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.3 (PPP) – CoStar WG

Data on application and efficacy

Rapporteur Member State: Denmark

Co- Rapporteur Member State: The Netherlands

Version history

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

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B.3 Data on application and efficacy

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 Subsequently Regulation (EC) No 1107/2009 repealed and replaced Directive 91/414/EEC and the active substance Btk SA-12, was deemed to be approved under that Regulation and included in the Annex to Regulation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	*Cydia pomonella*	Foliar spray	BBCH 67-89	a) 6 (7) b) 6 (7)	a) 1.5 b) 9.0	a) 1275 / 1.35×10^{11} b) 7650 / 8.1×10^{11}	1000-1500
Tomato	G	*Tuta absoluta*	Foliar spray	BBCH 12-89	a) 6 (7) b) 6 (7)	a) 1.0 b) 6.0	a) 850 / 9.0×10^{10} b) 5100 / 5.4×10^{11}	200-1000
Ornamentals	F	*Spodoptera* spp.	Foliar spray	BBCH 12-89	a) 6 (7) b) 6 (7)	a) 2.0 b) 12.0	a) 1700 / 1.8×10^{11} b) 10200 / 1.1×10^{12}	500-1000

Biopotency of CoStar WG: 90000 IU/mg
Max. CFU content in CoStar WG: 5.7×10^{13} CFU/kg

B.3.1 Field of use envisaged

CoStar WG is an insecticide for foliar application against lepidopteran pests in orcharding, horticulture and floriculture. For the renewal of approval of *Bacillus thuringiensis* subsp. *kurstaki* SA-12 the GAP includes pome fruits, Solanaceous fruits and ornamentals.

B.3.2 Mode of action

CoStar WG is a non-systemic insecticide. It is used for the control of leaf consuming caterpillars on various crops.

The MPCA in CoStar WG, *Bacillus thuringiensis* subsp. *kurstaki* SA-12, is a ubiquitous bacterium occurring worldwide, mainly in soils as well as on insects and on plant surfaces. *B. thuringiensis* belongs to the spore forming bacteria of the family *Bacillaceae*. Dormant spores of *B. thuringiensis* can persist for a long period in the environment and contribute to the transmission of the species in the environment, but are metabolically inactive. During sporulation *B. thuringiensis* produces inclusion bodies which are composed of insecticidal crystal proteins (ICP, also called Cry proteins or δ-endotoxins). These Cry toxins are highly toxic to a wide variety of important agricultural and health related insect pests of the order Lepidoptera.

The crystal proteins of *B. thuringiensis* must be ingested to be effective against the target insect. Upon ingestion of *B. thuringiensis* by the larvae, the crystalline inclusions dissolve in the larval midgut, releasing the insecticidal crystal proteins (δ-endotoxins). Most of the crystal proteins are protoxins, converted proteolytically into smaller toxic polypeptides under the alkaline conditions in the insect midgut. The activated Cry toxins interact with the midgut epithelium cells of susceptible insects.

After binding to specific midgut receptors, they insert into the apical membrane to create ion channels, or pores, disturbing the osmotic balance, permeability and the regulation of the transmembrane electric potential. This can result in colloid-osmotic lysis of the cells, which is the main cytotoxic mechanism common to all ICPs. Spore germination and proliferation of the cells into the haemocoel may result in septicaemia, contributing to mortality of the insect larvae.

B.3.3 Details of intended use

CoStar WG is to be used in a wide range of crops against a huge number of pests. With this dossier, only the uses in pome fruits, Solanaceous fruits and ornamentals are intended. The details on the supported use of CoStar WG are provided in **Table 3.3-1**. Supported representative uses for CoStar WG and their current authorisation status are given in **Table 3.3-2**.

