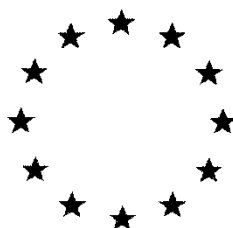


European Commission



**Draft Renewal Assessment Report prepared according to the Commission
Regulation (EU) N° 1107/2009**

Microbial Pest Control Agent (MPCA)
Bacillus thuringiensis
subsp. *kurstaki* SA-12

Volume 3 – B.1 (PPP) – CoStar WG
Identity

Rapporteur Member State: Denmark
Co- Rapporteur Member State: The Netherlands

Version history

When	What
2008	DAR
2011	Addendum to the DAR
2019	Initial RAR

Table of contents

B Summary, evaluation and assessment of the data and information

B.1	Identity of the plant protection product	4
B.1.1	Applicant.....	6
B.1.2	Manufacturer of the preparation and the micro-organism	6
B.1.3	Trade name or proposed trade name, and manufacturer's development code number of the preparation if appropriate.....	6
B.1.4	Detailed quantitative and qualitative information on the composition of the preparation	6
B.1.5	Physical state and nature of preparation	7
B.1.6	Function	7
B.1.7	References relied on.....	8

B.1 Identity of the plant protection product

INTRODUCTION

Bacillus thuringiensis subsp. *kurstaki* SA-12 (in the following abbreviated as Btk SA-12) was one of the existing active substances covered by the Regulation (EC) No 2229/2004 on the implementation of the fourth stage of the program of work referred to in Article 8(2) of Council Directive 91/414/EEC. In Annex I to Regulation (EC) No 2229/2004 the Commission designated Denmark as rapporteur Member State to carry out the assessment of Btk SA-12 on the basis of a joint dossier submitted for the Btk strains SA-11, SA-12 and EG 2348. The notifier for Btk SA-11 and SA-12 was Mitsui AgriScience International SA/NV while EG 2348 was notified by Mitsui AgriScience International SA/NV and Intrachem Bio Italia S.p.A. (now CBC (Europe) S.r.l.). In accordance with the provisions of Article 22(1) of Regulation (EC) No 2229/2004, Denmark submitted in January and February 2008 to the EFSA the draft assessment report, including, as required, a recommendation concerning the possible inclusion of Btk SA-12 in Annex I to the Directive. The Commission examined the draft assessment report, the recommendations by the rapporteur Member State and the comments received from other Member States in consultation with experts from a certain number of Member States. The Commission referred on 11 July 2008 a draft review report to the Standing Committee on the Food Chain and Animal Health, for final examination. The draft review report was finalized in the meeting of the Standing Committee on 11 July 2008. Subsequently Regulation (EC) No 1107/2009 repealed and replaced Directive 91/414/EEC and the active substance Btk SA-12, was deemed to be approved under that Regulation and included in the Annex to Regulation (EC) No 540/2011. EFSA delivered its conclusions on *Bacillus thuringiensis* ssp. *kurstaki* (strains ABTS-351, PB-54, SA-11, SA-12, EG2348) on the 16 December 2011 (published 23 February 2012). Based on this new information available, no need to change the conditions of approval of Btk SA-12 was identified. The Commission filed on 13 December 2013 an updated review report for Btk strains SA-11, SA-12 and EG 2348 to the Standing Committee on the Food Chain and Animal Health for examination.

The approval of Btk SA-12 under the Regulation (EC) No 1107/2009 expires 30 April 2019. In accordance with the same Regulation the original notifier Mitsui AgriScience International SA/NV has filed to the Commission an application for the renewal of the approval of the active substance Btk SA-12 on 30 April 2016. In accordance with Regulation (EU) 2016/183 the notifier submitted to the designated RMS Denmark, the co-RMS The Netherlands as well as to EFSA and Commission a dossier for renewal of Btk SA-12 considering the deadline stated in SANTE-2016-10616–rev. 3.

Btk SA-12 is a wild type strain originating from infested insects. Btk acts highly specific against insect species of the order Lepidoptera and is not expected to have any harmful effects on beneficials and other non-target species of other insect orders. The insecticidal activity of Btk is mainly attributed to spore bound insecticidal pro-proteins (Cry toxins) which are ingested by the target pests and activated under alkaline conditions in the midgut of the larvae. The first assessment of the strain proved that it does not have any harmful effects on human or animal health or on groundwater or any unacceptable influence on the environment. The overall conclusion from EFSA (2012) confirms that no critical areas of concern are identified within the framework of the use which was supported.

