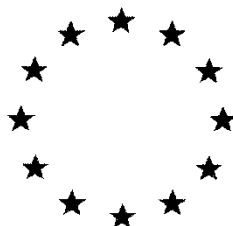


European Commission



**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.4 (PPP) – CoStar WG
Further information

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.4 Further information on 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 Subsequently Regulation (EC) No 1107/2009 repealed and replaced Directive 91/414/EEC and the active substance Btk SA-12, was deemed to be approved under that Regulation and included in the Annex to Regulation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.4.1 Packaging and compatibility of the preparation with proposed packaging materials

The chemically inert product does not require special stability or resistance properties of the packaging or the material used in packaging. A description of the size and material used for the packaging is briefly reported in the next paragraphs.

Taking into account the composition of the product and its anticipated physical properties, CoStar WG is characterised as non-reactive and non-hazardous; no further investigations and tests were conducted. The chemically inert product does not require special stability or resistance properties of the packaging or the material used in packaging.

Please, for any further information refer to the packaging description submitted in KMP 4.1/01.

Packaging for professional use

PACKAGING DECLARATION: primary packaging (1 kg formulated product)

Material:	48 gauge polyester/0.003 PE laminate
Weight:	17 g
Length:	16.5 cm
Width:	7.6 cm
Height:	33 cm
Content:	1 kg CoStar WG

PACKAGING DECLARATION: secondary packaging (box containing one primary packaging)

Material:	28 gauge solid unbleached sulphate (SUS)
Weight:	94 g
Length:	16.8 cm
Width:	7.6 cm
Height:	26 cm

PACKAGING DECLARATION: CoStar WG master shipping carton (cardboard box with 10 units of the primary packaging)

Material:	ECT (edge crush test) 48 double wall fibreboard
Weight:	650 g
Length:	38.9 cm
Width:	34.4 cm
Height:	26.8 cm

Packaging for non-professional use

With the renewal of the strain Btk SA-12 it is also applied for use of the product CoStar WG by non-professionals. For this particular area of use specific packaging information is provided below:

CoStar WG 25 g packaging	
Product code	Specification
1350000001	PET-Can 622, 40 M-Snap, transparent, weight: 14 g
1300000000	hinged lid white, 40 m-snap
33053	measuring spoon polystyrene, clear as glass, quantity of fill: 3 ml, total length: 94,5 mm
1100000006	folding box, 4-color, 400 g/qm chrome duplex board GD2 64x47x95 mm

CoStar WG 3 g packaging	
Product Code	Specification
1400000021	clay-coated craft paper / PE 60/40
1100000340	Chrome duplex board 350 g/qm, 4-color + lacquer, 106x21x136 mm

B.4.2 Procedures for cleaning application equipment

Equipment cleaning procedure

Rinse the application equipment thoroughly with water. Distribute the cleaning water on the treated area.

Protective clothing cleaning procedure

Protective clothing shall be washed according to manufacturer's instruction. If no such instructions for washables exist, use detergent and hot water. Keep and wash protective clothing separately from other laundry.

B.4.2.1 Effectiveness of the cleaning procedures

Not relevant

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

Pre-harvest interval for each relevant crop:	CoStar WG is not supposed to produce any relevant residues on the crop. <i>B. thuringiensis</i> subsp. <i>kurstaki</i> does not produce toxins or secondary metabolites of toxic concern to non-arthropods, including man and domestic animals. Fixing a pre-harvest interval is therefore not relevant.
Re-entry period for livestock, to areas to be grazed:	Not relevant (see above). CoStar WG is not intended for use on pastures.
Re-entry period for man to crops, buildings or spaces treated:	Not relevant (see above).
Withholding periods for animal feeding stuffs	Not relevant (see above).
Waiting period between application and handling treated products	Not relevant (see above).
Waiting period between last application and sowing or planting succeeding crops.	<i>B. thuringiensis</i> subsp. <i>kurstaki</i> does not cause injuries to plants. Due to restricted field persistence and absence of toxicity, waiting periods for planting or sowing of succeeding crops are not 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

None of the test results obtained or observations made were such that restrictions should be imposed.