Table 3.3-1 Intended uses supported in the EU for which data have been provided

PPP (product name/code): CoStar WG		Formulation type:	WG
Active Substance:	*Bacillus thuringiensis* subsp. *kurstaki* SA-12	Conc. of a.s.:	850 g/kg or 90,000 IU/mg, min. 8.5×10^{12} CFU/kg (nom/max. 5.7×10^{13} CFU/kg)
Safener:	-	Conc. of safener:	-
Synergist:	-	Conc. of synergist:	-
Applicant:	Mitsui AgriScience International SA/NV	professional use	☒
Zone(s):	EU	non-professional use	☒
Verified by RMS:	n		

1	2	3	4	5	6	7	8	9	10	11	12	13
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** **(additionally: develop-mental stages of the pest or pest group)**	**Application**			**Application rate**			**PHI (days)**	**Remarks**
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applica-tions) a) per use b) per crop/ season	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha IU/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1	EU	Pome fruits (apple, pear)	F	*Cydia pomonella*	Foliar spray	BBCH 67-89	a) 6 (7) b) 6 (7)	a) 1.5 b) 9.0	a) 1275 / 1.35 × 10^{11} b) 7650 / 8.1 × 10^{11}	1000-1500	-	-
2	EU	Solanaceous fruits (tomato, aubergine, sweet pepper)	G	*Tuta absoluta*	Foliar spray	BBCH 12-89	a) 6 (7) b) 6 (7)	a) 1.0 b) 6.0	a) 850 / 9.0 × 10^{10} b) 5100 / 5.4 × 10^{11}	200-1000	-	-
3	EU	Ornamentals	F	*Spodoptera littoralis*	Foliar spray	BBCH 12-89	a) 6 (7) b) 6 (7)	a) 2.0 b) 12.0	a) 1700 / 1.8 × 10^{11} b) 10200 / 1.1 × 10^{12}	500-1000	-	-

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

Table 3.3-2 Supported representative uses for CoStar WG and their current authorisation status

Representative use				Existing authorisations						
Crop	**Target**	**Situation (F, G, I)**	**Application method**	**Country**	**Product**	**Registration number**	**Product application rate per treatment (max)**	**Active substance application rate per treatment (max)**	**Number of treatments per season/crop**	**Active substance total dose/ha (max)**
Pome fruits (apple, pear)	*Cydia pomonella*	F	Foliar spray	Italy	CoStar WG	11257	1.5 kg/ha	0.27 kg/ha	6	1.62 kg/ha
Solanaceous fruits (tomato, aubergine, sweet pepper)	*Tuta absoluta*	G	Foliar spray	Italy	CoStar WG	11257	1.0 kg/ha	0.18 kg/ha	6	1.08 kg/ha
				Spain	COSTAR	22.060	50 g/hL	0.09 kg/ha*	Not stated	-
Ornamentals	*Spodoptera littoralis*	F	Foliar spray	Italy	CoStar WG	11257	2.0 kg/ha	1.7 kg/ha	6	5.1 kg/ha

* On the basis of 1000 L water/ha

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)
Pome fruits	Foliar spray	Maximum rate of 1.5 kg product/ha	Corresponds to 1.275 kg a.s./ha
Solanaceous fruits (greenhouse)	Foliar spray	Maximum rate of 1.0 kg product/ha	Corresponds to 0.850 kg a.s./ha
Ornamentals	Foliar spray	Maximum rate of 2.0 kg product/ha	Corresponds to 1.7 kg a.s./ha

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

CoStar WG is a biological insecticide formulated as a water dispersible granule formulation, containing 8.5×10^{12} colony forming units (CFU, max. 5.7×10^{13}) (or 850 g) of *Bacillus thuringiensis* subsp. *kurstaki* SA-12 in 1 kg product. The biopotency of CoStar WG is 90000 IU/mg.

