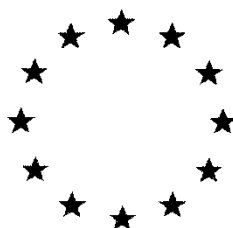


European Commission



**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.2 (PPP) – CoStar WG
Physical and chemical properties

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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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 Subsequently Regulation (EC) No 1107/2009 repealed and replaced Directive 91/414/EEC and the active substance Btk SA-12, was deemed to be approved under that Regulation and included in the Annex to Regulation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 ap- plications) a) per use b) per crop/ season | Kg product / ha a) max. rate per appl. b) max. total rate per crop/seaso n | 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 po- monella</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 absolu- ta</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 |
| Ornamen- tals | 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.2 Physical and chemical properties of the plant protection product CoStar WG

| Test or Study & Data point | Guideline and method | Test material purity and specification | Used methods / Results | Comments (Acceptable / Non acceptable) | GLP | Reference |
|---|---|--|---|--|-----|---------------|
| B.2.1 Appearance | | | | | | |
| Physical state and colour B.2.1/01 | Visual and smelling FAO, PSD and Pesticide Chemistry Branch Specification of PPP | CoStar WG Batch n°: 20100638 Purity: not stated | Small brown green granules with a fishmeal odour. Colour specification: RAL 8000 | Acceptable | GLP | Aversa, 2013 |
| B.2.2 Explosive and oxidising properties | | | | | | |
| Explosive properties B.2.2/01 | EEC A.14 | CoStar WG Batch n°: 20100638 Purity: 85% of a.i. | The formulation has no explosive properties according to European Commission Regulation (EC) No 440/2008. | Acceptable | GLP | Ahrens, 2011a |
| Oxidising properties B.2.2/02 | EEC A.17 | CoStar WG Batch n°: 20100638 Purity: 85% of a.i. | Typical oxidizers include chemicals with the oxygen-containing groups peroxides, nitrates, nitrites, perchlorates, chlorates, chlorites, hypochlorites, dichromates, permanganates, and persulfates. Due to the fact, that none of the formulants of CoStar WG contains such oxygen-containing groups, CoStar WG has no oxidising properties. The formulation has no oxidising properties according to | Acceptable | GLP | Ahrens, 2011b |

| | | | | | | |
|--|----------------------------------|---|--|------------|-----|---------------|
| | | | European Commission Regulation (EC) No 440/2008. | | | |
| B.2.3 Flammability and auto-flammability | | | | | | |
| Flash point of the liquids formulations B.2.3/01 | EEC A.9 | CoStar WG Batch n°: 20100638 Purity: 85% of a.i. | Not applicable to granules | - | - | - |
| Flammability of solid formulations B.2.3/02 | EEC A.10 | CoStar WG Batch n°: 20100638 Purity: 85% of a.i. | The formulation is neither a highly flammable according to European Commission Regulation (EC) No 440/2008, nor a flammable solid according to the classification criteria as laid down in Regulation (EC) No 1272/2008. | Acceptable | GLP | Ahrens, 2011c |
| Self-heating of formulations B.2.3/03 | EEC A.16 | CoStar WG Batch n°: 20100638 Purity: 85% of a.i. | The relative self-ignition temperature is 362°C at atmospheric pressure. | Acceptable | GLP | Ahrens, 2011d |
| B.2.4 Acidity/alkalinity and pH value | | | | | | |
| pH of the neat aqueous formulation B.2.4/01 | - | - | Not relevant, the formulation is solid. Please see below pH of an aqueous dilution of the formulation | - | - | - |
| pH of a 1 % dilution of the solid or non aqueous formulation B.2.4/02 | CIPAC MT 75.3 Glass electrode | CoStar WG Batch n°: 20100638 Purity: not stated | pH of a 1% dispersion: 6.00 (25°C). Because the pH was < 10 and > 4, the acidity/alkalinity test was not performed. | Acceptable | GLP | Aversa, 2013 |
| Acidity / Alkalinity B.2.4/03 | - | - | Not relevant as the pH of an aqueous dilution of the formulation is 6.63. Test is not required for formulations | Acceptable | - | - |

