriate to perform an accelerated storage study on a microorganism.	Acceptable	-	Waiver originally submitted in DAR(2008), B.2.2.1 (IIIM 2.1/01)
Effect of low temperature on stability of liquid formulation B.2.7/02	94/37/EC	XenTari WG Lot nos. 69-510-PG, 76-577-PG, 77-805-PG *Bacillus thuringiensis* mean potency – 15,000 IU per mg	Initial – 14858 to 15781 IU/mg After 12 months Frozen – 15020 to 16939 IU/mg After 24 months Frozen – 16989 to 17726 IU/mg	Acceptable Stored at -18ºC (frozen) for 12 and 24 months. As the formulation is an solid it is used only as a reference values. The effects of low temperature on the formulation is not required for a solid.	Y	Comb (2004) ZAB018/042800 (originally submitted for DAR(2008), B.2.2.1 (IIIM 2.1/01))
Shelf life following storage at ambient temperature B.2.7/03	94/37/EC	XenTari WG Lot nos. 69-510-PG, 76-577-PG, 77-805-PG *Bacillus thuringiensis* mean potency – 15,000 IU per mg	No change in potency following storage at < −18°C and 25°C for up to 24 months. Initial – 14858 to 15781 IU/mg After 12 months 25°C - 15815 to 17128 IU/mg After 24 months 25°C - 16925 to 18767 IU/mg	Acceptable Dust content, pH, wet sieving, suspension stability, dustiness, dispersibility, and attrition resistance were tested before and after storage at 25 °C. No significant changes occurred. See for the results of the tested properties the studies provided under the dif-	Y	Comb (2004) ZAB018/042800 (originally submitted for DAR(2008), B.2.2.1 (IIIM 2.1/01))

			No change in physical properties when stored for 24 months at 25°C. No significant change to containers. Weight difference 0.3% of original after 24 months. No swelling, discolouring or permeation by the formulation. In the shelf-life study the test material was stored in 500 g canister commercial packs consisting of cylindrical fibreboard containers with a metal base and top. The tops were ring pull openings with a HDPE re-sealing lid underneath the metal top.	ferent annex points. Although the in-use concentrations were not fully covered by the technical properties tested it is found acceptable as no negative effects are expected at lower or higher in-use concentrations based on the provided results. Information from the confidential volume 4 . As the results of 5-batches technical material show no growth of contaminating micro-organisms (E-coli, Staphylococcus aureus, Pseudomonas aeruginosa, Clostridium perfringens, Salmonella enteriditis and Enterococcus), it is not expected that this would occur after storage for a diluted version of the active substance. Additionally 1 batch of XenTari WG formulation (Lot No. 77-805-PG) has been tested following 2 years storage at room temperature. Results showed the absence of Salmonella species and <10 cfu/g count for Staphylococcus aureus, Pseudomonas aeruginosa, Clostridium perfringens and yeast and molds. A low count of Enterococcus species (<101 cfu/g) and other Clostridium species (10 cfu/g of which 98% C. clostridiiforme) were detected (Brand, 2004) and therefore it is considered to sufficiently show the absence of the MPCA to produce such contaminating micro-organisms..		

B.2.8 Technical characteristics of the plant protection product						
B.2.8.1 Wettability						
Wettability of solid formulation B.2.8.1/01	CIPAC MT 53.3	XenTari WG Lot no. 77-805-PG *Bacillus thuringiensis* mean potency – 15,000 IU per mg	Initial: 2 sec After 12 months, 25°C: 2 sec After 24 months, 25°C: 2 sec Concentration tested is 2% in standard CIPAC water C, without swirling.	Acceptable	Y	Comb (2004) ZAB018/042800 (originally submitted for DAR(2008), B.2.2.1 (IIIM 2.1/01))
B.2.8.2 Persistence foaming						
Persistence of foaming of the diluted formulation B.2.8.2/01	CIPAC MT 47.1	XenTari WG Lot no. 77-805-PG *Bacillus thuringiensis* mean potency – 15,000 IU per mg	No significant foam (max. 2 mL) after 30 sec at dilutions of 0.1 and 0.167%w/w in standard CIPAC water C.	Acceptable Although the in-use concentrations are between 0.05-0.25% and the results at 0.1% and 0.167% do not fully represent the lowest and highest in-use concentrations it is found acceptable as no significant foam (>60 mL) is expected at these in-use concentrations. As CIPAC MT 47.2 is the preferred method and information on the foam after 1 min. and the use of standard CIPAC water D is required, the results after 30 sec. indicate almost no foam production (max, 2 mL) and therefore this has been accepted.	Y	Comb (2004) ZAB018/042800 (originally submitted for DAR(2008), B.2.2.1 (IIIM 2.1/01))
B.2.8.3 Suspensibility						
Suspensibility of water	CIPAC MT	XenTari WG	Initial	Acceptable	Y	Comb (2004)