Crop	Method of application	Material used (e.g. diluted spray, baits, treated seed)	Content of microorganism in material used
Pome fruits	Foliar spray	1.5 kg product/ha and spray volumes of 1000 to 1500 L water/ha	0.085 to 0.128 kg MPCA/hL, respectively, corresponding to $0.9\text{-}1.35 \times 10^{10}$ IU/hL
Solanaceous fruits (greenhouse)	Foliar spray	1.0 kg product/ha and spray volumes of 200 to 1000 L water/ha	0.085 to.0.425 kg MPCA/hL, respectively, corresponding to $0.9\text{-}4.5 \times 10^{10}$ IU/hL
Ornamentals	Foliar spray	2.0 kg product/ha and spray volumes of 500 to 1000 L water/ha	0.17 to 0.34 kg MPCA/hL, respectively, corresponding to $1.8\text{-}3.6 \times 10^{10}$ IU/hL

B.3.6 Method of application

CoStar WG is applied as broadcast foliar spray in water volumes of 200 to 1500 L/ha using conventional spray equipment.

B.3.7 Number and timing of applications

Maximum number of applications and their timings:

CoStar WG is applied up to 6 times per crop/season in pome fruits, protected Solanaceous fruits and ornamentals.

Growth stages of crops or plants to be protected:

Use of CoStar WG is to be intended in pome fruits at BBCH 67 to 89.

Use of CoStar WG is to be intended in Solanaceous fruits and ornamentals at BBCH 12 to 89.

Development stages of the harmful organisms concerned:

CoStar WG is used against larval stages of various pests. It is essential that the first application of CoStar WG is conducted directly at, or immediately after, egg-hatching of the larvae of the target pests.

Duration of protection afforded by each application:

Each application of CoStar WG according to the GAP table under Point B.3.3 is expected to afford protection for at least 7 days before a further application is required.

Duration of protection afforded by the maximum number of applications:

The total number of 6 applications of CoStar WG according to the GAP table shown under Point MP 3.3 is expected to control the pest population and thus to afford protection until immigration of new pests.

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

CoStar WG is based on a micro-organism that is already commonly found in the phylloplane of plants and in soils. *Bacillus thuringiensis* subsp. *kurstaki* 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.3.9 Proposed instructions for use

CoStar WG is applied by foliar spraying. For an adequate effectiveness all plant parts should be sufficiently sprayed. Applications are performed at pest occurrence, independently from the crop growth stage.

B.3.10 Efficacy data

According to SANCO/12545/2014 rev. 2, Document M MP 6 is not required. The product CoStar WG is registered in the EU for the representative uses considered in this dossier. Therefore, it was already evaluated according to Uniform Principles (Regulation (EC) No 546/2011) and all relevant data have been evaluated at zonal and Member state level.

A multitude of products containing *Bacillus thuringiensis* is registered worldwide for the control of lepidopteran larvae in various agricultural crops, orchards, vegetables, and forests, in greenhouses and in the field. Several other products based on different *Bacillus thuringiensis* strains are currently marketed throughout several countries in Europe.

Products based on SA-12 has been approved in the EU since the mid 1990s. Please refer to Table 3.3-2 above, which gives an overview of supported representative uses for CoStar WG and their current authorisation status.

B.3.11 Information on the development of resistance

Development of resistance has not been reported for Btk SA-12. Resistance was however reported for other Btk strains, for example in *Plutella xylostella* and *Trichoplusia ni* in various countries. Besides these two species, the literature research revealed one record on resistant field-populations of *Helicoverpa armigera* in India. Please see Vol. 3MA, B.3.5 for details. It is noteworthy, that not a single report on resistant insect populations in Europe was obtained. For Btk SA-12 the development of resistance is unlikely due to the fact that it codes for more than one Cry protein.

B.3.12 Adverse effects on treated crops

No study on non-target terrestrial plants is available with the active substance and the plant protection product. The literature search covering the last 10 years and focusing to target possible toxicity or pathogenicity of Btk on terrestrial plants did not provide any relevant information.