| | | | | | | |
|--|---|--|---|------------|-----|---------------|
| | | | with pH <10 and >4 | | | |
| B.2.5 Viscosity and surface tension | | | | | | |
| Viscosity of the liquid formulation B.2.5/01 | - | - | Dynamic Viscosity: Not applicable to granules Kinematic viscosity Not applicable to granules | - | - | - |
| Surface tension of the formulation B.2.5/02 | - | - | Not applicable to granules | - | - | - |
| B.2.6 Relative density and bulk density | | | | | | |
| Relative density of the liquid formulation B.2.6/01 | - | - | Not applicable to granules | | - | - |
| Bulk density (pour and tap) of powder or granules B.2.6/02 | CIPAC MT 186 | CoStar WG Batch n°: 20100638 Purity: not stated | Pour density was found to be 0.475 g/mL and the tap density was found to be 0.529 g/mL. | Acceptable | GLP | Aversa, 2011b |
| B.2.7 Storage stability and shelf-life: effects of temperature on technical characteristics of the plant protection product | | | | | | |
| Accelerated storage at 30 ± 2°C for 18 weeks B.2.7/01 | Visual control of the test item container. Weight change of the test item container. Control of activity by | CoStar WG Batch n°: 20100638 Purity: not stated | Results after accelerated storage (18 weeks at 30 ± 2°C) No damage of the test item containers was observed. No loss in weight was found after storage. The activity of the test item was not significantly changed after the storage. The test item is stable after 18 weeks at 30 ± 2°C and therefore is expected to be stable also when stored for long periods. The shelf life study reports similar results attesting for the stability of the product CoStar WG when stored at 20°C for 2 years. | Acceptable | GLP | Aversa, 2011a |

| | | | | | | |
|--|---------------------------|--|---|--|--|--|
| | bioassay. | | The below-reported entries summarise the study results after accelerated storage (18 weeks at 30 ± 2°C), while the results for the shelf life study will follow. | | | |
| | Biopotency | | Before Storage: 35375 IU/mg, After Storage: 29760 IU/mg | | | |
| | CIPAC MT 75.3 | | pH of the diluted item (1% w/v in water) Before Storage: 6.63, After Storage: 6.63 | | | |
| | CIPAC MT 53.3.1-53.3.2 | | <u>Static wettability</u> Before storage: 7 s After storage: 6 s <u>Dynamic wettability</u> Before storage: 3 s After storage: 3 s | | | |
| | CIPAC MT 184 | | <u>Suspensibility of the diluted item at 0.03% (w/v in water D)</u> Before storage: 95.17% After storage: 94.76% <u>Suspensibility of the diluted item at 0.3% (w/v in water D)</u> Before storage: 74.81% After storage: 74.03% | | | |
| | CIPAC MT 174 | | <u>Dispersibility of the diluted item at 1% (w/v in water D)</u> Before storage: 88% After storage: 87% | | | |
| | CIPAC MT 185 | | <u>Wet Sieve Test (residue at 200 mesh – 75 µm ASTM)</u> Before storage: 0.66% After storage: 0.37% | | | |
| | CIPAC MT | | <u>Friability and attrition resistance</u> | | | |