The representative formulation for renewal of the approval of Btk SA-12 under Regulation (EC) 1107/2009 is CoStar WG. CoStar WG is a WG formulation having a biopotency of 90000 IU/mg. The content of the active ingredient is 85% corresponding to a maximum of 5.7×10^{13} CFU/kg product. CoStar WG was not the representative formulation for original approval of the strain. Therefore, no data have been submitted for this formulation before. However, CoStar WG, except for the active ingredient, is identical to the representative formulation for original approval, Delfin WG, containing Btk SA-11. Also the two Btk strains are very similar with regard to their biological properties and physiological requirements. It is therefore justified to use data for Delfin WG also for the evaluation of CoStar WG. In addition, the manufacturing process of SA-12 has not been changed since original approval all data previously submitted and referring to Btk SA-12 are considered fully applicable for the current evaluation.

In the following for ease of information, full study summaries/sections taken from the DAR (2008) or its Final Addendum (2011) are included if they are considered relevant for renewal of Btk SA-12. In order to facilitate discrimination between new data and data already evaluated during the first approval process, the headline “New information” begins the section with data, which have previously not been submitted or evaluated. Data and their evaluations from the original DAR and addenda to the DAR are highlighted by grey background. There might be some exceptions but in this case justifications/explanations are provided.

Representative uses chosen for renewal of Btk SA-12 cover control of *Cydia pomonella* in pome fruits and *Spodoptera* spp. in ornamentals as field uses, as well as *Tuta absoluta* in tomato in the greenhouse. Both, use by professionals and non-professionals is intended. Application rates range between 1 – 2 kg with 6 subsequent applications at an interval of 7 days.

It is considered that the Critical GAP of CoStar WG chosen for the renewal of the active substance Btk SA-12 covers worst case exposure scenarios for human, non-target organisms and the environment.

Critical GAP of CoStar WG for renewal of Btk SA-12

Crop	F G or I	Pest	Application			Application rate		
			Method / Kind	Growth stage of crop	Max. number (min. interval between applications) a) per use b) per crop/season	Kg product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha IU/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max
Pome fruits	F	<i>Cydia pomonella</i>	Foliar spray	BBCH 67-89	a) 6 (7) b) 6 (7)	a) 1.5 b) 9.0	a) $1275 / 1.35 \times 10^{11}$ b) $7650 / 8.1 \times 10^{11}$	1000-1500
Tomato	G	<i>Tuta absoluta</i>	Foliar spray	BBCH 12-89	a) 6 (7) b) 6 (7)	a) 1.0 b) 6.0	a) $850 / 9.0 \times 10^{10}$ b) $5100 / 5.4 \times 10^{11}$	200-1000
Ornamentals	F	<i>Spodoptera</i> spp.	Foliar spray	BBCH 12-89	a) 6 (7) b) 6 (7)	a) 2.0 b) 12.0	a) $1700 / 1.8 \times 10^{11}$ b) $10200 / 1.1 \times 10^{12}$	500-1000

Biopotency of CoStar WG: 90000 IU/mg

Max. CFU content in CoStar WG: 5.7×10^{13} CFU/kg

B.1.1 Applicant

Product name: CoStar WG

Applicant: Mitsui AgriScience International S.A./N.V.

Avenue de Tervueren 270
B-1150 Brussels
Belgium

Contact Point:

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

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

CONFIDENTIAL information. Please refer to Volume 4

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

Trade name: CoStar and WG, SAN 420 I WG, (Costar/Deliver), Thuricide (is a liquid formulation of SA-12).

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

Active micro-organism: *Bacillus thuringiensis* subsp. *kurstaki* (Btk), strain SA-12 (Btk strain SA-12)

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

The content of the active ingredient Btk strain SA-12 in CoStar WG is 85% (w/w), equivalent to 90000 International Units/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 CoStar 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 CoStar WG are considered to be 8.5×10^{12} CFU/kg and 5.7×10^{13} CFU/kg. A nominal value is not applicable to Bt-based products and was therefore not established.

The Btk strain SA-12 which is used in the formulated product CoStar WG, is deposited in the ARS Culture Collection (also known as Northern Regional Research Laboratory, NRRL), at the Microbial Properties Research Unit, National Centre for Agricultural Utilization Research, Agricultural Research Services, U.S. Department of Agriculture Peoria, Illinois 61604 USA. Reference Number NRRL B-30791.

CIPAC Number: 954

IUPAC and CAS number: not available

The development phase of Btk SA-12 in the formulated product is viable spores.

Pure active substance

content of pure active substance:	g/kg	(% w/w)	IU/mg	CFU/kg*
Btk SA-12	850 g/kg	85% w/w	90000	Minimum: 8.5×10^{12} Maximum: 5.7×10^{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, C.1.4.2.

B.1.5 Physical state and nature of preparation

Type: water dispersible granules

Code: [WG]

B.1.6 Function

Biological insecticide. Btk SA-12 acts as an insecticide, for biological control of Lepidopteran pests.

B.1.7 References relied on

No references are submitted in this dRAR section.