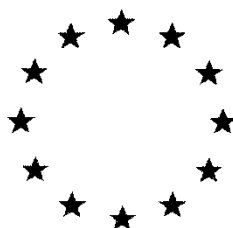


European Commission



**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 (MPCA)
Further information

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

Version history

When	What
Jan. 2019	Initial RAR

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B.4 Further information on the micro-organism

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 12 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 12 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 Subsequently Regulation (EC) No 1107/2009 repealed and replaced Directive 91/414/EEC and the active substance Btk SA-12, was deemed to be approved under that Regulation and included in the Annex to Regulation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.

As the manufacturing process of Btk SA-12 has not been changed since original approval, all data submitted for the original approval of the strain are considered fully applicable for the current evaluation.

For the renewal of the Btk strains SA-11, SA-12 and EG 2348 under Regulation (EC) 1107/2009, a separate dossier was submitted for each strain only including data, which have previously not been submitted or evaluated. Nevertheless, there is some information which is applicable to all three Btk strains, e.g. published information for Btk in general obtained during searches for peer reviewed literature according to EFSA Guidance (2011)¹ carried out for relevant sections.

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 Data” 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.

¹ Guidance of EFSA: Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009. EFSA Journal 2011;9(2):2092

B.4.1 Recommended methods and precautions concerning handling, storage, transport or fire

The following information is provided in the Material safety data Sheet for the Technical material of Btk SA-12 (submitted in Volume 4).

Precautions for safe handling

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.

Conditions for safe storage, including any incompatibilities

Store in a dry place. Store in a closed container. Protect from sunlight.

Transport hazard class: not applicable

Firefighting measures:

Suitable Extinguishing Media:	Dry chemical, water fog, alcohol foam, carbon dioxide.
Unsuitable Extinguishing Media:	Not available.
Special hazards arising from the substance or mixture	Dust may form explosive mixtures in air.
Hazardous combustion products:	Carbon monoxide. Carbon dioxide.
Protection of Firefighters:	Keep upwind of fire. Wear protective clothing and self-contained breathing apparatus.

B.4.2 Procedures for destruction or decontamination

Methods for Containment:	Contain spill. Reclaim material if possible.
Methods for Clean-Up:	Collect mechanically. Sweep, vacuum, or shovel material into a container for disposal. Clean up affected area with plenty of water. Avoid generation of dusts.
Other Information:	Dispose of in accordance with local regulations for disposal of non-hazardous waste.
Disposal Instructions:	Waste material must be disposed of in accordance with the Directive on waste 2008/98/EC as well as other national and local regulations. No mixing with other waste. Handle un-cleaned containers like the product itself. Waste should not be disposed of by release to sewers.

B.4.3 Measures in case of an accident

Description of first aid measures

Eye Contact:	IF IN EYES: 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.
Skin Contact:	IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.
Inhalation:	IF INHALED: 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:	IF SWALLOWED: 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.

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel: Avoid generation of dusts. Do not inhale dusts. Avoid substance contact. Ensure adequate ventilation. Evacuate the danger area and observe emergency procedures.

For emergency responders: Use personal protection. Isolate the hazard area and deny entry to unnecessary and unprotected personnel.

Environmental precautions

Keep out of drains, sewers, ditches, and waterways.

Methods and material for containment and cleaning up

Methods for Containment: Contain spill. Reclaim material if possible.

Methods for Clean-Up: Collect mechanically. Sweep, vacuum, or shovel material into a container for disposal. Clean up affected area with plenty of water. Avoid generation of dusts.

Other Information: Dispose of in accordance with local regulations for disposal of non-hazardous waste.

B.4.4 References relied on

Several literature review reports have been provided according to the guidance of EFSA (Guidance of EFSA: Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009. EFSA Journal 2011;9(2):2092). The aim of these reports was to provide a global overview of peer-reviewed literature concerning potential side effects of *B. thuringiensis* subsp. *kurstaki* strain SA-12.

Overview of literature reports provided according to the guidance of EFSA

Data point	Author	Year	Title	Section of RMS evaluation
KMA 2.7/12 & 3.5/06	Süß, J.	2016	Literature review on <i>B. thuringiensis</i> subsp. <i>kurstaki</i> strain SA-12: Biological properties	Vol. 3MA, B.2.10
KMA 6.1.1/07	Seehase, S.	2016	Literature review on <i>B. thuringiensis</i> subsp. <i>kurstaki</i> strain SA-12: Toxicology	Vol. 3MA, B.6.3
KMA 7.1/01	Cornelese, A.	2016a	Literature review on <i>B. thuringiensis</i> subsp. <i>kurstaki</i> strain SA-12 and metabolites: Residues in or on treated products, food and feed	Vol. 3MA, B.7.4
KMA 8.1/10	Cornelese, A.	2016b	Literature review on <i>B. thuringiensis</i> subsp. <i>kurstaki</i> strain SA-12: Fate and behaviour in the environment	Vol. 3MA, B.8.3
KMA 9/01	Schöbinger, U.	2016	Literature review on <i>B. thuringiensis</i> subsp. <i>kurstaki</i> strain SA-12: Effects on non-target organisms	Vol. 3MA, B.9.8

No references are relied on in this section