| | | | | | | |
|--|---|---|---|------------|-----|--------------|
| | 178.2 | | Before storage: 99.93% After storage: 99.77% | | | |
| | CIPAC MT 170 | | <u>Dry sieve analysis (particle size distribution)</u> Before storage: 0.075 – 1 mm After storage: 0.075 – 1 mm | | | |
| | CIPAC MT 171 | | <u>Dust content</u> Before storage: Nearly dust-free (1.79 mg) After storage: Nearly dust-free (2.29 mg) | | | |
| Shelf life after 2 years at 20 ± 2°C B.2.7/02 | Visual control of the test item container. Weight change of the test item container. Control of activity by bioassay. | CoStar WG Batch n°: 20100638 Purity: not stated | The study was carried out using commercial packaging as described in Vol. 3 MP, Section B.4, Point B.4.1 (Gallagher, 2013). Neither damage nor loss in weight of the test item containers (aluminium bag) was observed. The activity of the test item was not significantly changed after the storage. The test item is stable after 2 years at 20 ± 2°C. | Acceptable | GLP | Aversa, 2013 |
| | Content of active ingredient (viable spores) | | Before storage: 2.63×10^{10} CFU/g After storage: 2.23×10^{10} CFU/g | | | |
| | CIPAC MT 75.3 | | <u>pH of the diluted items (1% w/v in water)</u> Before storage: 6.00 (20.9°C) After storage: 6.03 (20.5°C) | | | |
| | CIPAC MT 53.3.1-53.3.2 | | <u>Static wettability</u> Before storage: 7 s After storage: 4.5 s | | | |

| | | | | | | |
|--|----------------|---|---|---|---|---|
| | | | <u>Dynamic wettability</u> Before storage: 3 s After storage: 2 s | | | |
| | CIPAC MT 184 | | <u>Suspensibility of the diluted item at 0.03% (w/v in water D)</u> Before storage: 95.17% After storage: 94.06% <u>Suspensibility of the diluted item at 0.3% (w/v in water D)</u> Before storage: 74.81% After storage: 76.72% | | | |
| | CIPAC MT 174 | | <u>Dispersibility of the diluted item at 1% (w/v in water D)</u> Before storage: 88% After storage: 82% | | | |
| | CIPAC MT 185 | | <u>Wet Sieve Test (residue at 200 mesh – 75 µm ASTM)</u> Before storage: 0.66% After storage: 0.45% | | | |
| | CIPAC MT 178.2 | | <u>Friability and attrition resistance</u> Before storage: 99.93% After storage: 99.27% | | | |
| | CIPAC MT 170 | | <u>Dry sieve analysis (particle size distribution)</u> Before storage: 0.075 – 1 mm After storage: 0.075 – 1 mm | | | |
| | CIPAC MT 171 | | <u>Dust content:</u> Before storage: Nearly dust-free (1.79 mg) After storage: Nearly dust-free (0.95 mg) | | | |
| Effect of low temperature on stability of liquid | - | - | Not applicable | - | - | - |

| | | | | | | |
|--|--|---|---|--|-----|---------------|
| formulation B.2.7/02 | | | | | | |
| Shelf life following storage at ambient temperature B.2.7/03 | - | - | - | - | - | - |
| B.2.8 Technical characteristics of the plant protection product | | | | | | |
| B.2.8.1 Wettability | | | | | | |
| Wettability of solid formulation B.2.8.1/01 | CIPAC MT 53.3.1 CIPAC MT 53.3.2 | CoStar WG Batch n°: 20100638 Purity: not stat- ed | 7 s (static) 3 s (dynamic) | Acceptable | GLP | Aversa, 2013 |
| B.2.8.2 Persistence foaming | | | | | | |
| Persistence of foaming of the diluted formulation B.2.8.2/01 | .2 | CoStar WG Batch n°: 20100638 Purity: not stat- ed | The persistent foaming of diluted suspensions (at 0.3% w/v standard water D) was found to be: 39 mL after 10 s, 4 mL after 1 min, 2 mL after 3 min, 2 mL after 12 min. | Acceptable The test and the result are accepted as the persistent foaming is minimal. | GLP | Aversa, 2011b |
| B.2.8.3 Suspensibility | | | | | | |
| Suspensibility of water dispersible formulation B.2.8.3/01 | CIPAC MT 184 | CoStar WG Batch n°: 20100638 Purity: not stated | Suspensibility of the diluted item at 0.03% (w/v in water D): 95.17% Suspensibility of the diluted item at 0.3% (w/v in water D): 74.81% | Acceptable | GLP | Aversa, 2013 |
| Spontaneity of dispersion | CIPAC MT | CoStar WG | | Acceptable | GLP | Aversa, 2013 |

