

Renewal Assessment Report

***Bacillus thuringiensis* subsp. *aizawai*
*strain GC-91***

- Agree 50 WG -

Volume 3 – B.1 Identity

July 2018

Rapporteur Member State: The Netherlands

Co-Rapporteur Member State: Germany

Version history

When	What
July 2018	Initial RAR

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B.1 Identity of the plant protection product

Agree 50 WG was not the representative formulation for first approval of the strain. Therefore, no data have been submitted for this product before and only new data are provided in this part of the dossier.

B.1.1 Applicant

Agree 50 WG

Name Mitsui AgriScience International S.A./N.V.

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Belgium

Contact person

Phone

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Email



B.1.2 Manufacturer of the preparation and the micro-organism

CONFIDENTIAL information, see volume 4..

B.1.3 Trade name or proposed trade name, and manufacturer's development code number of the preparation if appropriate

Trade name: Agree 50 WG, Agree WG, Turex WG, Turex technical

B.1.4 Detailed quantitative and qualitative information on the composition of the preparation

Active micro-organism: *Bacillus thuringiensis* subsp. *aizawai* strain GC-91

Taxonomy: Bacillaceae, *Bacillus* subsp. *aizawai*

The content of the active ingredient *B. thuringiensis* subsp. *aizawai* strain GC-91 in Agree 50 WG is 50% (w/w). The average biopotency was determined to be 25000 IU/mg.

Colony Forming Units (CFU) is theoretically not a parameter for a specification of a Bt-based product as the CFU content is not necessarily related to the insecticidal activity of the product. However, the parameter is required for risk assessment purposes and therefore ten production batches of Agree 50 WG have been submitted to CFU determination. The detailed information is provided in Doc J, Point MA 1.4.3. The minimum and maximum CFU content in Agree 50 WG are considered to be 8.5×10^{12} CFU/kg and 3.3×10^{13} CFU/kg, respectively. A nominal value is not applicable for Bt-based products and was therefore not established.

The strain Bta GC-91 is deposited in the National Collection of Type Cultures (NCTC), at the Health Protection Agency, Centre for Emergency Preparedness and Response, Porton Down, Salisbury, Wiltshire, SP4 0JG (for-

Bacillus thuringiensis subsp. *aizawai* strain GC-91 (Agree 50 WG)

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merly Central Public Health Laboratory, Colindale Avenue, London NW9 5HT) under the reference number NCTC 11821.

CAS Number: 68038-71-1

IUPAC number: not available

The development phase of Bta strain GC-91 in the formulated product is viable spores.

Pure active substance

content of pure active substance:	g/kg	(% w/w)	IU/mg	CFU/kg [*]
Bta GC-91	500 g/kg	50% w/w	25000	Minimum: 8.5×10^{12} Maximum: 3.3×10^{13}

^{*} the CFU content is not part of the specification of a Bt product as activity is specified by the International Units (IU) and not the CFU.
The CFU content is provided for formal reasons and for purposes of risk assessment.

Safeners, synergists and co-formulants

CONFIDENTIAL information. Please refer to Volume 4.

B.1.5 Physical state and nature of preparation

Type: water dispersible granules

Code: [WG]

B.1.6 Function

Biological insecticide. Bta strain GC-91 acts as an insecticide, for biological control of Lepidopteran pests.

B.1.7 References relied on

No references are submitted in this dossier section.