dispersible formulation B.2.8.3/01	168	Lot no. 77-805-PG *Bacillus thuringiensis* mean potency – 15,000 IU per mg	86% at 0.1%w/w 87% at 0.167%w/w After 12 months, 25°C 84% at 0.1%w/w 85% at 0.167%w/w After 24 months, 25°C 87% at 0.1%w/w 88% at 0.167%w/w Tested in standard CIPAC water D.	Although the in-use concentrations are between 0.05-0.25% and the results at 0.1% and 0.167% do not fully represent the lowest and highest in-use concentrations it is found acceptable as no suspensibility (<70% and >105%) is expected at these in-use concentrations. As an precaution measure it is advised to state on the label that the formulation must be continuous agitated during application. As CIPAC MT 184 is the preferred method and information on the suspensibility at 30ºC (after 30 min.) is required, the results indicate sufficient suspensibility (at 25ºC) and therefore this has been accepted.		ZAB018/042800 (originally submitted for DAR(2008), B.2.2.1 (IIIM 2.1/01))
Spontaneity of dispersion of water dispersible formulation B.2.8.3/02	CIPAC MT 174 Dispersibility	XenTari WG Lot no. 77-805-PG *Bacillus thuringiensis* mean potency – 15,000 IU per mg	Initial: 98% After 12 months, 25°C: 94% After 24 months, 25°C: 91% Tested concentration is 1 g/L (0.1%) in standard CIPAC water D.	Acceptable Although the highest in-use concentrations is 0.25% and the results at 0.1% do not fully represent the highest in-use concentrations it is found acceptable as the dispersion stability (>90%) is expected at these in-use concentrations. As an precaution measure it is advised to state on the label that the formulation must be continuous agitated during application.	Y	Comb (2004) ZAB018/042800 (originally submitted for DAR(2008), B.2.2.1 (IIIM 2.1/01))
Dispersion stability of SE, OD or EG formulation B.2.8.3/03			Not applicable			

B.2.8.4 Degree of dissolution and dilution stability						
Degree of dissolution of water soluble formulation B.2.8.4/01			Not applicable			
Dilution stability of water soluble formulation B.2.8.4/02			Not applicable			
B.2.8.5 Particle size distribution, dust content, attrition and mechanical stability						
B.2.8.5.1 Particle size distribution						
Wet sieve test of water dispersible formulation B.2.8.5.1/01	CIPAC MT 167	XenTari WG Lot no. 77-805-PG *Bacillus thuringiensis* mean potency – 15,000 IU per mg	Initial 0.31% residue on a 75 µm sieve After 12 months, 25°C 0.38% residue on a 75 µm sieve After 24 months, 25°C 0.35% residue on a 75 µm sieve Tested concentration is 10% (10g/100mL).	Acceptable Although CIPAC MT 185 is the preferred method, CIPAC MT 167 is similar to CIPAC MT 185 and the results show no residue >2% and therefore this has been accepted.	Y	Comb (2004) ZAB018/042800 (originally submitted for DAR(2008), B.2.2.1 (IIIM 2.1/01))
Size distribution of particles of powder or suspension concentrate formulation B.2.8.5.1/02	CIPAC MT 58.2 Particle size	XenTari WG Lot no. 77-805-PG *Bacillus thuringiensis* mean potency – 15,000 IU per mg	Initial 850 – 250 µm – 78.0% 250 – 150 µm – 21.2% <150 µm – 0.8% After 12 months, 25°C 850 – 250 µm – 80.6% 250 – 150 µm – 18.5% <150 µm – 1.0% After 24 months, 25°C 850 – 250 µm – 82.6% 250 – 150 µm – 16.2%	Acceptable The granules do not contain a significant proportion of particles of diameter < 50 µm (> 1 % on a weight basis), therefore no additional data is required.	Y	Comb (2004) ZAB018/042800 (originally submitted for DAR(2008), B.2.2.1 (IIIM 2.1/01))