| | | | | | | |
|--|--------------|--|--|------------|-----|---------------|
| of water dispersible formulation B.2.8.3/02 | 174 | Batch n°: 20100638 Purity: not stated | Dispersibility of the diluted item at 1% (w/v in water D): 88% | | | |
| Dispersion stability of SE, OD or EG formulation B.2.8.3/03 | - | - | Not applicable | - | - | - |
| B.2.8.4 Degree of dissolution and dilution stability | | | | | | |
| Degree of dissolution of water soluble formulation B.2.8.4/01 | - | - | Not applicable for micro-organisms | - | - | - |
| Dilution stability of water soluble formulation B.2.8.4/02 | - | - | Not applicable for micro-organisms | - | - | - |
| B.2.8.5 Particle size distribution, dust content, attrition and mechanical stability | | | | | | |
| B.2.8.5.1 Particle size distribution | | | | | | |
| Wet sieve test of water dispersible formulation B.2.8.5.1/01 | CIPAC MT 185 | CoStar WG Batch n°: 20100638 Purity: not stated | Wet Sieve Test (residue at 200 mesh – 75 µm ASTM): 0.66% | Acceptable | GLP | Aversa, 2013 |
| Size distribution of particles of powder or suspension concentrate formulation B.2.8.5.1/02 | CIPAC MT 170 | CoStar WG Batch n°: 20100638 Purity: not stated | <u>Dry sieve analysis (particle size distribution)</u> Before storage: 0.075 - 1 mm | Acceptable | GLP | Aversa, 2011b |
| Nominal size range of granule B.2.8.5.1/03 | - | - | - | - | - | - |

| | | | | | | |
|---|----------------|--|--|------------|-----|---------------|
| B.2.8.5.2 Dust content | | | | | | |
| Dust content of granular formulation B.2.8.5.2/01 | CIPAC MT 171 | CoStar WG Batch n°: 20100638 Purity: not stated | <u>Dust content</u> Before storage: Nearly dust-free (1.79 mg) | Acceptable | GLP | Aversa, 2011b |
| B.2.8.5.3 Attrition | | | | | | |
| Attrition characteristics of granules and tablets B.2.8.5.3/01 | CIPAC MT 178.2 | CoStar WG Batch n°: 20100638 Purity: not stated | <u>Friability and attrition resistance</u> Before storage: 99.93% | Acceptable | GLP | Aversa, 2011b |
| B.2.8.5.4 Hardness and integrity | | | | | | |
| Hardness of tablets B.2.8.5.4/01 | - | - | Not applicable to granules | - | - | - |
| Integrity of tablets B.2.8.5.4/02 | - | - | Not applicable to granules | - | - | - |
| B.2.8.6 Emulsifiability, re-emulsifiability, emulsion stability | | | | | | |
| Emulsifiability, emulsion stability and re-emulsifiability of formulation B.2.8.6/01 | - | - | Not applicable to granules | - | - | - |
| B.2.8.7 Flowability, pourability and dustability | | | | | | |
| Flowability of granular formulation B.2.8.7/01 | CIPAC MT 172 | CoStar WG Batch n°: 20100638 | The product CoStar flows naturally through the sieve. | Acceptable | GLP | Aversa, 2011b |