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

Handling and storage precautions:

Avoid breathing dust. Avoid contact with skin and eyes. Avoid contact with open wounds. Wash hands thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace. Keep away from excessive heat and open flames. After handling, wash hands before eating, drinking or smoking. Protect from direct sunlight, store in a closed container and a dry location.

Transport:

Transport of CoStar WG does not require special precautions.

Procedures to minimize the generation of waste:

Remainder of spray shall be diluted and sprayed over already treated areas. Totally cleaned packages can be given to the waste disposal or recycling system.

Hazardous combustion products:

Combustion or thermal decomposition may generate toxic vapours: carbon monoxide, carbon dioxide and/or oxides of sulphur. Suitable extinguishing media: carbon dioxide (CO₂), dry chemical powder, alcohol resistant foam. Unsuitable extinguishing media: not available.

Please, for any further information refer to the Material Safety Data Sheet submitted in KMP 4.4/01.

B.4.5 Measures in the case of an accident

Containment of spillages:

Contain spill. Reclaim material if possible. Collect mechanically. Sweep, vacuum, or shovel material into a container for disposal. Avoid generation of dusts. Clean up affected area with plenty of water containing a strong detergent. Flush the area with water to remove any residue. Do not allow wash water to contaminate water supplies. Dispose of in accordance with local regulations for disposal of non-hazardous waste.

Decontamination of areas, vehicles and buildings:

Refer to the above statement on spillages.

Disposal of damaged packaging, adsorbents and other materials:

Refer to the above statement on spillages.

Protection of emergency workers:

Wear chemical safety glasses with side shields, or chemical goggles. Wear suitable protective clothing. For brief contact, no precautions other than clean body-covering clothing should be needed. Wear protective gloves. Wear appropriate respiratory protection. Particulate filter: P3 (EN 143) or Filtering Face Piece: FFP3 (EN149). Handle according to established industrial hygiene and safety practices.

First aid measures:

- Eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. Do not apply any medicating agent except on the advice of a physician.

- Skin contact: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse. Do not apply any medicating agent except on the advice of a physician.

- Inhalation: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If signs/symptoms persist, get medical advice/attention.

- Ingestion: Call a poison center or doctor/physician if you feel unwell. Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.

Please, for any further information refer to the Material Safety Data Sheet submitted in KMP 4.5/01.

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 CoStar WG, 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.

Please, for any further information refer to the Material Safety Data Sheet submitted in KMP 4.6/01.

B.4.6.1 Controlled incineration

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

B.4.6.2 Others

Not applicable

B.4.7 References relied on

Please refer to Volume 3, MCPA, chapter B.4 for how the literature search was carried.

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMP 4.1/01	Gallager, S.	2013	Statement on packaging CoStar WG Certis USA LLC, not stated [REDACTED] Columbia, Maryland GLP/GEP: no Published: no	no	yes	protected	Certis USA	New data for existing formulation, not previously submitted nor evaluated
KMP 4.4/01	Anonymous	2016	SDS CoStar WG_2016 Certis USA LLC, not applicable GLP/GEP: no Published: no	no	no	not protected	Certis USA	New data for existing formulation, not previously submitted nor evaluated
KMP 4.5/01	Anonymous	2016	SDS CoStar WG_2016 Certis USA LLC, not applicable GLP/GEP: no Published: no Submitted in: KMP 4.4/01	no	no	not protected	Certis USA	New data for existing formulation, not previously submitted nor evaluated
KMP 4.6/01	Anonymous	2016	SDS CoStar WG_2016 Certis USA LLC, not applicable GLP/GEP: no Published: no Submitted in: KMP 4.4/01	no	no	not protected	Certis USA	New data for existing formulation, not previously submitted nor evaluated