Btk acts highly specific against members of the insect family of Lepidoptera. Some are also active against Diptera or Coleoptera. Strain specific Cry protein pattern confirmed main action of Btk SA-12 against Lepidopteran pests. Therefore, any adverse effects on treated crops are highly unlikely.

B.3.12.1 Effects on the quality of plants or plant products

Any adverse effects are unlikely.

B.3.12.2 Effects on the transformation process

Any adverse effects are unlikely.

B.3.12.3 Effects on the yield of treated plants or plant products

Any adverse effects are unlikely.

B.3.13 Phytotoxicity to target plants (including different cultivars), or to target plant products

No study on non-target terrestrial plants is available with the active substance and the plant protection product. The literature search covering the last 10 years and focusing to target possible toxicity or pathogenicity of Btk on terrestrial plants did not provide any relevant information.

Btk acts highly specific against members of the insect family of Lepidoptera. Some are also active against Diptera or Coleoptera. Strain specific Cry protein pattern confirmed main action of Btk SA-12 against Lepidopteran pests. Therefore, any adverse effects on treated crops are highly unlikely.

B.3.14 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.3.14.1 Impact on succeeding crops

No study on non-target terrestrial plants is available with the active substance and the plant protection product. The literature search covering the last 10 years and focusing to target possible toxicity or pathogenicity of Btk on terrestrial plants did not provide any relevant information.

Btk acts highly specific against members of the insect family of Lepidoptera. Some are also active against Diptera or Coleoptera. Strain specific Cry protein pattern confirmed main action of Btk SA-12 against Lepidopteran pests. Btk occurs ubiquitously worldwide and is a common member of soil microbial communities. Therefore, any adverse effects on succeeding crops are highly unlikely.

B.3.14.2 Impact on other plants, including adjacent crops

No study on non-target terrestrial plants is available with the active substance and the plant protection product. The literature search covering the last 10 years and focusing to target possible toxicity or pathogenicity of Btk on terrestrial plants did not provide any relevant information.

Btk acts highly specific against members of the insect family of Lepidoptera. Some are also active against Diptera or Coleoptera. Strain specific Cry protein pattern confirmed main action of Btk SA-12 against Lepidopteran pests. Therefore, any adverse effects on adjacent crops are highly unlikely.

B.3.14.3 Impact on treated plants or plant products to be used for propagation

No study on non-target terrestrial plants is available with the active substance and the plant protection product. The literature search covering the last 10 years and focusing to target possible toxicity or pathogenicity of Btk on terrestrial plants did not provide any relevant information.

Btk acts highly specific against members of the insect family of Lepidoptera. Some are also active against Diptera or Coleoptera. Strain specific Cry protein pattern confirmed main action of Btk SA-12 against Lepidopteran pests. Therefore, any adverse effects on treated crops are highly unlikely.

B.3.14.4 Effects on beneficial and other non-target organisms

Btk acts highly specific against members of the insect family of Lepidoptera. Some are also active against Diptera or Coleoptera. Strain specific Cry protein pattern confirmed main action of Btk SA-12 against Lepidopteran pests. Therefore, any adverse effects on beneficial and other non-target organisms are highly unlikely.

B.3.15 Summary and evaluation of efficacy data (3.9-3.13)

Bacillus thuringiensis subsp. *kurstaki* SA-12 is effective against lepidopteran pests in fruit crops, vegetable crops, viticulture, urban green and forestry. The proposed GAP of Btk SA-12 includes pome fruits, protected Solanaceous fruits and ornamentals for the renewal of the active substance. No new efficacy studies are to be presented for the renewal of the active substance. The product CoStar WG is registered in the EU for the representative uses considered in this dossier. Therefore, it was already evaluated according to Uniform Principles (Regulation (EC) No 546/2011) and all relevant data have been evaluated at zonal and Member State level.

B.3.16 References relied on

Please refer to point with References relied on in chapter B.3, in Volume 3 (MCPA) with regard to the evaluation of the literature search.

No references are submitted.