| | | | | | | |
|---|---|--------------------|---|---|---|---|
| | | Purity: not stated | | | | |
| Pourability of suspensions B.2.8.7/02 | - | - | Not applicable to granules | - | - | - |
| Dustability of dustable powders after accelerated storage B.2.8.7/03 | - | - | Not applicable to granules | - | - | - |
| B.2.9 Physical and chemical compatibility with other products including plant protection products with which its use is to be authorised | | | | | | |
| B.2.9/01 Physical compatibility of tank mixtures | - | - | Product dispensability in water does not negatively affect the possibility of preparing tank mixes with other plant protection products in solid or liquid form, given that they are equally soluble/dispersible. | As no data have been provided, the compatibility of tank mixtures is not demonstrated. Therefore no tankmixtures can be proposed on the product label. If tank mixtures with other plant protection products are to be proposed on the product label, information on the physical and chemical (and biological) compatibility should be provided during the zonal application. | - | - |
| B.2.9/02 Chemical compatibility of tank mixtures | - | - | The nature of the active ingredient and the co-formulants contained in CoStar WG and the recommended distribution in aqueous dispersions, exclude the possibility of chemical reactions with other plant protection products commonly used in agriculture. | | - | - |
| B.2.9/03 Biological compatibility of tank mixtures | - | - | The form of the active ingredient Btk strain SA-12 in CoStar WG is the dormant spore and crystal protein inclusions therein. Germination and growth of the bacterium is not required for insecticidal activity that relies on the ingestion of the spores by the target pests. Due to the nature of the spore coat, spores are generally considered to be highly resistant against treatments to which vegetative cells exhibit sensitivity such as exposure to organic solvents, heat treatment, enzymatic attack or desiccation. It can be therefore concluded, that the probability that insecticidal properties of CoStar WG are adversely affected by the presence of other pesticides in tank mixes appears to be rather low. | | - | - |

| | | | | | | |
|---|---|---|---|---|---|---|
| B.2.10 Adherence and distribution to seeds | | | | | | |
| Distribution and adhesion to seeds B.2.9.10/01 | - | - | Not relevant | - | - | - |
| B.2.11 Other studies | | | | | | |
| | | | No other studies are considered necessary | | | |

| | |
|----------------|--|
| RMS evaluation | <p>CoStar WG was not the representative formulation for the first approval of Btk strain SA-12. Data has not been evaluated before.</p> <p>Physical, chemical and technical properties were determined for the plant protection product CoStar WG. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of a brown green, water dispersible granules-based formulation with a fishmeal odour.</p> <p>In conclusion CoStar WG is not explosive and flammable, and has no oxidising properties. In aqueous solution, it has a pH value of 6.0 which is within the range naturally occurring e.g. in soil. The product has a good suspension stability. Its stability allows storage for at least 2 years at 20°C. The data indicate that CoStar WG is stable when stored at 30°C for 18 weeks. According to the physical, chemical and technical properties of CoStar WG, no particular problems are expected when the product is used as recommended.</p> |
|----------------|--|

B.2.12 References relied on

Please refer to point with References relied on in chapter B.2, in Volume 3 (MCPA) with regard to the evaluation of the literature search.