			<150 μm – 1.0%			
Nominal size range of granule B.2.8.5.1/03						
B.2.8.5.2 Dust content						
Dust content of granular formulation B.2.8.5.2/01	CIPAC MT 171 Dust content	XenTari WG Lot no. 77-805-PG *Bacillus thuringiensis* mean potency – 15,000 IU per mg	Initial Nearly dust free (0 and 0.07 mg dust) After 12 months, 25°C Nearly dust free (0.36 and 0.47 mg dust) After 24 months, 25°C Nearly dust free (0.06 and 0.14 mg dust)	Acceptable	Y	Comb (2004) ZAB018/042800 (originally submitted for DAR(2008), B.2.2.1 (IIIM 2.1/01))
B.2.8.5.3 Attrition						
Attrition characteristics of granules and tablets B.2.8.5.3/01	CIPAC MT 178 Attrition resistance	XenTari WG Lot no. 77-805-PG *Bacillus thuringiensis* mean potency – 15,000 IU per mg	Initial 99.6% After 12 months, 25°C 99.3% After 24 months, 25°C 99.8%	Acceptable Although CIPAC MT 178.2 is the preferred method, CIPAC MT 178 is similar to CIPAC MT 178.2 and the results show an attrition resistance >99% and therefore this has been accepted.	Y	Comb (2004) ZAB018/042800 (originally submitted for DAR(2008), B.2.2.1 (IIIM 2.1/01))
B.2.8.5.4 Hardness and integrity						
Hardness of tablets B.2.8.5.4/01			Not applicable			
Integrity of tablets B.2.8.5.4/02			Not applicable			

B.2.8.6 Emulsifiability, re-emulsifiability, emulsion stability						
Emulsifiability, emulsion stability and re-emulsifiability of formulation B.2.8.6/01			Not applicable			
B.2.8.7 Flowability, pourability and dustability						
Flowability of granular formulation B.2.8.7/01	CIPAC MT 172 flowability	XenTari WG Lot no. 30-297-BJ DBM mean potency – 35,000 Diamondback Moth Units per mg	100% Passed spontaneously through a 4.75 mm sieve	Acceptable	Y	Young (1997) ABT 372/973849 (originally submitted for DAR(2008), B.2.2.3 (IIIM 2.3/01))
Pourability of suspensions B.2.8.7/02			Not applicable			
Dustability of dustable powders after accelerated storage B.2.8.7/03			Not applicable			
B.2.9 Physical and chemical compatibility with other products including plant protection products with which its use is to be authorised						
Physical and biological compatibility of tank mixtures B.2.9/01			Not relevant as there are no label claims			

B.2.10 Adherence and distribution to seeds						
Distribution and adhesion to seeds B.2.9.10/01			Not relevant as product is not used as a seed treatment			
B.2.11 Other studies						
			No further studies were performed			

B.2.12 References relied on

In every chapter (B.1, B.2, etc.) in Volume 3 (AS) the reference relied on heading should start with a paragraph indicating how the literature search was carried out and if this is considered acceptable. It should also be indicated if the RMS can agree with the justifications given by the notifier (especially for non-relevant literature).This is not expected to be a detailed study-by-study consideration. Relevant literature would be evaluated and assessed in the normal way within each section.

For (draft) renewal assessment reports the reference lists at the end of each section/chapter (sorted by data requirement) should include the newly submitted data relied upon as well as those original submitted tests and studies that are still considered relevant to support the application for renewal. However these studies should be clearly identified in the reference list as well as in the individual study sections. This could be done by consistent use of a statement for each study: Previous evaluation: responded “N.A.” for NAS, “Submitted for the purpose of renewal”, or “In DAR (year)”, “In addendum to DAR (year)” or any other appropriate.