

Renewal Assessment Report

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

- XenTari® WG -

Volume 3 – B.4 Further information

Rapporteur Member State: The Netherlands

Co-Rapporteur Member State: Germany

Version history

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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

The product is either packaged in HDPE bottles (1 kg content) or composite cans (0.5 kg content).

HDPE Bottles:

Four 1kg bottles packaged in an outer corrugated box.

Material: HDPE

Dimensions: Finish 100 – 400mm bottle height 6.187" \pm 0.062"
Diameter: 4.156" \pm 0.062"
"H": max = 0.740" min = 0.710"
"T": max = 3.937" min = 3.902"
"E": max = 3.817" min = 3.782"

Closure: continuous thread, molded polypropylene, white cap, 53 – 40mm. The liner is a pull-tab induction seal.

Composite Cans:

Twelve composite cans (401 x 509 mm) packaged into a corrugated box.

Material: Foil/Fiber with aluminium full panel ring pull top.

Dimensions: Other diameter: 4-1/16" height: 5-9/16"
Overseam diameter: 4.056" \pm 0.010" aluminum end
Seam width (after 2nd operation): 0.080" \pm 0.004"
aluminum end
Seam length (after 2nd operation): 0.113" \pm 0.003"
aluminum end

Closure: plastic overcap allied to top of the can.

B.4.2 Procedures for cleaning application equipment

Procedures for cleaning application equipment: Immediately after use, clean the spray equipment thoroughly. Drain the system completely and rinse the spray tank, boom and nozzles with clean water until all traces of product have been removed. No specific protective clothing is recommended for cleaning the application equipment.

Procedures for cleaning protective clothing: No specific cleaning procedure for protective clothing is proposed.

B.4.2.1 Effectiveness of the cleaning procedures

No data on the effectiveness of the cleaning procedure has been provided. However, based on the proposed cleaning procedure and composition of the formulation this is considered not necessary. The

cleaning procedure should be sufficient to remove all residues of the formulation. Additionally as the formulation is used as an insecticide it is considered that any leftover residues do not harm any successive crops, which will be sprayed after use with this formulation.

B.4.3 Re-entry periods, necessary waiting periods or other precautions to protect man, livestock and the environment

B.4.3.1 Pre-harvest intervals, re-entry or withholding periods to minimise residues in crops, plants, plant products, treated areas or spaces

The product is based on a micro-organism that is already commonly found in the phylloplane of plants and in soils. *Bacillus thuringiensis* is not considered a plant pathogen or to exhibit any adverse effects on treated crops or non-target plants. Due to the absence of toxicity and active growth in soils, no adverse effects on succeeding crops are to be expected and therefore, no minimum waiting periods between the last application and the sowing or planting of succeeding crops are required.

B.4.3.2 Information on any specific agricultural, plant health or environmental conditions under which the preparation may or may not be used

B.4.4 Recommended methods and precautions concerning: handling, storage, transport or fire

Safe handling:	<p>The usual precautions for handling chemicals should be observed.</p> <p>Respiratory: In case of dust formation, use dust mask.</p> <p>Hand: Wear protective gloves of nitrile.</p> <p>Eye: Wear safety goggles or face shield.</p> <p>Skin and body: Wear suitable protective clothing.</p> <p>Other information: Launder clothes before reuse.</p>
Storage:	<p>Store in a dry and cool place.</p> <p>Keep container in a well-ventilated place.</p> <p>Keep away from food, drink and animal feeding stuffs.</p> <p>Do not drink, eat and smoke in work areas.</p>
Transport:	<p>Transport hazard class(es):</p> <p>Land transport ADR/RID class: not restricted</p> <p>Sea transport IMO/IMDG code class: not restricted</p> <p>Air transport ICAO-TI/IATA-DGR class: not restricted</p>
Fire-fighting measures:	<p>Suitable extinguishing media: Dry chemical powder, carbon dioxide, foam, sand or water.</p> <p>Unsuitable extinguishing media: none known.</p> <p>Special hazards arising from the substance or mixture: Thermal decomposition during combustion may evolve toxic and irritant vapours.</p> <p>Advice for fire-fighters Wear self-contained breathing apparatus.</p> <p>Wear suitable protective clothing and eye/face protection.</p> <p>Other information Water used to extinguish a fire should not be allowed to enter the drainage system or watercourses.</p>

B.4.5 Measures in the case of an accident

First aid measures

General:	In all cases of doubt, seek medical attention.
Inhalation:	Move to fresh air. If symptoms persist, seek medical advice.
Skin:	Remove contaminated clothing. Wash skin immediately with water. Launder clothes before reuse.
Eye:	Rinse thoroughly with plenty of water. Eyelids should be held away from the eyeball to ensure thorough rinsing. Seek medical advice if irritation develops.
Ingestion:	Rinse mouth. Never induce vomiting in unconscious or confused persons. Always seek medical attention.

B.4.6 Procedures for destruction or decontamination of the plant protection product and its packaging

The disposal of product has to be performed in accordance with all applicable federal, state and local environmental regulations. Wastes resulting from the use of product, i.e. residual water dispersions can be disposed of at an approved waste disposal facility. Remainder of spray can also be diluted and sprayed over already treated areas.

The same procedure is applicable to larger quantities, which may occur very rarely only
Totally cleaned packages can be given to the regular waste disposal.

Product:	According to local regulations. For further advice contact manufacturer.
Contaminated packaging:	According to local regulations.

B.4.6.1 Controlled incineration

In accordance with local authority regulations, take to special waste incineration plant.

B.4.6.2 Others

Accidental release measures

Non-emergency personnel:	Avoid contact with skin. Wear protective gloves, safety goggles or face shield, and suitable protective clothing. Remove of ignition sources. Evacuate the danger area.
Emergency responders:	Avoid contact with skin. Wear protective gloves (nitrile), safety goggles or face shield, and suitable protective clothing. Remove of ignition sources. Evacuate the danger area or consult an expert.
Environmental precautions:	Do not allow to escape into sewage system or water courses. Do not wash residues into drains or other waterways.

Containment of a spill:	Do not allow to escape into sewage system or water courses.
Clean-up procedures:	<p>Clean up spills immediately.</p> <p>Sweep up and place into sealable containers.</p> <p>Dig up heavily contaminated soil and place into drums.</p> <p>Use a damp cloth to clean floors and other objects, and also place in sealable container.</p> <p>Dispose of all waste and contaminated clothing in the same manner as waste chemicals (i.e. via an authorized disposal facility).</p> <p>Do not wash residues into drains or other waterways.</p>

B.4.7 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