| 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 2.1/01 | Aversa, S. | 2013 | PHYSICO-CHEMICAL PROPERTIES OF PRODUCT COSTAR AFTER 2 YEARS SHELF LIFE Certis USA LLC, BT123/10 Biotechnologie BT Srl, Fraz. Pantalla, Italy GLP: yes Published: no | no | yes | protected | Certis USA | New data for existing formulation, not previously submitted nor evaluated |
| KMP 2.2/01 | Ahrens, A. | 2011 a | COSTAR WG EXPLOSIVE PROPERTIES A.14 Certis USA LLC, 20100638.02 Siemens AG, Prozess-Sicherheit, Frankfurt am Main, Germany GLP: yes Published: no | no | yes | protected | Certis USA | New data for existing formulation, not previously submitted nor evaluated |
| KMP 2.2/02 | Ahrens, A. | 2011 b | COSTAR WG OXIDIZING PROPERTIES A.17 Certis USA LLC, 20100638.04 Siemens AG, Prozess-Sicherheit, Frankfurt am Main, Germany GLP: yes Published: no | no | yes | protected | Certis USA | New data for existing formulation, not previously submitted nor evaluated |
| KMP 2.3/02 | Ahrens, A. | 2011 c | COSTAR WG FLAMMABILITY (SOLIDS) A.10 Certis USA LLC, 20100638.01 Siemens AG, Prozess-Sicherheit, Frankfurt am Main, Germany GLP: yes Published: no | no | yes | protected | Certis USA | New data for existing formulation, not previously submitted nor evaluated |
| KMP 2.3/03 | Ahrens, A. | 2011 d | COSTAR WG AUTO-FLAMMABILITY (SOLIDS - DETERMINATION OF RELATIVE SELF-IGNITION TEMPERATURE) A.16 Certis USA LLC, 20100638.03 Siemens AG, Prozess-Sicherheit, Frankfurt am Main, Germany GLP: yes Published: no | no | yes | protected | Certis USA | New data for existing formulation, not previously submitted nor evaluated |

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| KMP 2.4/02 | Aversa, S. | 2013 | PHYSICO-CHEMICAL PROPERTIES OF PRODUCT COSTAR AFTER 2 YEARS SHELF LIFE Certis USA LLC, BT123/10 Biotechnologie BT Srl, Fraz. Pantalla, Italy GLP: yes Published: no Submitted in: KMP 2.1/01 | no | yes | protected | Certis USA | New data for existing formulation, not previously submitted nor evaluated |
| KMP 2.6/02 | Aversa, S. | 2011 b | PHYSICO-CHEMICAL PROPERTIES: FLOWABILITY, BULK DENSITY AND PERSISTENT FOAMING OF PRODUCT COSTAR. Certis USA LLC, BT121/10 Biotechnologie BT Srl, Fraz. Pantalla, Italy GLP: yes Published: no Submitted in: KMP 2.7.2/01 | no | yes | protected | Certis USA | New data for existing formulation, not previously submitted nor evaluated |
| KMP 2.7/01 | Aversa, S. | 2011 a | PHYSICO-CHEMICAL PROPERTIES OF PRODUCT COSTAR BEFORE AND AFTER ACCELERATED STORAGE AT 30 ± 2°C FOR 18 WEEKS. Certis USA LLC, BT122/10 Biotechnologie BT Srl, Fraz. Pantalla, Italy GLP: yes Published: no | no | yes | protected | Certis USA | New data for existing formulation, not previously submitted nor evaluated |
| KMP 2.7/02 | Aversa, S. | 2013 | PHYSICO-CHEMICAL PROPERTIES OF PRODUCT COSTAR AFTER 2 YEARS SHELF LIFE Certis USA LLC, BT123/10 Biotechnologie BT Srl, Fraz. Pantalla, Italy GLP: yes Published: no Submitted in: KMP 2.1/01 | no | yes | protected | Certis USA | New data for existing formulation, not previously submitted nor evaluated |
| KMP 2.7/03 | Gallager, S. | 2013 | STATEMENT ON PACKAGING COSTAR WG Certis USA LLC, not stated Certis U.S.A., L.L.C., Columbia, Maryland GLP/GEP: no Published: no | no | yes | protected | Certis USA | New data for existing formulation, not previously submitted nor evaluated |
| KMP 2.8.1/01 | Aversa, S. | 2013 | PHYSICO-CHEMICAL PROPERTIES OF PRODUCT COSTAR AFTER 2 YEARS SHELF LIFE Certis USA LLC, BT123/10 Biotechnologie BT Srl, Fraz. Pantalla, Italy | no | yes | protected | Certis USA | New data for existing formulation, not previously submitted nor evaluated |

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| | | | GLP: yes Published: no Submitted in: KMP 2.1/01 | | | | | ously submitted nor evaluated |
| KMP 2.8.2/01 | Aversa, S. | 2011 b | PHYSICO-CHEMICAL PROPERTIES: FLOWABILITY, BULK DENSITY AND PERSISTENT FOAMING OF PRODUCT COSTAR. Certis USA LLC, BT121/10 Biotechnologie BT Srl, Fraz. Pantalla, Italy GLP: yes Published: no | no | yes | protected | Certis USA | New data for existing formulation, not previously submitted nor evaluated |
| KMP 2.8.3/01 | Aversa, S. | 2013 | PHYSICO-CHEMICAL PROPERTIES OF PRODUCT COSTAR AFTER 2 YEARS SHELF LIFE Certis USA LLC, BT123/10 Biotechnologie BT Srl, Fraz. Pantalla, Italy GLP: yes Published: no Submitted in: KMP 2.1/01 | no | yes | protected | Certis USA | New data for existing formulation, not previously submitted nor evaluated |
| KMP 2.8.3/02 | Aversa, S. | 2013 | PHYSICO-CHEMICAL PROPERTIES OF PRODUCT COSTAR AFTER 2 YEARS SHELF LIFE Certis USA LLC, BT123/10 Biotechnologie BT Srl, Fraz. Pantalla, Italy GLP: yes Published: no Submitted in: KMP 2.1/01 | no | yes | protected | Certis USA | New data for existing formulation, not previously submitted nor evaluated |
| KMP 2.8.5.1/01 | Aversa, S. | 2013 | PHYSICO-CHEMICAL PROPERTIES OF PRODUCT COSTAR AFTER 2 YEARS SHELF LIFE Certis USA LLC, BT123/10 Biotechnologie BT Srl, Fraz. Pantalla, Italy GLP: yes Published: no Submitted in: KMP 2.1/01 | no | yes | protected | Certis USA | New data for existing formulation, not previously submitted nor evaluated |
| KMP 2.8.5.1/02 | Aversa, S. | 2011 b | PHYSICO-CHEMICAL PROPERTIES: FLOWABILITY, BULK DENSITY AND PERSISTENT FOAMING OF PRODUCT COSTAR. Certis USA LLC, BT121/10 Biotechnologie BT Srl, Fraz. Pantalla, Italy GLP: yes Published: no Submitted in: KMP 2.7.2/01 | no | yes | protected | Certis USA | New data for existing formulation, not previously submitted nor evaluated |
| KMP | Aversa, | 2011 | PHYSICO-CHEMICAL PROPERTIES: FLOWABILITY, BULK | no | yes | protected | Certis USA | New data for |

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| 2.8.5.2/01 | S. | b | DENSITY AND PERSISTENT FOAMING OF PRODUCT COSTAR. Certis USA LLC, BT121/10 Biotechnologie BT Srl, Fraz. Pantalla, Italy GLP: yes Published: no Submitted in: KMP 2.7.2/01 | | | | | existing formulation, not previously submitted nor evaluated |
| KMP 2.8.5.3/01 | Aversa, S. | 2011 b | PHYSICO-CHEMICAL PROPERTIES: FLOWABILITY, BULK DENSITY AND PERSISTENT FOAMING OF PRODUCT COSTAR. Certis USA LLC, BT121/10 Biotechnologie BT Srl, Fraz. Pantalla, Italy GLP: yes Published: no Submitted in: KMP 2.7.2/01 | no | yes | protected | Certis USA | New data for existing formulation, not previously submitted nor evaluated |
| KMP 2.8.7/01 | Aversa, S. | 2011 b | PHYSICO-CHEMICAL PROPERTIES: FLOWABILITY, BULK DENSITY AND PERSISTENT FOAMING OF PRODUCT COSTAR. Certis USA LLC, BT121/10 Biotechnologie BT Srl, Fraz. Pantalla, Italy GLP: yes Published: no Submitted in: KMP 2.7.2/01 | no | yes | protected | Certis USA | New data for existing formulation, not previously submitted nor evaluated |